

THE LAW OF UKRAINE

“On Introduction of Changes to the Law of Ukraine “On Veterinary Medicine”

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

To introduce changes to the Law of Ukraine "On Veterinary Medicine" (Vidomosti of Verkhovna Rada of Ukraine, 2002., №8, p. 62, 2003, №16, p.126, №27, p. 209, 2005, № 9, p. 180) that shall read:

“THE LAW OF UKRAINE

“On Veterinary Medicine”

SECTION I. GENERAL PROVISIONS

Article 1. Definitions of Basic Terms

In this Law terms shall be used in the following meaning:

- 1) Risk analysis – the process composed of hazard identification, animal disease risk assessment, risk management, and risk communication.
- 2) Arbitration analysis – laboratory analyses conducted in response to an appeal by a person against the results of previous laboratory analyses;
- 3) Safety of the objects of veterinary-sanitary control and supervision – assurance that the objects of veterinary-sanitary control and supervision will not cause harm to animal and human health when raised, produced and/or used according to their intended use. Safety shall be ensured through compliance with the requirements prescribed by this Law and other veterinary-sanitary measures and/or technical regulations.
- 4) Buffer zone – a zone established within, and along the border of, an infected zone using measures based on the epizootic characteristics of the relevant animal disease to prevent spread of the pathogenic agent into a country or zone free of such animal disease. These measures shall be not limited to vaccination of animals;
- 5) Veterinary Administration – the state service of veterinary medicine having authority in the whole country for coordination, organization and implementation of veterinary-sanitary measures and verification of the adherence of commodities to the requirements specified by a country of destination, issuance of international veterinary certificates in accordance with the recommendations and guidelines of the relevant international organizations, and supervision or verification of their application;
- 6) Veterinary pharmacy – an establishment of veterinary medicine that carries out wholesale, retail trade in veterinary preparations and provides consultations on issues of application of veterinary preparations;

- 7) Veterinary documents – international veterinary certificate, veterinary affidavit, veterinary card and information notes issued by state inspectors of veterinary medicine and authorized doctors of veterinary medicine, attesting to the veterinary-sanitary state of animals, products of animal origin, reproductive material, biological products, pathological material and feed;
- 8) Veterinary immune-biological means (products) – means (products) intended for correcting the active or passive immunity of animals, defining the state of immunity of animals and diagnosing the transmissible diseases;
- 9) Veterinary card – a document, issued by a state doctor of veterinary medicine or an authorized doctor of veterinary medicine, with a record of veterinary-sanitary state of the farm, medical treatments and other anti-epizootic procedures for a specific animal, which supplements the animal passport;
- 10) Veterinary medicinal means (products) – substances or combination of substances intended for medical treatment and prophylaxis of animal diseases, or substances or combination of substances administered to animals in order to make a diagnosis of animals, or for restoring, correcting, or modifying physiological functions, metabolic processes in animals;
- 11) Veterinary medicine – a sphere of science and practical knowledge on animal diseases, their prophylaxis, diagnostics, medical treatment, determination of safety of products of animal origin, and in agri-food market – of products of plant origin as well, aimed at preservation of health and productivity of animals, prevention of animal diseases and protection of humans from zoonosis and prion diseases;
- 12) Veterinary practice – activity of rendering services related to prophylaxis, diagnostics and medical treatment of animal diseases, and providing consultations on veterinary medicine issues, which is carried out by establishments of veterinary medicine, including licensed doctors of veterinary medicine, state institutions of veterinary medicine;
- 13) Veterinary preparations – veterinary medicinal means, veterinary immune-biological means, antiseptics, disinfectants, insectoacaricides, deratizides, diagnosticums that are used in veterinary medicine and animal-raising sector;
- 14) Veterinary affidavit (information note)– a document of single use, issued by a state inspector of veterinary medicine or authorized doctor of veterinary medicine, confirming the veterinary-sanitary state of the consignment of animals, non-edible products of animal origin, reproductive material, biological products, feed of animal origin and plant origin, including compulsory attestation of the veterinary-sanitary status of the territory (facility) of origin and, for animals, the record of vaccination and diagnostic analysis. Veterinary information note may be issued by specialists of veterinary medicine;
- 15) Veterinary-sanitary expertise – a set of necessary laboratory and special analysis, conducted by the specialists of the state service of veterinary medicine or authorized doctors of veterinary medicine with regard to safety of non-edible products of animal origin, products of animal origin, reproductive material, biological products, veterinary preparations, substances, feed additives, premixes and feed, analysis of production technology and production equipment for compliance with veterinary-sanitary measures;
- 16) Veterinary-sanitary and epizootic welfare – ensuring protection of human and animal life and health from hazards associated with animal diseases, including zoonosis, ensuring optimum conditions for animal life, which prevent animal diseases and harmful effect of environmental factors on animal health and productivity;

17) Veterinary-sanitary measures – any measures, including all relevant laws, regulations, other normative-legal acts, rule books, requirements and procedures including in particular anti-epizootic measures; end product criteria; processes and production methods; testing, inspection, certification, and approval procedures; quarantine treatments, including relevant requirements associated with transportation of the objects of veterinary-sanitary control and supervision, provisions on relevant statistical methods, sampling procedures and methods of animal disease risk assessment, that are applied to:

1. Protect animal life and health from risks arising from the entry, establishment or spread of animal diseases, animal disease-carrying organisms, as well as animal disease-causing organisms;
2. Protect human and animal life and health from risks arising from contaminants, toxins or disease-causing organisms in products of animal origin or feed;
3. Protect human life or health from risks resulting from diseases carried by animals or products produced thereof.

18) Veterinary-sanitary state – the presence or absence of a notifiable disease and/or the level of contaminants relative to maximum allowed level;

19) Veterinary-sanitary status – the status of a country or a territory (facility) with respect to animal disease, determined according to the criteria specified by the relevant international organizations;

20) Relevant international organizations – International Office Epizootic (the World Animal Health Organization (hereinafter – OIE) and other international organizations, in which international standards, guidelines, and recommendations associated with protection of animal health and safety of commodities are developed;

21) Random veterinary-sanitary control – periodic verification of safety of commodities by means of extended control that is conducted by the state service of veterinary medicine;

22) Conclusion of the state veterinary-sanitary expertise (expert conclusion) – a document issued by the state or authorized laboratory of veterinary medicine, attesting to safety of non-edible products of animal origin, products of animal origin, reproductive material, biological products, veterinary preparations, substances, feed additives, premixes and feed;

23) Ruling – information-methodological document, issued by the Chief State Inspectors of Veterinary Medicine of Ukraine, Autonomous Republic of Crimea, the oblasts, cities of Kyiv and Sebastopol, cities, rayons, regional services of the state veterinary-sanitary control and supervision on the state border of Ukraine and transport, or by their deputies;

24) Finished feed – feed of animal and plant origin for non-food-producing animals, including fish and birds;

25) Central Body of Executive Power on Veterinary Medicine Issues – central body of executive power on veterinary medicine issues enjoying special status that carries out functions of the administration of veterinary medicine;

26) State service of veterinary medicine of Ukraine – system of state management bodies of veterinary medicine and state institutions of veterinary medicine;

27) State veterinary-sanitary control – functions performed by state inspectors of veterinary medicine and authorized doctors of veterinary medicine, which consist of continuously ensuring fulfillment of veterinary-sanitary measures and technical regulations established by current legislation;

- 28) State veterinary-sanitary supervision – functions performed by state inspectors of veterinary medicine and authorized doctors of veterinary medicine, which consist of periodic verification of the adherence to the requirements of current legislation in the sphere of veterinary medicine;
- 29) State inspector of veterinary medicine – a doctor of veterinary medicine employed by the state service of veterinary medicine or authorized by the central body of executive power on veterinary medicine issues or in the case of a foreign country, its Veterinary Administration, to perform inspections of commodities, devices of veterinary medicine and accompanying items with the purpose of protecting human and/or animal health and, when appropriate, to perform certification of their veterinary-sanitary state in conformity with the requirements of the relevant international organizations and conduct other functions of state veterinary-sanitary control and supervision;
- 30) State doctor of veterinary medicine – a doctor of veterinary medicine employed by state bodies or state institutions of veterinary medicine;
- 31) State bodies of veterinary medicine – central body of executive power on veterinary medicine issues and territorial bodies;
- 32) State institutions of veterinary medicine – institutions of veterinary medicine, carrying out prophylactic, diagnostic, medical treatment and other anti-epizootic measures, scientific research and control works, that have been assigned with control-supervision functions in the sphere of veterinary medicine, or authorized to perform such functions;
- 33) Mandate – written authorization, by which Chief State Inspectors of Veterinary Medicine of Ukraine, Autonomous Republic of Crimea, the oblasts, cities of Kyiv and Sebastopol, cities and rayons, regional services of state veterinary-sanitary control and supervision on the state border and transport, or their deputies, assign another person or institution with the right to perform certain legal actions or receive material values on their behalf;
- 34) Export facilities (objects) – facilities used for production of the objects of state veterinary-sanitary control or supervision, for which the central body of executive power on veterinary medicine issues has verified compliance with the requirements established by a country of destination for such facilities to allow export of the above objects to such country;
- 35) Contaminants – any biological substance, including microorganisms and their parts, or chemical substances (pesticides, toxins), veterinary preparations, including hormones, sedatives and thyreostatic substances, antibiotics, other veterinary preparations, salts of non-organic substances, radioactive substances, and decayed products thereof, or other substances that may be harmful to animal and human health;
- 36) National Control Program – a program developed by the central body of executive power on veterinary medicine issues and implemented by the state service of veterinary medicine, or in the case of a foreign country - its Veterinary Administration, for the purpose of controlling (including containment and/or elimination) an animal disease and contaminants in products of animal origin and feed by specific measures applied throughout the country or within a zone or zones of the country;
- 37) Interested trading partners – states and other subjects of international law that are participants of multilateral and bilateral agreements, of which Ukraine is also a participant, governing the application of veterinary-sanitary measures, and members of relevant international organizations, of which Ukraine is also a member;
- 38) Establishment of veterinary medicine – a legal entity that employs at least one doctor of veterinary medicine or a natural person – entrepreneur, who has qualification of a doctor of veterinary medicine, obtained a license for veterinary practice, including rendering of services related to prophylaxis,

diagnostics and medical treatment of animal diseases and maladies, providing consultations on veterinary medicine issues, or a license for production of veterinary preparations, retail, wholesale trade in veterinary preparations, or a license for conducting disinfection, disinsection and deratization works;

39) Devices of veterinary medicine – materials, equipment, instruments, specialized motor vehicles, and other mechanisms and tools intended for use in veterinary medicine;

40) Means of animal care – means that are intended for raising and taking care of animals that have no medical treatment or prophylaxis effect;

41) Zone – a clearly defined part of the territory of a country with a defined veterinary-sanitary status;

42) Zone free of notifiable disease – a zone, in which the absence of certain animal disease has been confirmed by satisfying the requirements for free status, prescribed by the relevant international organizations. Within the zone and at its borders, appropriate control (containment) measures shall be effectively applied for commodities and other objects, which may carry relevant animal diseases, including transportation vehicles;

43) Zone of low prevalence of notifiable disease – a zone, whether all of a country, part of a country, or several countries or parts thereof, as determined by the administration of veterinary medicine, in which an animal disease occurs at a low level and in which effective surveillance, control (containment) or elimination measures are conducted;

44) Surveillance zone – a zone established within, and along the border of, a zone free of notifiable disease separating the zone that is free of notifiable disease from infected zone where rigorous surveillance measures are conducted;

45) Zoonosis - diseases that can be transmitted by vertebrate animals to humans;

46) Hazard identification - the process of detecting pathogenic agents of animal disease that could potentially be introduced into the territory of Ukraine by importation of commodities and accompanying items;

47) Infected zone - a zone, in which absence of animal disease has not been confirmed according to the requirements prescribed by the relevant international organizations;

48) Quarantine zone – a zone, within which animal quarantine is being implemented, and which includes an infected zone and a buffer zone, and may also include a surveillance zone;

49) Quarantine station (post) – specially equipped location (site), under the control of the state bodies of veterinary medicine where groups of animals are kept in isolation, with no direct or indirect contact with other animals, in order to undergo observation for a specified length of time and, if appropriate, testing or medical treatment;

50) Animal quarantine – special legal regime that is implemented in an infected and buffer zones, and, when appropriate, surveillance zone with the objective of containing an outbreak of animal disease and eliminating such animal disease according to relevant veterinary-sanitary measures, laws and normative-legal acts issued pursuant to this Law;

51) Quarantine veterinary militia post – a temporary, specially equipped location at the border of a quarantine zone established according to the decision of the State Emergency Anti-Epizootic Committee under the Cabinet of Ministers of Ukraine to contain and prevent spread of a notifiable disease;

52) Quantitative risk assessment – an assessment where the outputs of the assessment of risk may be expressed numerically;

- 53) Feed - finished feed, feed of plant and animal origin;
- 54) Feed of plant origin - forage grain, feed concentrates, mixed feed, cake, shorts, root crops, tuber crops, hay, straw and other feed of plant origin;
- 55) Feed of animal origin – meat-meal, bone-meal, meat-and-bone meal, fish-meal, liver-meal, blood-meal, feather-meal, pork fat, live fish for feeding, milk and milk products and other products of animal origin intended for animal feeding, based on animal protein;
- 56) Feed additives – substances, micro-organisms and preparations, other than feed material and premixes, which are not normally consumed as feed by itself, but are intentionally added to feed or water in order to favorably affect the characteristics of feed, or products of animal origin, favorably affect the color of ornamental fish and birds, satisfy the nutritional needs of animals, reduce unfavorable effect of animal production on the environment, affect animal production, performance or welfare, by means of affecting the gastro-intestinal flora or digestibility of feed;
- 57) Laboratory of veterinary medicine – appropriately equipped laboratory, accredited by the National Accreditation Agency or relevant accreditation body of a foreign country that is staffed by specially trained personnel, competent to perform relevant technical procedures, and lead by a doctor of veterinary medicine;
- 58) Medicated feed – any mixture of veterinary medicinal means or medicated premixes and feed, manufactured under control of a specialist of veterinary medicine that is ready for circulation and is intended for animal feeding without prior treatment;
- 59) Licensed doctor of veterinary medicine - a doctor of veterinary medicine, permanently employed in the establishment of veterinary medicine or veterinary pharmacy, or a natural person-entrepreneur, who has qualification of a doctor of veterinary medicine and obtained a license for carrying out certain types of activities in the sphere of veterinary medicine;
- 60) Maximum residue limit (maximum allowed residue level) – maximum allowed content of an active substance of veterinary preparations and their metabolites (conversion products in live systems) and toxicants in non-edible products of animal origin, products of animal origin and feed, which, if exceeded, may negatively affect animal and human health;
- 61) International veterinary certificate – a certificate of the form and with the content recommended by the relevant international organizations, issued in the exporting country in conformity with the guidelines of the relevant international organizations, attesting to the animal health and/or human health requirements, which are fulfilled by exported commodities;
- 62) International standards, guidelines and recommendations – standards, guidelines, and recommendations that are developed and adopted by the OIE and other international organizations engaged in development of recommendations, guidelines and standards with regard to protection of animal and human life and health from animal diseases;
- 63) Minimum quality indicators - organoleptic, chemical, biological and physical indicators that must be met by the specific object in order for it to be deemed acceptable for use as intended;
- 64) Monitoring - a system and procedure of surveillance of the veterinary-sanitary state of the objects of veterinary-sanitary control and supervision;
- 65) Emergency circumstances – epizootic state of a country, when the following is confirmed or suspected: presence of a notifiable disease in a country of origin or transit that may cause an immediate and irreparable damage to the health of susceptible animals throughout Ukraine or in a part of Ukraine, if commodities and accompanying items, which may carry a notifiable disease, are imported;

- 66) Good Manufacturing Practice (for veterinary preparations, feed additives, premixes, and finished feed) – a system, that applies to all aspects of the production process, for ensuring consistent production and control in conformity with quality standards, aimed at minimization of risks associated with safety and other risks associated with production of veterinary preparations, feed additives, premixes and finished feed, which can not be eliminated through testing/verification of the final product. Such practices are based on international standards, principles and recommendations, and are necessary to ensure conformity with relevant veterinary-sanitary measures, technical regulations, and other requirements prescribed by this Law. In case relevant international standards, guidelines or recommendations do not exist, or do not ensure necessary level of protection, veterinary-sanitary measures shall be based on objective scientific criteria, including on the basis of risk assessment analysis according to the technique, developed by relevant international organizations;
- 67) Appropriate level of animal and related human health protection – level of protection deemed appropriate by the State when developing veterinary-sanitary measures to protect animal and human health and life from an adverse effect that the veterinary-sanitary measure is designed to address;
- 68) Maladies - conditions of animals other than animal diseases that require care or medical treatment by a doctor of veterinary medicine;
- 69) Non-edible products of animal origin – raw materials of animal origin not normally used for human consumption, but that are used for pharmaceutical, surgical, agricultural, and industrial purposes;
- 70) Objects of state veterinary-sanitary control and supervision – commodities, devices of veterinary medicine, means of animal care and accompanying items;
- 71) Circulation – moving (transporting) or storing, and any other actions related to the transfer of ownership or possession right, including, sale, exchanging or granting;
- 72) Operator of facilities – natural person or legal entity, which carries out activities, envisaged by this law, using facilities (objects), for which the person/entity has the right of ownership or use;
- 73) Especially dangerous diseases of the OIE List – transmissible animal diseases that have a potential of rapid and significant spread, irrespective of national borders, which may have severe socio-economic consequences or present a threat to animal or human health, and which may significantly affect international trade in animals and products of animal origin;
- 74) Risk assessment – the evaluation of the likelihood of the biological and economic consequences of entry, establishment, or spread of a pathogenic agent within the territory of Ukraine;
- 75) Consignment – any defined quantity of animals, non-edible products of animal origin, veterinary preparations, feed additives, feed, reproductive material, biological products and accompanying items with the same name and properties, which are produced (grown) under the same conditions in the same facilities (objects), transported by the same transportation vehicles, and when necessary, accompanied by the same relevant veterinary document;
- 76) Pathological material – samples taken from live or dead animals, which contain or may contain infectious or parasitic agents, that are intended for sending to the laboratory of veterinary medicine;
- 77) Withdrawal period - the time-period between the last administration of a veterinary preparation to the animal and the production of products intended for human consumption from such animal, which is necessary in order that such products do not contain residues in quantities, exceeding established levels;
- 78) Risk communication – the interactive exchange of information on risk among risk assessors, risk managers, interested trading partners, and other interested parties;

- 79) Facilities (objects) – any building, collection of buildings, premises, structures or area, including the equipment therein or thereon, used for animal breeding, raising, training, competition, keeping, displaying (viewing), tendering, selling, slaughtering or harvesting of animals; for producing and circulating non-edible products of animal origin, veterinary preparations, feed additives, premixes, feed, reproductive material, to destroy carcasses or other parts of animals;
- 80) Premixes – mixtures of feed additives or mixtures of one or several feed additives with feed of animal or plant origin or water used as carriers, not intended for direct feeding of animals;
- 81) Border state inspector of veterinary medicine – state inspector of veterinary medicine of the regional service of state veterinary-sanitary control and supervision on the state border and transport, who verifies import, transit and export consignments, which are the objects of state veterinary-sanitary control and supervision, and also allows their bringing in (entry) or bringing out (exit), depending on their veterinary-sanitary state, and issues relevant veterinary documents;
- 82) Border inspection posts – premises located at the entry/exit points on the state border of Ukraine, including entry/exit points at the highways, railway stations, airports, sea and river ports, where veterinary-sanitary control and supervision of consignments with the objects of state veterinary-sanitary control and supervision, crossing the state border of Ukraine, are conducted;
- 83) Directive – written requirement of the Chief State Inspectors of Veterinary Medicine of Ukraine, Autonomous Republic of Crimea, the oblasts, cities of Kyiv and Sebastopol, cities, rayons, regional services of the state veterinary-sanitary control and supervision on the state border and transport, and their deputies, which shall be provided to legal entities and natural persons, with the aim to terminate revealed violation of legislation on veterinary medicine issues and eliminate its consequences. The latter shall be compulsory for execution;
- 84) Products of animal origin – products of animal origin intended for human consumption, products of animal origin for pharmaceutical and surgical use, and products of animal origin for agricultural and industrial use, feed of animal origin;
- 85) Products of animal origin intended for agricultural or industrial use – products of animal origin, except those intended for human consumption, pharmaceutical or surgical purposes and feed of animal origin;
- 86) Products of animal origin for human consumption – products of animal origin for human consumption – meat, meat products, gelatin, eggs, egg products, milk, milk products, fish, fish products and seafood, honey and other products of animal origin when the latter are intended for human consumption;
- 87) Products of animal origin intended for pharmaceutical or surgical use – animal organs, tissues and organic fluids intended for the production of pharmaceutical products or surgical devices;
- 88) Anti-epizootic measures – organizational-economic and veterinary-sanitary activities, including prophylactic and diagnostic activities, aimed at prevention, detection, and elimination of transmissible animal diseases;
- 89) Prophylactic animal quarantine – a system of veterinary-sanitary measures, which are applied before and/or after movement of animals to prevent introduction or spread of animal diseases;
- 90) Regional service of the state veterinary-sanitary control and supervision on the state border of Ukraine and transport of the central body of executive power on veterinary medicine issues (hereinafter – regional services) – state institution of veterinary medicine, which carries out state veterinary-sanitary control and supervision at the relevant regional level with the aim to protect the territory of Ukraine from the entry of animal diseases from the territories of other countries and to ensure the fulfillment by

legal entities and natural persons of veterinary-sanitary measures in course of international and domestic transportation of the objects of state veterinary-sanitary control and supervision;

91) Registration certificate – a document allowing circulation of veterinary preparations, feed additives, premixes and finished feed and their use in animal-raising sector;

92) Reproductive material – semen, zygotes, fertilized fish eggs, incubate eggs, fertilized ova, embryos, and other biological material that enables reproduction;

93) Reference laboratory – an accredited laboratory, authorized by the central body of executive power on veterinary medicine issues, which is involved as a "third party" for resolution of disputable issues of the results of laboratory analysis;

94) Risk – the likelihood of the occurrence and the likely magnitude of the consequences of an adverse event during a specified time period;

95) Market – a specially equipped and specially allocated place that is used for rendering of services on creating appropriate conditions for sale of animals, non-edible products of animal origin, feed additives, premixes, feed, devices of veterinary medicine and means of animal care;

96) Instruction – a legal act, issued by the Chief State Inspectors of Veterinary Medicine of Ukraine, Autonomous Republic of Crimea, the oblasts, cities of Kyiv and Sebastopol, cities, rayons, regional services of state veterinary-sanitary control and supervision on the state border and transport, or their deputies, to resolve the internal organizational issues;

97) Extended veterinary-sanitary control – process of verification of safety of commodities on the basis of laboratory analysis, conducted by the state service of veterinary medicine;

98) Hazard Analysis and Critical Control (Regulation) Points System (HACCP) - a system for identification, evaluation, analysis and control of hazards, which affect safety of animals, non-edible products of animal origin, reproductive material, biological products, veterinary preparations, substances, feed additives, premixes, feed etc.;

99) Outbreak of a disease – occurrence of a notifiable disease in facilities (objects), including all buildings and adjoining premises, where animals are located; and in the territory where, taking into account local conditions, it is impossible to guarantee that susceptible and non-susceptible animals have had no direct contact with diseased or suspected animals;

100) Veterinary medicine specialists – doctors of veterinary medicine and veterinary technicians, which carry out activities of prophylaxis, recovery, diagnostics, and medical treatment of animals, veterinary-sanitary testing, or carry out other veterinary activities;

101) Standard – a document developed on the basis of consensus and adopted by an authorized body, which establishes for general and multiple uses the rules, guidelines, or characteristics related to the activity or its results, including products, processes or services, with which compliance is not compulsory. The standard may include requirements to terminology, symbols, packaging, marking as they apply to a certain product, process or service. Safety requirements for non-edible products of animal origin shall not be prescribed in standards, but in veterinary-sanitary measures;

102) Standard border veterinary-sanitary control – process of verification by the border state inspectors of veterinary medicine of safety of the objects of veterinary-sanitary control and supervision on the basis of studying the accompanying documents, visual examination of the consignment when the latter is brought into the territory of Ukraine (import), brought out of the territory of Ukraine (export) and moved through the territory of Ukraine (transit);

103) Stamping-out – set of measures that are conducted under the authority of the relevant chief state inspector of veterinary medicine, including the slaughtering of diseased and infected animals in the herd and, where appropriate, those in other herds that may have had a direct or indirect contact with the animals of infected herd, which may have resulted in the pathogenic agent transmission. All suspected animals, regardless of whether they have been vaccinated or not, shall be slaughtered, and their carcasses shall be destroyed by burning, burial or otherwise, which guarantees prevention of spread of the infection via carcasses or other products of slaughtered animals. It shall be also necessary to carry out measures of cleansing and disinfection recommended by relevant international organizations.

104) Substance – any matter that may be used for production of veterinary preparations or feed additives of the following origin:

- a) Human bodies, e.g., human blood and human blood products;
- b) Animal, e.g., micro-organisms (microbiological products), parts of organs, and animal secretions, toxins, extracts, blood products;
- c) Plant, e.g., micro-organisms (microbiological products), plants, parts of plants, plant secretions, extracts;
- d) Chemical, e.g., naturally occurring chemical elements and/or chemical products obtained by chemical reaction or synthesis;

105) Accompanying items – items that are capable of carrying or transmitting animal diseases to other animals or humans, including straw, hay, tackle, and other items, that accompany animals or are used for animals;

106) Animals – mammals, poultry, birds, bees, fish, crustaceans, mollusks; frogs, amphibians, and reptiles;

107) Territorial bodies – bodies of state executive power created by the central body of executive power on veterinary medicine issues in the form of the offices of veterinary medicine in the Autonomous Republic of Crimea, the oblasts, cities of Kyiv and Sebastopol, cities and rayons to perform the functions of the central body of executive power on veterinary medicine issues in a certain territory;

108) Technical regulation – a normative-legal act, adopted by the body of executive power, which lays down characteristics of products or their related processes or production methods, as well as the requirements for services, including applicable administrative provisions, with which compliance is compulsory. Technical regulation may include requirements to terminology, symbols, packaging, marking as they apply to a certain product, process or production method. Safety requirements for non-edible products of animal origin shall be prescribed in veterinary-sanitary measures;

109) Commodities – animals, products of animal origin, reproductive material, biological products, pathological material, veterinary preparations, substances, feed additives, premixes and feed;

110) Authorized laboratory – an accredited laboratory of veterinary medicine, authorized by the relevant state body to test (measure parameters and analyze) non-edible products of animal origin, products of animal origin, reproductive material, veterinary preparations, substances, feed additives, premixes, feed, etc. according to special methods and procedures defined by national or international standards, guidelines and recommendations;

111) Authorized (official) doctor of veterinary medicine – a doctor of veterinary medicine, who has been authorized by the central body of executive power on veterinary medicine issues to perform certain functions of state veterinary-sanitary control and supervision;

112) Risk management – the process of identifying, selecting, and implementing measures that are applied with the aim to reduce the level of risk;

113) Notifiable disease – animal disease from the list approved by the central body of executive power on veterinary medicine issues, and which, as soon as detected or suspected, must be immediately reported to the state inspector of veterinary medicine or an authorized doctor of veterinary medicine;

114) Animal diseases – the clinical, immunological and/or histopathological manifestations of pathogenic agents;

115) Micro-organism strains – genetically homogeneous populations of micro-organisms within a species, which have certain stable specific morphological features and biological properties;

116) Qualitative risk assessment – an assessment where the outputs on the likelihood of the outcome or the magnitude of the consequences associated with the subject of risk assessment are expressed in qualitative terms such as 'high', 'medium', 'low' or 'negligible';

117) Quality of the objects of veterinary-sanitary control and supervision – aggregate properties and characteristic features of the objects of veterinary-sanitary control and supervision, capable of satisfying the needs (requirements) to those, who are using the latter.

Article 2. Legislation on Veterinary Medicine

Legislation on veterinary medicine shall be based on the Constitution of Ukraine, this Law, and other normative-legal acts issued in compliance thereto.

Article 3. Main Tasks of the State in the Sphere of Veterinary Medicine

The main tasks of the State in the sphere of veterinary medicine shall be:

- 1) To reduce or eliminate the risks with regard to the population falling sick of zoonosis;
- 8) To protect the territory of Ukraine from the entry of animal diseases from the territories of other countries or from quarantine zones;
- 9) To protect animals and the population from animal diseases by applying prophylactic, diagnostic, and medical treatment measures;
- 10) To ensure that commodities, means of animal care and accompanying items do not transmit and do not act as a means of transmitting animal diseases;
- 11) To establish effective and efficient means for detecting, containing, controlling, and if possible, eliminating endemic animal diseases, and eliminating exotic animal diseases that have been introduced into the territory of Ukraine;
- 12) To ensure reliable and efficient measures to eliminate outbreaks of animal diseases with the purpose to minimize losses of animals and, in the case of zoonosis, reduce the risk to humans;
- 13) To monitor feed and water for ensuring that feed and water for animals are suitable for consumption and not capable of transmitting animal diseases;
- 14) To ensure the proper, appropriate, effective, and safe use of veterinary preparations;
- 15) To protect the environment from negative effects associated with production and circulation of animals;
- 16) To protect animal welfare by means of ensuring humane attitude to animals throughout their life span and particularly during development and application of veterinary-sanitary measures;

- 17) To conduct clinical examination of animals before slaughter and conduct veterinary-sanitary testing of products of animal origin (including animals killed at hunting) including bacteriological, radiological, parasitological and toxicological laboratory analysis;
- 18) To implement state veterinary-sanitary control and supervision during the process of production and circulation of products of animal origin, and in the markets – of plant origin as well, veterinary preparations, substances, premixes, feed, microorganism strains, reproductive material, pathologic material, and to implement state veterinary-sanitary supervision during circulation of the devices of veterinary medicine and means of animal care;
- 19) To implement a national program of monitoring residue amounts of veterinary preparations and other contaminants in animals, products of animal origin and feed;
- 20) To implement standard border veterinary-sanitary control and/or extended veterinary-sanitary control of the objects of state veterinary-sanitary control and supervision;
- 21) To control the movement of the objects of state veterinary-sanitary control and supervision within Ukraine;
- 22) To facilitate the implementation of an animal identification system;
- 23) To facilitate continuing education and upgrading of the qualification of specialists of veterinary medicine;
- 24) To facilitate the practical introduction and wide application of the achievements of veterinary medicine.

SECTION II. STATE MANAGEMENT IN THE SPHERE OF VETERINARY MEDICINE

Article 4. Bodies of State Management in the Sphere of Veterinary Medicine

State management in the sphere of veterinary medicine shall be carried out by the Cabinet of Ministers of Ukraine, central body on veterinary medicine issues enjoying special status. its territorial bodies.

Article 5. Authorities of the Cabinet of Ministers of Ukraine in the Sphere of Veterinary Medicine

Authorities of the Cabinet of Ministers of Ukraine shall include:

- 2) Ensuring implementation of state policies in the sphere of veterinary medicine;
- 25) Development and implementation of the relevant national programs;
- 26) Organization of the implementation of veterinary-sanitary measures, aimed at ensuring veterinary-sanitary and epizootic welfare, including protection of the territory of Ukraine from the entry of pathogenic agents of animal diseases from territories of other countries or from quarantine zones, ensuring safety of products of animal origin, imposing animal quarantine, and protecting the environment from potential negative effects associated with animal raising;
- 27) Ensuring financing and logistic support of the state institutions of veterinary medicine;
- 28) Implementing state policies as to licensing in the sphere of veterinary medicine;
- 29) Concluding international agreements;

30) Executing other authorities according to legislation.

Article 6. State Bodies of Veterinary Medicine and Officials Thereof.

1. The central body of executive power on veterinary medicine issues shall be a central body of executive power enjoying special status in the sphere of veterinary medicine. The Cabinet of Ministers of Ukraine shall direct and coordinate activities of the central body of executive power on veterinary medicine.

2. In order to fulfill its assigned tasks the central body of executive power on veterinary medicine shall create relevant territorial bodies, regional services and state institutions.

3. The central body of executive power on veterinary medicine issues and its territorial bodies shall constitute an integral system of state bodies of veterinary medicine.

4. The Head of the central body of executive power on veterinary medicine issues, his/her deputies, and heads of the offices of the central body of executive power on veterinary medicine issues which have been assigned with the functions of conducting state veterinary-sanitary control and supervision, shall be concurrently, according to their positions, the Chief State Inspector of Veterinary Medicine of Ukraine and his/her deputies, respectively

5. The heads of the territorial bodies of the Autonomous Republic of Crimea, the oblasts, cities of Kyiv and Sebastopol, cities, rayons and regional services, and their deputies shall be concurrently, according to their positions, chief state inspectors of veterinary medicine and deputy chief state inspectors of veterinary medicine of the above regions, respectively, and state doctors of veterinary medicine of the state bodies of veterinary medicine and regional services shall be, concurrently, according to their positions, state inspectors of veterinary medicine. The Law of Ukraine "On State Service" shall apply to the heads of regional services and their deputies.

6. The central body of executive power on veterinary medicine issues shall develop, review and approve veterinary-sanitary measures, including measures on prophylaxis, medical treatment, diagnostics, and elimination of notifiable diseases;

7. The authorities of the state bodies of veterinary medicine shall include:

1) Application of veterinary-sanitary measures to protect Ukraine's territory from the introduction of the pathogens of animal diseases from the territories of other countries or from quarantine zones;

31) Implementation of state veterinary-sanitary control and supervision for animals, products of animal origin, veterinary preparations, substances, feed additives, premixes, feed of plant and animal origin, finished feed, micro-organism strains, reproductive material, pathological material, devices of veterinary medicine, means of animal care, and for facilities (objects), which are used for production, processing, storage and circulation of the above objects of state veterinary-sanitary control and supervision;

32) Implementation of state veterinary-sanitary control and supervision of the territory of Ukraine from the introduction of the pathogens of transmissible diseases from the territories of other countries or from quarantine zones in case of export, import and transit of the objects of veterinary-sanitary control and supervision;

33) Implementation of state veterinary-sanitary supervision of the activities of authorized (official) doctors of veterinary medicine with regard to implementation of veterinary-sanitary measures;

- 34) Carrying out extended veterinary-sanitary control on the basis of professional evaluation of the state inspector of veterinary medicine or within the framework of the program for random veterinary-sanitary control in order to verify safety of commodities;
 - 35) Carrying out standard veterinary-sanitary border control of feed additives, veterinary preparations and devices of veterinary medicine;
 - 36) Coordination and organization of the implementation of veterinary-sanitary measures;
 - 37) Determining the veterinary-sanitary status of Ukraine and particular zones within its territory, and the veterinary-sanitary state of facilities (objects) within Ukraine;
 - 38) Organizing, jointly with the bodies and establishments of health care, State Sanitary Epidemiological Service, structural units of central body of executive power on emergency issues the protection of the population from zoonosis and timely exchange of information on such animal diseases;
 - 39) Issuance of veterinary documents;
 - 40) Carrying out ante-mortem inspection of animals and organizing veterinary-sanitary testing of non-edible products of animal origin;
 - 41) Issuance of operating permits for facilities (objects) used for production, processing, and circulation of non-edible products of animal origin, veterinary preparations, feed, and feed additives, and keeping the register of such facilities (objects);
 - 42) Suspending an operating permit or restricting the activities of facilities (objects), which are used for production, processing and circulation of animals, non-edible products of animal origin, veterinary preparations, feed, and feed additives, as well as vehicles, which are used for transportation thereof, in case their operators violate veterinary-sanitary measures;
 - 43) Carrying out testing and providing consent to projects on planning and construction of animal farms, facilities (objects) engaged in animal slaughter, processing enterprises, enterprises for production of veterinary preparations, the markets; participating in the activities of Working and State Commissions for approving the start-up of these facilities (objects), and in allocation of land plots for all above-mentioned types of construction and water supply for animals;
 - 44) State veterinary-sanitary supervision over the implementation of veterinary-sanitary testing at facilities (objects), which are used for production, processing, storage and circulation of animals, products of animal origin, and in the markets- of plant origin as well;
 - 45) Organizing laboratory-clinical (bacteriological, virus, chemic-toxicology, pathology-anatomy, histology, parasitology, radiology) and other analysis in order to diagnose animal diseases and evaluate the safety of non-edible products of animal origin, reproductive material, feed, feed additives, veterinary preparations, and water for animals;
 - 46) Analyzing causes of animal diseases, maladies, and murrain, development of recommendations on their prophylaxis;
 - 47) Providing insurance companies with the conclusions as to diseased animals forcedly slaughtered, perished or destroyed;
 - 48) Coordinating the activities of state doctors of veterinary medicine and specialists of veterinary medicine employed by state institutions of veterinary medicine, regardless of their subordination;
 - 49) Organizing measures on disinfection and control of insects and rodents;
8. The authorities of the central body of executive power on veterinary medicine issues shall include:

- 1) Registration of veterinary preparations, feed additives, premixes and finished feed;
- 2) Organization of the development and adoption of technical regulations for veterinary preparations, feed additives, premixes, finished feed, devices of veterinary medicine, means of animal care, and other objects of state veterinary-sanitary control and supervision, including Good Manufacturing Practices for veterinary preparations, feed additives, premixes, and finished feed;
- 3) Keeping the State Register for Veterinary Preparations;
- 4) Organization of the implementation of state veterinary-sanitary control and supervision at facilities (objects), which are used for production, processing, storage and circulation of animals, products of animal origin, veterinary preparations, substances, feed additives, premixes, feed of animal origin, finished feed, reproductive material, etc;
- 5) Introduction of the program for random veterinary-sanitary control of commodities during their circulation, and implementation of the national program for monitoring residue amounts of veterinary preparations and other contaminants in animals, products of animal origin and feed;
- 6) Organization of the evaluation of the use of veterinary preparations, feed additives, premixes, finished feed, and their effect on animal health;
- 7) Authorization of accredited laboratories for carrying out analysis (testing) of commodities;
- 8) Adoption of measurement techniques, testing methods for commodities, their lists, and attestation;
- 9) Adoption of the list of reference laboratories for carrying out arbitration analysis for commodities;
- 10) Distribution of funds, allocated from the State Budget of Ukraine, for financing the programs in the sphere of veterinary medicine among the state bodies of veterinary medicine and state institutions of veterinary medicine;
- 11) Notifying the Office International Epizootic (OIE) on the imposition, expected duration and the date of revocation of animal quarantine for especially dangerous diseases of the OIE List;
- 12) Introducing restrictions or prohibitions for import, transit and export of commodities and other objects of veterinary-sanitary control and supervision, which may carry especially dangerous diseases of the OIE List, or other notifiable diseases from certain countries or quarantine zones due to confirmed outbreaks of especially dangerous diseases of the OIE List or other notifiable diseases;
- 13) Participating in preparation and drafting of international agreements on veterinary medicine issues, entering into inter-departmental agreements with Veterinary Administrations of other countries, participating in the activities of the relevant international organizations;
- 14) Drafting and adopting the regulations on territorial bodies and state institutions of veterinary medicine, including stipulation of the structure of the state service of veterinary medicine, and staff numbers necessary for efficient operation thereof;
- 15) Drafting and adopting veterinary-sanitary measures, normative-legal acts on veterinary medicine issues within its authorities;
- 16) Establishing maximum permitted limits of veterinary preparations, feed additives and other contaminants in feed.
- 17) Ensuring implementation of state policies in the sphere of veterinary medicine and protecting the territory of Ukraine from introduction of pathogens of especially dangerous diseases of the OIE List from the territories of other countries or from quarantine zones;

18) Coordinating activities of the state bodies of veterinary medicine to ensure veterinary-sanitary and epizootic welfare and adherence to the procedure regulating state veterinary-sanitary control and supervision;

19) Ensuring implementation of state policies in the sphere of veterinary medicine, application of the state veterinary-sanitary control and supervision over the safety of products of animal origin.

9. State veterinary-sanitary supervision on the state border of Ukraine and transport shall be conducted by the Chief State Inspector of Veterinary Medicine of Ukraine, Chief State Inspectors of Veterinary Medicine of the Autonomous Republic of Crimea, the oblasts, cities of Kyiv and Sebastopol, cities, rayons, regional services, their deputies, and state inspectors of veterinary medicine.

10. Normative-legal acts of the central body of executive power on veterinary medicine issues issued within its authorities shall be compulsory for execution by the state bodies, legal entities (both Ukrainian and foreign), citizens of Ukraine, foreigners, and persons without citizenship residing/staying in the territory of Ukraine.

Article 7. Veterinary Medicine Subdivisions of the Ministries, Other Central Bodies of Executive Power, and Their Territorial Bodies

(1) Subdivisions of veterinary medicine of the ministries, other central bodies of executive power and their territorial bodies shall organize and perform their work in accordance with this Law and shall be subordinated to the central body of executive power on veterinary medicine issues on issues specified by this Law. The heads of these subdivisions shall be appointed to and dismissed from their offices upon consent of the central body of executive power on veterinary medicine issues.

(2) Subdivisions of veterinary medicine of the ministries, other central bodies of executive power and their territorial bodies shall operate on the basis of the provisions adopted by the heads of these bodies upon consent of the central body of executive power on veterinary medicine issues and its territorial bodies.

Article 8. Subdivisions of Veterinary Militia on Quarantine Veterinary Measures Enforcement

(1) Subdivisions of veterinary militia on quarantine veterinary measures enforcement of the Ministry of the Interior of Ukraine and relevant subdivisions of its main offices and offices in the Autonomous Republic of Crimea, the oblasts, cities of Kyiv and Sebastopol, city and rayon offices and units shall be created to provide practical assistance to the state bodies of veterinary medicine in organizing and conducting control and supervision over the fulfillment of the requirements of veterinary-sanitary measures, including with regard to prophylaxis, containment and, elimination of diseases, and shall be staffed exclusively with the doctors of veterinary medicine, who, according to their positions, shall be the state inspectors of veterinary medicine.

(2) Subdivisions of veterinary militia on quarantine veterinary measures enforcement of the Ministry of the Interior of Ukraine and relevant subdivisions of the relevant main offices and offices in the Autonomous Republic of Crimea, the oblasts, cities of Kyiv and Sebastopol, city and rayon offices and units shall be functionally subordinated to the central body of executive power on veterinary medicine issues and its territorial bodies.

(3) Subdivisions of veterinary militia on quarantine veterinary measures enforcement shall be financed from budgetary funds allocated to the central body of executive power on veterinary medicine issues and its territorial bodies for carrying out anti-epizootic measures.

- (4) The Cabinet of Ministers of Ukraine shall approve regulations for subdivisions of veterinary militia on quarantine veterinary measures enforcement.

SECTION III. STATE VETERINARY-SANITARY CONTROL AND SUPERVISION

Article 9. Officials Implementing State Veterinary-Sanitary Control

- (1) State veterinary-sanitary control shall be implemented by the state inspectors of veterinary medicine.
- (2) The Chief State Inspector of Veterinary Medicine of Ukraine may empower doctors of veterinary medicine, employed by the state institutions of veterinary medicine, and licensed doctors of veterinary medicine with the authorities of state inspectors of veterinary medicine to conduct state veterinary-sanitary control. It shall be prohibited to interfere into the activities of authorized doctors of veterinary medicine with regard to implementation of veterinary-sanitary control.
- (3) State veterinary-sanitary control at the objects of certain central bodies of executive power may, upon consent from the central body of executive power on veterinary medicine issues be conducted by the subdivisions of veterinary medicine of these bodies.

Article 10. Rights and Obligations of the Officials, Implementing State Veterinary-Sanitary Control

- (1) State inspectors of veterinary medicine and authorized doctors of veterinary medicine implementing state veterinary-sanitary control shall have the right to:
- 1) Verify the adherence by persons to veterinary-sanitary measures for transportation of the objects of state veterinary-sanitary control and supervision, and the availability of relevant accompanying veterinary documents;
 - 2) Verify safety of non-edible products of animal origin, including by means of extended veterinary-sanitary control, with regard to their conformity to the requirements of legislation and technical regulations;
 - 3) Take samples of commodities and other objects of state veterinary-sanitary control and supervision for veterinary-sanitary testing;
 - 4) Evaluate samples of non-edible products of animal origin and other objects of state veterinary-sanitary control and supervision for the purpose of verifying their adherence to veterinary-sanitary measures and minimum quality indicators established in relevant technical regulations;
 - 5) Verify the veterinary-sanitary state of production premises and storage conditions for reproductive material;
 - 6) Verify the adherence to veterinary-sanitary measures at the facilities (objects) used for keeping animals, production and circulation of non-edible products of animal origin, veterinary preparations, substances, feed additives, premixes, feed of animal origin, finished feed, reproductive material, and means of animal care;
 - 7) Inspect and, if necessary, issue instructions or directives with regard to disinfection of transportation vehicles, which are moving through quarantine zones for notifiable diseases;
 - 8) Conduct standard border veterinary-sanitary control of the objects of state veterinary-sanitary control and supervision, which are being moved as transit;

- 9) Conduct standard border veterinary-sanitary control, and if necessary, random or extended control of the objects of state veterinary-sanitary control and supervision, which are imported or exported;
 - 10) Issue international veterinary certificates for commodities, which are exported.
- (2) State inspectors of veterinary medicine and authorized doctors of veterinary medicine implementing state veterinary-sanitary control shall be obliged to:
- 1) Observe the requirements of the laws and normative-legal acts on issues of veterinary medicine and labor protection;
 - 2) Immediately notify the heads of relevant state bodies of veterinary medicine on revealed violations of veterinary-sanitary requirements, established by legislation.

Article 11. Officials Implementing State Veterinary-Sanitary Supervision

- (1) State veterinary-sanitary supervision shall be carried out by the Chief State Inspector of Veterinary Medicine of Ukraine, chief state inspectors of veterinary medicine of the Autonomous Republic of Crimea, the oblasts, cities of Kyiv and Sebastopol, cities, rayons, chief state inspectors of veterinary medicine of the regional services, their deputies and state inspectors of veterinary medicine.
- (2) The Chief State Inspector of Veterinary Medicine of Ukraine shall coordinate the implementation of state veterinary-sanitary supervision.
- (3) The Chief State Inspector of Veterinary Medicine of Ukraine may provide the doctors of veterinary medicine, employed by the state institutions of veterinary medicine, and licensed doctors of veterinary medicine with the authorities of state inspectors of veterinary medicine for the implementation of state veterinary-sanitary supervision;
- (4) Officials implementing state veterinary-sanitary supervision shall be provided with the uniforms according to the procedure, adopted by the Cabinet of Ministers of Ukraine, and financed from funds of the State Budget of Ukraine.
- (5) Specimens of the uniforms and mark of rank for officials implementing state veterinary-sanitary supervision shall be adopted by the Cabinet of Ministers of Ukraine.

Article 12. Rights and Obligations of State Inspectors of Veterinary Medicine Implementing State Veterinary-Sanitary Supervision

- (1) State inspectors of veterinary medicine implementing state veterinary-sanitary supervision shall be empowered to:
 - 1) For the purpose of implementing veterinary-sanitary supervision - have unhindered access within working hours to facilities (objects), which are used for production, processing and circulation of commodities, veterinary preparations, feed additives, premixes and feed;
 - 2) In case of an outbreak of a notifiable disease - have unhindered access at any time to the facilities (objects) engaged in production or circulation of commodities, if such facilities (objects) are located within a quarantine zone to verify the veterinary-sanitary state of such facilities (objects) and/or the commodities and/or implement necessary measures, imposed during animal quarantine;
 - 3) Obtain information necessary to determine the veterinary-sanitary state of non-edible products of animal origin, to reveal causes of animal diseases with the aim of determining the veterinary-sanitary status of the relevant zone;

- 4) Verify the state of implementation of veterinary-sanitary control;
 - 5) Issue orders, instructions and directives compulsory for implementation of veterinary-sanitary measures (including animal slaughter, forced animal slaughter, neutralization, utilization or destruction of non-edible products of animal origin, adherence to the procedures of processing, utilization or destruction of objects if they are carrying notifiable diseases or there is a suspicion that these objects are infected with or are carrying a notifiable disease, or contain contaminants, radio-nuclides in the amounts exceeding maximum residue limits);
 - 6) Prohibit export, import, transit and other circulation of commodities, substances, feed, feed additives, veterinary preparations, and devices of veterinary medicine, which do not comply with relevant veterinary-sanitary measures and/or technical regulations;
 - 7) Issue instructions on withdrawing from circulation commodities and means of animal care, which do not comply with relevant veterinary-sanitary measures and/or technical regulations;
 - 8) Issue directives on the suspension, termination, renewal and annulment (cancellation) of operating permits and veterinary documents;
 - 9) Set up, if necessary, the commissions of experts of veterinary medicine experts, involving specialists of veterinary medicine of sectoral scientific-and-research institutions and higher educational establishments in order to identify animal diseases and causes of death in animals;
 - 10) Restrict, prohibit or terminate, according to legislation, economic activities of legal entities or natural persons, in case the latter violate veterinary-sanitary measures, established by legislation, if such violations may cause immediate danger to human and animal life and/or health;
 - 11) Organize implementation of anti-epizootic measures by legal entities and natural persons carrying out professional activity in the sphere of veterinary medicine;
 - 12) Impose administrative penalties pursuant to the procedure established by legislation.
- (2) State inspectors of veterinary medicine implementing state veterinary-sanitary supervision shall be obliged to:
- 1) Immediately after detection or suspicion of an outbreak of especially dangerous diseases of the OIE List, or an outbreak of other notifiable disease, or mass-scale poisoning of animals, - notify the relevant bodies of executive power on the necessity of establishing emergency conditions of a special regime of operation of the facilities (objects), and measures of animal disease control.
 - 2) Inform licensing bodies in the sphere of veterinary medicine on violation of licensing conditions by persons, which obtained relevant licenses.
 - 3) Participate in the activities of the State commissions for approving the start-up of the facilities (objects), at which the objects of state veterinary-sanitary control and supervision are produced, or which are used for their circulation.

Article 13. Guarantees of Rights of the Officials Implementing State Veterinary-Sanitary Control and Supervision

- (1) State inspectors of veterinary medicine and authorized doctors of veterinary medicine veterinarians implementing state veterinary-sanitary control or supervision shall be independent in their activities and shall be governed by this and other laws, normative-legal acts on veterinary medicine issues. State bodies, legal entities, citizens of Ukraine, foreigners, and persons without citizenship residing/staying in the territory of Ukraine shall be obliged to assist the latter during execution of their official duties.

(2) Offence of a person implementing state veterinary-sanitary control or supervision as well as resistance, threats, violence and other actions that hinder execution of such person's duties shall entail liability, established by the law.

(3) Losses caused to the property of a person implementing state veterinary-sanitary control or supervision, due to the performance of this person's official duties, shall be fully compensated at the expense of guilty persons according to the procedure established by legislation.

(4) No rulings of the officials may constitute grounds for an unlawful action or inaction, which contradicts official duties of the state inspectors of veterinary medicine and authorized doctors of veterinary medicine.

Article 14. State Veterinary-Sanitary Control and Supervision of Animal Movements

(1) State veterinary-sanitary control and supervision of animals that are being moved outside the facilities (objects) where they were kept shall be conducted by the relevant state bodies of veterinary medicine.

(2) Circulation of animals that have a notifiable disease or are suspected of potentially having such disease, shall be prohibited. Any movements of such animals may be performed only under permission of the relevant state inspector of veterinary medicine.

(3) State inspectors of veterinary medicine and authorized doctors of veterinary medicine shall control the adherence to the requirements for animal identification, circulation, and movement, including forms and documents required to move or transport animals.

(4) The system for registration of animal facilities (objects), the animal identification system, and the recording of animal movement's data shall be such as to enable clear identification of animals and traceability of their facilities (objects) of origin, movement, and circulation.

(5) Loading, unloading, and reloading of animals into a transportation vehicle shall be allowed only in those places that have facilities in compliance with veterinary- sanitary measures.

Article 15. State Veterinary-Sanitary Control and Supervision at Markets

(1) The State veterinary-sanitary control and supervision shall be conducted at any market where there is organized trade of live animals and non-edible products of animal origin.

(2) State veterinary-sanitary control in the markets shall be conducted by the specialists of state institutions of veterinary medicine, and state veterinary-sanitary supervision shall be conducted by state inspectors of veterinary medicine.

(3) Trade in animals shall be allowed only in places designated for the latter, in compliance with veterinary-sanitary measures.

(4) It shall be prohibited to circulate animals and non-edible products of animal origin that are not accompanied by necessary veterinary documents.

(5) Should state inspector of veterinary medicine determine that trade in the markets is carried out with violation of veterinary-sanitary measures, including in places not designated for the latter, state inspector of veterinary medicine shall issue a directive to prohibit circulation of such animals or non-edible products of animal origin until the determined violations are corrected and shall levy a penalty.

Article 16. State Control and Supervision of Safety and Quality of Veterinary Preparations, Substances and Devices of Veterinary Medicine

1. The purpose of state control and supervision of veterinary preparations, substances and devices of veterinary medicine shall be to implement organizational and legal measures, aimed at ensuring compliance by legal entities and natural persons with the requirements of this Law and relevant veterinary-sanitary measures and technical regulations.
2. State control and supervision of veterinary preparations, substances, devices of veterinary medicine shall include registration of veterinary preparations; licensing and attestation of economic entities, engaged in production or circulation of veterinary preparations; inspection of licensed economic entities for ensuring compliance by the latter with licensing requirements; verification of quality, efficiency and safety of veterinary preparations and substances in course of registration, production, circulation and /or use (application). Regulations on state control and supervision of veterinary preparations, substances and devices of veterinary medicine shall be adopted by the central body of executive power on veterinary medicine issues.
3. State control and supervision with regard to safety and quality of veterinary preparations, substances and devices of veterinary medicine shall be conducted by the state institutions of veterinary medicine, authorized by the central body of executive power on veterinary medicine issues. Such control shall be conducted without prior notice by means of unscheduled verifications or scheduled verifications, according to inspection programs, which shall be composed in advance, and which shall envisage the frequency of inspections and procedures, which shall be applied, including the grounds for higher probability that veterinary preparations, substances and devices of veterinary medicine will not comply with prescribed requirements.
4. State institutions of veterinary medicine, authorized by the central body of executive power on veterinary medicine issues, shall implement the national program of monitoring residue amounts of veterinary preparations and other contaminants in animals, products of animal origin and feed, to verify appropriate use of preparations by the owners (keepers) of animals and to prevent an adverse effect on animal and human health. Results of the national program of monitoring shall be informed to the National Commission on Codex Alimentarius of Ukraine.
5. Should residue amounts of veterinary preparations in products of animal origin, which were produced with changes of their normal state without adding any other substances, exceed established maximum allowed limits of residues, authorized institutions of veterinary medicine shall inform their conclusions to the central body of executive power on veterinary medicine issues and the relevant chief state inspector of veterinary medicine so that the latter may take necessary measures, according to legislation, to prevent placing such products into circulation.
6. State control of veterinary preparations shall include an analysis of safe residue amount of such preparations, and side effects of the application of veterinary preparations. For this purpose, National reference laboratories on controlling residue amounts of veterinary preparations and feed additives shall be created under State scientific-research control institute of veterinary preparations and feed .
7. State scientific-research control institute of veterinary preparations and feed shall be responsible for carrying out testing for revealing and/or identifying veterinary preparations and feed additives, and State scientific-control institute of biotechnologies and microorganism strains – for veterinary immunobiological means.

Article 17. State Veterinary-Sanitary Control and Supervision on the State Border of Ukraine and Transport

1. State veterinary-sanitary control and supervision on the state border of Ukraine and transport shall be conducted by regional services of state veterinary-sanitary control and supervision on the state border of Ukraine and transport, their structural subdivisions (points).

2. State veterinary-sanitary control and supervision on the state border of Ukraine and transport shall be compulsory in course of export, import and transit movement of the objects of state veterinary-sanitary control and supervision by all types of transport.

3. State Veterinary-sanitary control and supervision on the state border of Ukraine and transport shall be conducted by the state inspectors of veterinary medicine with drawing up of relevant documents. Working places of the above persons shall be created at border inspection posts.

4. State veterinary-sanitary supervision on the state border of Ukraine and transport shall be conducted by the Chief State Inspector of Veterinary Medicine of Ukraine, his/her deputies, state inspectors of veterinary medicine of the central body of executive power on veterinary medicine issues, chief state inspectors of veterinary medicine, their deputies, state inspectors of veterinary medicine of regional services.

5. Regulations on the regional service of state veterinary-sanitary control and supervision on the state border of Ukraine and transport shall be adopted by the Cabinet of Ministers of Ukraine.

Article 18. State Veterinary and Sanitary Control and Supervision for Hunting

(1) Hunting season within a defined territory shall be opened upon permission of the relevant state bodies of veterinary medicine after compulsory epizootic surveillance of hunting areas.

(2) Users of hunting and fishing areas shall inform the nearest state inspector of veterinary medicine on suspicious (unnatural) animal behavior and suspicious deaths of animals. State inspector of veterinary medicine shall consider such reports, and when applicable, after inspecting the carcasses and, based on his/her professional judgment, take samples of animal tissue for an analysis in the relevant laboratory of veterinary medicine.

SECTION IV. PRINCIPLES FOR DEVELOPING, ADOPTING, AND APPLYING VETERINARY-SANITARY MEASURES

Article 19. Objectives of Veterinary-Sanitary Measures

The central body of executive power on veterinary medicine issues jointly with other bodies of state management in the sphere of veterinary medicine shall undertake appropriate and necessary veterinary-sanitary measures in order:

1) To protect animal life or health from the risks resulting from the introduction, establishment or spread of animal diseases, disease-carrying and also disease-causing organisms;

2) To protect human or animal life and health from the risks resulting from the additives, contaminants, toxins or disease-causing organisms, which are contained in the products of animal origin or feed;

3) To protect human life or health from the risks resulting from diseases, which are carried by animals or products, manufactured thereof.

Article 20. Appropriate Level of Animal and Related Human Health Protection

- (1) The central body of executive power on veterinary medicine issues, jointly with other bodies of state management in the sphere of veterinary medicine, shall determine the appropriate level of animal and related human health protection.
- (2) The appropriate level of animal and related human health protection shall be determined based on:
 - 1) The presence of animal diseases in Ukraine and implementation of the national programs for such animal diseases;
 - 2) Estimated economic costs to the animal-raising sector of Ukraine, associated with the introduction of animal disease pathogens, which are not present in Ukraine, or with the spread of animal diseases, which are present in Ukraine;
 - 3) Determination of the level of risk acceptable by the neighboring countries and interested trading partners;
 - 4) International standards, guidelines, and recommendations;
 - 5) Minimization of negative effects of veterinary-sanitary measures on international and domestic trade.

Article 21. Developing, Reviewing, Revising and Approving Veterinary-Sanitary Measures

- (1) Veterinary-sanitary measures shall be developed, reviewed, revised and approved by the central body of executive power on veterinary medicine issues based on the following:
 - 1) Pursuant to item 4 of this paragraph, all veterinary-sanitary measures shall be based on scientific principles and available scientific justifications, including relevant processes and production methods; relevant inspection, sampling, and testing methods; determination of prevalence of specific animal diseases; existence of zones that are free of or have low prevalence of animal diseases; relevant ecological and environmental conditions; and prophylactic animal quarantine or other regimes.
 - 2) All veterinary-sanitary measures shall be based on international standards, guidelines, and recommendations of the relevant international organizations.
 - 3) In case international standards, guidelines, and recommendations do not exist or are insufficient to fulfill the appropriate level of animal and related human health protection, veterinary-sanitary measures shall be developed on the basis of a risk analysis according to the technique developed by the relevant international organizations.
 - 4) When scientific justifications needed for risk analysis are insufficient, or in emergency circumstances, veterinary-sanitary measures shall be developed on the basis of available relevant information, obtained from the relevant international organizations, or the veterinary-sanitary measures employed by interested trading partners.
- (2) When developing, reviewing, revising, and approving veterinary-sanitary measures applicable to imported commodities, the central body of executive power on veterinary medicine issues shall take into account Ukraine's veterinary-sanitary status relative to that of the country of origin of commodities.
- (3) When developing, reviewing, revising, and approving veterinary-sanitary measures, arbitrary or unjustifiable discrimination shall be prohibited between interested trading partners, which are bringing

commodities into the territory of Ukraine, when Ukraine and the country of origin of commodities (one country of origin relative to another country of origin) have identical or similar veterinary-sanitary status.

(4) When developing, reviewing, revising, and approving veterinary-sanitary measures, relevant measures, which are applied in another country, shall be considered equivalent to those that are applied and approved in Ukraine, if the other country proves in an objective manner that its measures achieve the same or higher level of protection of animal health and life relative to those required by Ukraine.

(5) All veterinary-sanitary measures referred to in this Article, including measures approved in emergency circumstances, shall be reviewed and updated as new scientifically justified information becomes available or on the basis of significant (substantive) comments from interested trading partners or from Ukrainian persons in order to make sure that such measures facilitate achievement, but not exceeding of the appropriate level of animal and related human health protection.

(6) All veterinary-sanitary measures approved in emergency circumstances shall be reviewed and updated no later than within six months of the date of approval or the last date of review, as referred to in paragraph 5 of this Article, in order to make sure that such measures facilitate achievement, but not exceeding of the appropriate level of animal and related human health protection.

(7) The central body of executive power on veterinary medicine issues shall approve a procedure for development and revision of veterinary-sanitary measures, which shall be applied pursuant to this Article.

Article 22. Conducting Risk Analysis

(1) Risk analysis conducted by the specialists of the state service of veterinary medicine, which shall be defined by the central body of executive power on veterinary medicine issues, in conjunction with the possible import of commodities, shall be drawn up only in written form. This document shall contain the following information:

- 1) Purpose for risk analysis;
- 2) Revelation of animal diseases and means of entry (hosts, mode of transmission), which contribute to their introduction, establishment and spread;
- 3) Sources of information;
- 4) Conclusions of the animal disease risk assessment, including the probability of harm to animals and humans and possible consequences thereof;
- 5) The risk management options that were determined and the reasons for rejecting alternative options.

(2) When there is a sufficient amount of scientific and other technical information, a quantitative risk assessment shall be undertaken according to the requirements of the relevant international organizations.

(3) When scientific and other technical information do not exist or are insufficient for the purpose of a quantitative risk assessment, a qualitative risk assessment shall be undertaken.

(4) The risk analysis document, referred to in paragraph 1 of this Article, shall be made available to all interested persons in writing and/or electronic form.

Article 23. Risk Management Procedures

- (1) When importing commodities, the objective of risk management shall be to reduce relevant risks in line with the appropriate level of animal and related human health protection, as defined for Ukraine.
- (2) When considering alternative options for reducing the risk of introduction of animal disease pathogens from imported commodities, the chosen veterinary-sanitary measures shall not be more trade-restrictive than necessary to achieve the appropriate level of animal and related human health protection, taking into account the technical and economic feasibility of proposed alternative measures.
- (3) Evaluation of economic feasibility of veterinary-sanitary measures shall include the evaluation of the potential harm in form of losses of production and sale of animals or products of animal origin in the event of introduction, establishment or spread of animal disease pathogens; the costs of containment, control, or elimination of such diseases, and the relative evaluation of cost-effectiveness of alternative options for measures, aimed at limiting the risks.
- (4) Risk management shall be implemented by the central body of executive power on veterinary medicine issues.

Article 24. Notifying Proposed Veterinary-Sanitary Measures

- (1) Except as provided in paragraphs 5 through 8 of this Article, whenever relevant international standards do not exist, or a proposed veterinary-sanitary measures do not conform to international standards, the central body of executive power on veterinary medicine issues shall :
 - 1) immediately publish a notice in mass media publications in such a manner as to enable interested parties to become acquainted with the content of proposed measures;
 - 2) prepare a relevant notification, which shall be sent by the Centre for Processing Inquiries and Providing Notifications Regarding Veterinary-Sanitary Measures (hereinafter: Enquiry and Notification Centre) to interested trading partners, when a proposed veterinary-sanitary measure is expected to significantly affect the exporting opportunities of other countries, .
- (2) The notice, referred to in item 2 of paragraph 1 of this Article, shall be submitted no less than 60 days before the adoption of proposed veterinary-sanitary measure. The notice shall be prepared in the format required by the relevant international organizations or international agreements, to which Ukraine is a party. It shall include the commodities to be covered and/or affected by the veterinary-sanitary measure together with a brief indication of the objective and rationale of the proposed measure.
- (3) Upon written request of persons or interested trading partners, the central body of executive power on veterinary medicine issues shall provide the text of the proposed veterinary-sanitary measure and, whenever possible, stipulate the provisions, which substantially deviate from international standards, guidelines and recommendations.
- (4) Upon written request of persons or interested trading partners, prior to finalizing the veterinary-sanitary measure, the central body of executive power on veterinary medicine issues shall consider comments that were received, and, in case of their expediency, take those into account when preparing the final draft of the veterinary-sanitary measure.
- (5) When emergency circumstances arise, and a veterinary-sanitary measure is adopted, a notice on application of the emergency veterinary-sanitary measure shall be published in mass media.
- (6) If the emergency veterinary-sanitary measure referred to in paragraph 5 of this Article is expected to significantly affect the exporting opportunities of other countries, the central body of executive

power on veterinary medicine issues shall immediately send a notification through the Enquiry and Notification Centre to interested trading partners. The notification shall be prepared in the format required by the relevant international organizations or international agreements concluded by Ukraine. The notification shall include the commodities to be covered and/or affected by the emergency veterinary-sanitary measure with a brief indication of the objective and the rationale for the emergency veterinary-sanitary measure, including the explanation of the nature of the emergency circumstances.

(7) Upon written request, the central body of executive power on veterinary medicine issues shall provide the text of the emergency veterinary-sanitary measure to interested trading partners and persons.

(8) The central body of executive power on veterinary medicine issues shall review written comments about the emergency veterinary-sanitary measure received from interested trading partners and persons, and upon their written request, discuss such comments and take the comments and results of the discussion into account when considering revision of the emergency veterinary-sanitary measure.

(9) The central body of executive power on veterinary medicine issues shall approve the criteria for determining whether a proposed veterinary-sanitary measure or adopted emergency veterinary-sanitary measure will significantly affect the exporting opportunities of other countries and assign the officials with the responsibility for publishing and sending notifications to the Enquiry and Notification Centre.

Article 25. Publishing and Applying Veterinary-Sanitary Measures

Immediately after their approval, all new and revised veterinary-sanitary measures shall be published in the relevant official publication and made available on the web site of the central body of executive power on veterinary medicine issues. Except for those emergency veterinary-sanitary measures adopted in response to emergency circumstances, and also in case of measures that reduce import restrictions, which shall come into force from the date of approval, veterinary-sanitary measures shall come into force no sooner than six months after relevant publication.

Article 26. Principles for Applying Veterinary-Sanitary Measures

The central body of executive power on veterinary medicine issues shall take the following into account when applying veterinary-sanitary measures:

- 1) Veterinary-sanitary measures shall be applied only to the extent necessary to achieve the objectives, referred to in Article 19 of this Law;
- 2) Veterinary-sanitary measures shall not be applied in a manner that would constitute a disguised restriction on international trade;
- 3) Veterinary-sanitary measures shall be applied in such a manner as to avoid arbitrary or unjustifiable distinctions in the levels considered to be appropriate in different situations, if such distinctions result in discrimination or a disguised restriction of international trade.

Article 27. Equivalence Agreements for Veterinary-Sanitary Measures

The central body of executive power on veterinary medicine issues shall, upon request of interested trading partners, conduct consultations on the equivalency of general or special veterinary-sanitary measures aimed at further conclusion of bilateral and multilateral agreements on such equivalency by the relevant bodies of state power.

Article 28. Determining the Effectiveness of a Foreign Veterinary Service

(1) Assessment of the effectiveness of the Veterinary Administration of another country (hereinafter: foreign Veterinary Administration) shall be based on the following:

- 1) Membership of the country in the relevant international organizations;
- 2) Fulfillment of reporting requirements to the relevant international organizations and application of veterinary-sanitary measures pursuant to international agreements concluded by Ukraine;
- 3) Necessary level of qualification for staff members of the foreign Veterinary Administration, including the level of their scientific background, necessary experience, and competence to make solid professional decisions;
- 4) Independence of staff members of the foreign Veterinary Administration from any commercial, financial, administrative, political and other pressures, which may affect their judgments and decisions;
- 5) The impartiality of staff members, impartiality of provision of services, and impartiality of decision making by the foreign Veterinary Administration;
- 6) The integrity of staff members of the foreign Veterinary Administration and prevention of fraud, corruption and falsification;
- 7) The transparency of decision making by the foreign Veterinary Administration;
- 8) Availability of appropriate legislation and organization that ensures control over the establishment and fulfillment of veterinary-sanitary measures and of international veterinary certification activities, including legislative acts, stipulating the competence and the structure of the foreign Veterinary Administration;
- 9) Establishment of procedures and standards relating to:
 1. Planning and management of activities, including international veterinary certification activities;
 2. Prevention and control of animal disease outbreaks;
 3. Epizootic surveillance and zoning of the territory of the country with regard to veterinary-sanitary status;
 4. Inspection and sampling techniques;
 5. Diagnostic analysis for animal diseases;
 6. Development, production, registration and control of biological products, used for the diagnostics of animal diseases and for production of veterinary preparations;
 7. Treatments intended to destroy pathogenic agents in products of animal origin;
 8. Minimum qualification level (education and professional training) for laboratory specialists and those officials authorized to inspect commodities and issue international veterinary certificates;
 9. Use of international standards, guidelines, and recommendations when issuing international veterinary certificates;
 10. Use of international standards, guidelines, and recommendations in course of application of measures to control animal disease outbreaks;
 11. Frequency of serological surveys for animal diseases.

- 10) The frequency of invalid international veterinary certificates, and also certificates, attesting to an import consignment's freedom from animal disease, which were issued by the officials of the foreign Veterinary Administration for import consignment of commodities, but were invalidated by laboratory analysis (testing) of samples from such shipment;
 - 11) Other factors recommended by the relevant international organizations.
- (2) All factors considered and relevant conclusions made when evaluating the effectiveness of a foreign Veterinary Administration shall be fully documented and immediately made available to the foreign Veterinary Administration upon request. Should the foreign country request consultations and submit comments with regard to the evaluation, consultations shall commence immediately, and the results of the consultations and clarifications shall be analyzed to determine whether there is a basis for revising the evaluation of the effectiveness of the foreign Veterinary Administration.

Article 29. Control, Inspection, and Approval Procedures

- (1) The central body of executive power on veterinary medicine issues shall ensure, with respect to any procedure of verification and ensuring the fulfillment of the requirements of veterinary-sanitary measures, that:
 - 1) Such procedures conform to the standards, recommendations, and guidelines of the relevant international organizations;
 - 2) Such procedures are executed expeditiously and without unjustifiable delay in a manner which is as favorable for imported goods as for analogue domestic goods;
 - 3) Sampling requirements for control, inspection, and approval procedures are limited to what is necessary and reasonable;
 - 4) The applicant requesting control, inspection and approval procedures must be immediately informed of any deficiencies in the application so as to avoid any delay in the execution of control, inspection, and approval procedures, and if there are deficiencies in the application, the above procedures shall be undertaken as far as practicable upon request of the applicant;
 - 5) The expected time for completing such procedures shall be communicated to the applicant upon his/her request;
 - 6) The results of the procedure shall be immediately transmitted to the applicant in written form and in a complete volume;
 - 7) Such procedures shall be applied equally to the objects of state veterinary-sanitary control and supervision of foreign as well as domestic origin;
 - 8) All adopted procedures, including procedures to ensure that a product that has been changed (treated, processed or otherwise changed) continues to meet requirements of veterinary-sanitary measures, as well as the information required to conduct control, inspection, and approval procedures must be limited to what is necessary to fulfill veterinary-sanitary measures;
 - 9) Confidentiality of provided information shall be protected in order to ensure the commercial interests of the applicants;
 - 10) The fees collected for control, inspection, and approval procedures for imported commodities shall be the same in relation to those for domestic commodities and not exceed the actual costs of services rendered;
 - 11) The sampling procedure and requirements associated with the use of particular facilities for carrying out control, inspection, and approval procedures shall minimize related inconveniences and be

equitable for all objects of state veterinary-sanitary control and supervision of foreign and domestic origin;

12) Procedure for reviewing complaints with regard to implementation of control, inspection, and approval procedures shall be established, aimed at taking corrective action when a complaint is justified.

Article 30. Documentation of Veterinary-Sanitary Measures

(1) The Chief State Inspector of Veterinary Medicine of Ukraine shall appoint a group of the officials in the central body of executive power on veterinary medicine issues, which shall be responsible for receiving and coordinating responses to all questions associated with veterinary-sanitary measures, including control, inspection and approval procedures, from interested parties and for the provision of the copies of relevant documents, upon their request, which shall include at least:

- 1) Approved or proposed veterinary-sanitary measures;
- 2) Control, inspection, and approval procedures;
- 3) Procedures for animal disease risk assessment, factors to be taken into consideration, and means of determining the appropriate level of animal and related human health protection.
- 4) Information regarding membership and participation of Ukraine in the relevant international organizations (OIE, the UN Food and Agriculture Organization, FAO, etc) or international agreements regarding veterinary-sanitary measures and the texts of such agreements.

SECTION V. PROTECTION OF ANIMAL HEALTH

Article 32. Notifiable Diseases

(1) The list of notifiable diseases shall be determined by the central body of executive power on veterinary medicine issues and include:

- 1) All the especially dangerous diseases of the OIE List;
- 2) Exotic animal diseases, which, in case of the introduction and further spread in Ukraine, may result in an unacceptable level of risk for animals and/or humans;
- 3) Those animal diseases, which have manifestation in Ukraine, and which, in case of an outbreak or spread in the territory of Ukraine, may result in an unacceptable level of risk to the animal and/or human health.

(2) Upon the recommendation of the Chief State Inspector of Veterinary Medicine of Ukraine, an animal disease may be included into the list of notifiable diseases in order to collect information regarding the prevalence of such disease.

Article 32. Registration of Animal Facilities

(1) Persons, engaged in raising animals for personal consumption, including cattle, pigs, sheep, goats, rabbits, and poultry, but excluding non-food-producing animals, as well as animals raised for recreational purposes, shall be obliged to register with the relevant state bodies of veterinary medicine. Such register shall include the name of the owner of animals, address, telephone number, and other information, the species of animals, which are kept by the relevant person, and the number of animals within each species.

(2) Operators of facilities (objects) used for commercial raising (rearing) of animals shall be obliged to register them with the relevant bodies of veterinary medicine. Such register shall include the species of animals, which are kept in the relevant facilities (objects), number of animals of each species, name of the operator of facilities (objects), and, when necessary, of the owner of animals, their address, telephone number, and other information.

Article 33. Implementation of Prophylactic Animal Quarantine

Animals that are being introduced into a herd from other facilities (objects), or animals that were purchased in a domestic market shall be subject to compulsory prophylactic animal quarantine for a defined period of time. During prophylactic animal quarantine, animals shall be kept separately in specially designated and isolated places (quarantine points) under the supervision of a state inspector of veterinary medicine or authorized doctor of veterinary medicine, and shall be subject to veterinary-sanitary survey. Animals shall be included in the herd only upon completion of prophylactic animal quarantine, based on a written permit from the state inspector of veterinary medicine.

Article 34. Rights of the Persons With Regard to Ensuring Veterinary-Sanitary and Epizootic Welfare

With the aim to ensure veterinary-sanitary and epizootic welfare, legal entities and natural persons, whose activities are related to keeping, transportation and circulation of animals, and also with production, processing and circulation of non-edible products of animal origin, veterinary preparations, substances, feed additives, premixes, feed and reproductive material shall have the right to:

1) obtain from the state bodies of veterinary medicine, other state institutions of veterinary medicine, local bodies of executive power and bodies of local self-governance information on the epizootic state of serviced territory;

2) appeal to the relevant chief inspector of veterinary medicine, or to court, the decisions and actions of the officials of the state bodies of veterinary medicine, authorized doctors of veterinary medicine and other persons authorized by the central body of executive power on veterinary medicine issues to perform certain functions.

Article 35. Obligations of Persons Keeping Animals or Participating in their Circulation

Legal entities and natural persons, whose activities are related to keeping and circulating of animals, shall be obliged to:

ensure that animals, which they are raising, keeping and/or circulating, do not have notifiable diseases;

fulfill lawful requirements of state inspectors of veterinary medicine and authorized doctors of veterinary medicine with regard to the implementation of anti-epizootic measures and /or measures of animal quarantine, including restrictions on movement of animals and/or persons, which had a contact with the animals that have a notifiable disease or are suspected of having a notifiable disease, and with regard to other veterinary-sanitary measures;

immediately inform the state inspector of veterinary medicine, authorized doctor of veterinary medicine or the officials of the state bodies of veterinary medicine on sudden murrain of animals, suspicion or detection of a notifiable disease, or unnatural behavior of animals;

before moving animals from the facilities (objects), where they are kept,- obtain from the state inspector of veterinary medicine a permit for their movement;

protect animal health and welfare by means of:

a) ensuring the implementation of veterinary-sanitary measures, including zoo-hygienic requirements and conditions, which shall be observed at the facilities for keeping animals;

b) supplying animals with quality and safe feed and water;

c) application of prophylactic veterinary-sanitary measures with regard to animal health;

d) timely application for services of the doctor of veterinary medicine with regard to diagnostics and medical treatment of diseased animals;

e) use of veterinary preparations in accordance with the rulings of the doctor of veterinary medicine;

f) prevention of cruel treatment of animals;

g) providing for appropriate transportation vehicles for movement of animals;

fulfillment of the requirements of identification of animals, which they own, including cats, dogs and other small domestic pets, which shall be identified with the help of micro-chips;

deliver animals to a defined place, or ensure appropriate conditions in the place of keeping animals, for carrying out veterinary visual examination, diagnostic, prophylactic-medical treatments, including analysis and vaccination. If necessary, provide for securing the animals during provision of care, transportation (delivery) of samples of tissue, blood and other materials for diagnostic analysis;

keep records for each food-producing animal with regard to purchase and use of veterinary medicinal means, veterinary immune-biological means and medicated feed, and save these records for no less than three years;

facilitate state inspectors of veterinary medicine and authorized doctors of veterinary medicine during execution by the latter of their official duties;

upon request of state inspectors of veterinary medicine or an authorized doctor of veterinary medicine, provide samples of non-edible products of animal origin for carrying out relevant analysis.

SECTION VI. REGULATION OF CIRCULATION OF ANIMALS AND REPRODUCTIVE MATERIAL

Article 36. Permits for Events Featuring Animals

(1) Persons conducting exhibitions of animals, animal competitions, fairs, auctions, performances with traveling animals, operating traveling zoos etc. shall be obliged to obtain a permit for such from the chief state inspector of veterinary medicine of the relevant territorial body.

(2) The permit, referred to in paragraph 1 of this Article (hereinafter: permit for exhibition), shall be issued upon fulfillment of the veterinary-sanitary measures within thirty calendar days of receipt of an application.

(3) The person conducting an event featuring animals shall be obliged to display the permit for exhibition in a prominent place where the event is conducted.

- (4) The permit for conducting exhibition shall be valid for a specified period of time but shall not exceed 30 calendar days.
- (5) The form and content of the application for a permit for conducting exhibition, accompanying information related to animals, which shall be required, the requirements that must be met by facilities (objects) shall be prescribed by the central body of executive power on veterinary medicine issues.

Article 37. Monitoring of Health of Breeding Animals

- (1) Animal breeding centers shall be obliged to systematically monitor the health of animals, from which reproductive material is obtained, and the reproductive material to confirm their veterinary-sanitary state.
- (2) Animal breeding centers shall keep records of the results of systematic monitoring, including records of the results of artificial insemination, and shall be obliged to present such to a state inspector of veterinary medicine upon request.
- (3) State inspector of veterinary medicine shall be obliged to issue a written directive on temporary prohibition of the production of semen, fertilized ova, and embryos if it is suspected that breeding animals have become infected with an animal disease that can be transmitted by animal semen, fertilized ova, and embryos.
- (4) Upon suspicion of infection of breeding animals with an animal disease that can be transmitted by reproductive material, the operator of the facilities (objects) or the owner of the animals shall be obliged to provide samples of material to an authorized laboratory for laboratory analysis. Should no animal disease be found, the temporary prohibition, referred to in paragraph 3, shall be lifted. Should animal disease be confirmed, diseased animal and any other animals found to be similarly infected shall be removed from production of reproductive material according to the relevant rules.
- (5) Upon the request of the owner of the animal breeding centre or the owner of the animals, an arbitration analysis shall be conducted to confirm the animal disease or to lift the suspicion of the animal disease according to the procedure prescribed by the central body of executive power on veterinary medicine issues.
- (6) The central body of executive power on veterinary medicine issues shall establish the procedure for systematic monitoring.

Article 38. Circulation of Reproductive Material

It shall be prohibited to circulate semen for artificial insemination, fertilised ova, or embryos, if their biochemical, biophysical, or morphological properties, do not meet the basic requirements necessary for reproduction, or if the content of bacteria or animal disease agents exceeds permitted levels.

SECTION VII. EMERGENCY ANTI-EPIZOOTIC COMMISSIONS AND ANIMAL QUARANTINE

Article 39. Establishment of the State Emergency Anti-Epizootic Commission under the Cabinet of Ministers of Ukraine and Local State Emergency Anti-Epizootic Commissions

- (1) The Cabinet of Ministers of Ukraine shall establish a permanent State Emergency Anti-Epizootic Commission under the Cabinet of Ministers of Ukraine.

(2) The authorities of the State Emergency Anti-Epizootic Commission under the Cabinet of Ministers of Ukraine shall include implementation of operative control, guidance, and coordination of the activities of the bodies of executive power, state services, enterprises, establishments, organizations and persons with regard to prevention and elimination of the outbreaks of mass animal diseases and poisoning.

(3) The State Emergency Anti-Epizootic Commission under the Cabinet of Ministers of Ukraine shall be chaired by the Vice-Prime-Minister of Ukraine, and shall consist of the Chief State Inspector of Veterinary Medicine of Ukraine, who shall be the Deputy-Chairman of the Commission, the deputies of the Chief State Inspector of Veterinary Medicine of Ukraine, the heads of central bodies of executive power: on issues of agrarian policy, the interior, economy, health protection, transport, emergency situations, finance, communication and informatization, forestry, state border protection, customs service, and also Ukrainian Academy of Agrarian Sciences and other officials, as determined by the Cabinet of Ministers of Ukraine.

(4) Veterinary medicine specialists included on the State Emergency Anti-Epizootic Commission under the Cabinet of Ministers of Ukraine shall be authorized to perform functions of state inspectors of veterinary medicine for the time-period of the above Commission activities.

(5) Members of the State Emergency Anti-Epizootic Commission under the Cabinet of Ministers of Ukraine shall be provided with necessary means for containing an animal disease outbreak and eliminating the latter, including devices of veterinary medicine, veterinary preparations, communication means, and with a priority right for using communication channels, specialized transportation vehicles of veterinary medicine and other transportation vehicles, for purchasing tickets for all types of transport, and for hotel lodging while exercising their official duties. Expenses for means necessary to counteract an animal disease outbreak shall be reimbursed from the funds allocated for conducting veterinary-sanitary and anti-epizootic measures.

(6) Local state emergency anti-epizootic commissions shall be created by the Council of Ministers of the Autonomous Republic of Crimea, oblast state administrations, state administrations of the cities of Kyiv and Sebastopol, city Radas, and rayon state administrations. In case of suspicion or confirmation of an outbreak of especially dangerous diseases of the OIE List, local state anti-epizootic commissions shall be obliged to follow the instructions of the State Emergency Anti-Epizootic Commission under the Cabinet of Ministers of Ukraine, and regularly report on their activities to the latter.

(7) Regulations on the State Emergency Anti-Epizootic Commission under the Cabinet of Ministers of Ukraine and standard regulations on the state emergency anti-epizootic commissions under the Council of Ministers of the Autonomous Republic of Crimea, state administrations of the oblasts, cities of Kyiv and Sebastopol, cities and rayons shall be adopted by the Cabinet of Ministers of Ukraine.

Article 40. Suspicion of an Outbreak of a Notifiable Disease

(1) Owners (keepers) of animals, operators of facilities (objects), licensed doctors of veterinary medicine, state doctors of veterinary medicine, and authorized doctors of veterinary medicine shall be obliged to immediately inform the relevant chief state inspector of veterinary medicine on the suspicion or detection of a notifiable disease or an animal disease that was not registered in Ukraine before.

(2) The state inspector of veterinary medicine, who received a notification on a suspicion of or detection of a notifiable disease, shall immediately inform the chief state inspector of veterinary medicine of the relevant territory. In case the notification that was received pertains to especially dangerous diseases of the OIE List, the chief state inspector of veterinary medicine of the relevant

territory shall immediately inform the Chief State Inspector of Veterinary Medicine of Ukraine, who in turn shall inform the Chairman of the State Emergency Anti-Epizootic Commission under the Cabinet of Ministers of Ukraine.

(3) The Chairman of the State Emergency Anti-Epizootic Commission under the Cabinet of Ministers of Ukraine shall immediately make a decision to start operation of the local state emergency anti-epizootic commissions.

Article 41. Confirmation of an Outbreak of Especially Dangerous Diseases of the OIE List

(1) In case of a suspicion of especially dangerous diseases of the OIE List, the state inspector of veterinary medicine, attending the animals, which have a disease or are suspected of having a disease, shall collect pathological material, according to the procedures specified in the relevant rules, and dispatch such to an authorized laboratory for carrying out necessary diagnostic analysis.

(2) Upon the confirmation of especially dangerous diseases of the OIE List, the State Emergency Anti-Epizootic Commission of Ukraine, or relevant state emergency anti-epizootic commissions shall determine the boundaries of infected and buffer zones, and if necessary, surveillance zone.

(3) The State Emergency Anti-Epizootic Commission under the Cabinet of Ministers of Ukraine or relevant state emergency anti-epizootic commissions shall issue a decision to implement one or several measures prescribed in the relevant contingency plan or rule book, or in the absence of such - to implement one or several measures listed in Article 42 of this Law, according to the nature of especially dangerous diseases of the OIE List and the level of risk in the infected and buffer zones, and surveillance zone.

(4) The Chairman of the State Emergency Anti-Epizootic Commission under the Cabinet of Ministers of Ukraine, due to an outbreak of an especially dangerous disease of the OIE List, shall issue a notice in the mass media, which must contain information on the boundaries of the infected and buffer zones and surveillance zone, and, if necessary, on veterinary-sanitary measures applied in each of these zones.

(5) The Chairman of the State Emergency Anti-Epizootic Commission under the Cabinet of Ministers of Ukraine shall inform the Chief State Sanitary Doctor of Ukraine on necessary measures, which shall be taken to restrict movement of people, and perform disinfection, when appropriate.

(6) After imposition of the animal quarantine for especially dangerous diseases of the OIE List, the Chief State Inspector of Veterinary Medicine of Ukraine shall send notifications, pursuant to approved procedures, about the details of the outbreak of especially dangerous diseases of the OIE List, probable source of infection, measures applied to control the outbreak, as well as planned veterinary-sanitary measures, to the relevant international organizations and Veterinary Administrations of neighboring countries and to interested trading partners, which may be affected by the outbreak of especially dangerous diseases of the OIE List.

(7) The List of especially dangerous (quarantine) diseases shall be adopted by the Cabinet of Ministers of Ukraine.

Article 42. Veterinary-Sanitary Measures Applied During Animal Quarantine

1. The State Emergency Anti-Epizootic Commission under the Cabinet of Ministers of Ukraine or the relevant local state emergency anti-epizootic commissions, according to the nature of a notifiable disease, an outbreak of which has been declared, and the level of risk in an infected zone, buffer zone,

and, if necessary, surveillance zones, may issue a decision to implement measures, deemed appropriate to contain, control and, when necessary, eliminate a notifiable disease:

- 1) Conduct thermometry, separate healthy animals from sick animals and perform diagnostic analysis;
- 2) Isolate sick animals, and close the facilities (objects), within which a notifiable disease has been found;
- 3) Prohibit or restrict animal movements;
- 4) Prohibit movement of any commodities, means of animal care, accompanying items, and excreta outside infected facilities (objects);
- 5) Implement stamping-out measures in a professional and humane way;
- 6) Seize and safely destroy the carcasses of animals that have died or have been killed, and of other commodities or excreta, should it be impossible to decontaminate those by conventional cleansing and disinfection methods;
- 7) Implement special veterinary-sanitary measures in an infected, buffer zones, and surveillance zone;
- 8) Prohibit organization of fairs, markets, exhibitions, auctions, public or other events featuring animals, and also prohibit functioning of animal sale yards;
- 9) Change an operation regime for facilities (objects), which are used for animal breeding, animal raising, training, competition, keeping, exhibitions (viewing), tender, sale, slaughter, harvesting with the aim of production and circulation of non-edible products of animal origin;
- 10) Prohibition or restriction of the mating of animals as well as of the collection, treatment, storage, and use of semen for artificial insemination of animals, fertilized ova, and embryos originating in an infected, buffer, or surveillance zone;
- 11) Vaccination, clinical survey, and medical treatment of animals;
- 12) Restriction of the movement of those persons who come into contact with infected animals, with animals suspected of having become infected or with other commodities or excreta from infected animals;
- 13) Closing and blocking the approaches to infected zones and the erection of signs on such approaches to warn of the presence of especially dangerous diseases of the OIE List, and organization of the relevant control;
- 14) Disinfection, disinsection of animal premises, stables, yards, pastures, watering places, and other places where infected animals, or animals suspected of being infected, are kept, and also of accompanying items that have been in contact with infected animals, or animals suspected of being infected;
- 15) Reliable isolation of dogs and cats of known owners and extermination of stray dogs and cats in a humane way;
- 16) Surveillance of animals, including the taking of samples of blood or pathological material with the aim to conduct an analysis, and access to farm records in infected, buffer, and surveillance zones and in other facilities (objects) under surveillance outside such zones;
- 17) Involvement of the personnel of the bodies of the interior and, in accordance with established procedure, the military, if necessary and appropriate, to assist the relevant state anti-epizootic

commissions in the imposition and implementation of measures of containment and elimination of especially dangerous disease of the OIE List.

2. All or some of the measures, specified in paragraph one of this Article shall be applied during the period of imposed animal quarantine.
3. There shall be the guard, quarantine veterinary-militia posts and signs, indicating a compulsory detour of the quarantine zone at the entrance to infected and buffer zones, and according to a decision of local state emergency anti-epizootic commission– at the entrance to surveillance zone.
4. Relevant chief state inspector of veterinary medicine, by his/her instruction, may impose a quarantine or apply all or some of the measures, specified in paragraph one of this Article for the time-period no longer than 72 hours.
5. Movement of animals and other commodities out of the quarantine zone shall be allowed only under a decision of the relevant chief state inspector of veterinary medicine.
6. Legal entities and natural persons, whose activities are related to production, processing and circulation of commodities and other products and materials, which may carry the pathogens of an animal disease, for which quarantine has been imposed, shall be obliged to provide business premises, necessary equipment and means of communication for use by specialists of veterinary medicine, engaged in the implementation of quarantine measures for the period of animal quarantine.

Article 43. Special Instructions during Quarantine

(1) During animal quarantine, the Chairman of the State Emergency Anti-Epizootic Commission of Ukraine under the Cabinet of Ministers of Ukraine or the heads of the relevant local state emergency anti-epizootic commissions may issue a decision ordering all or some licensed doctors of veterinary medicine, state doctors of veterinary medicine, authorized doctors of veterinary medicine, and other relevant veterinary medicine specialists to immediately implement special professional and other tasks in accordance with veterinary-sanitary measures.

(2) Should an animal quarantine be declared due to an outbreak of especially dangerous animal disease of the OIE List, the Cabinet of Ministers may, upon the proposal of the State Emergency Anti-Epizootic Commission under the Cabinet of Ministers of Ukraine, issue relevant acts with regard to:

- 1) Mobilization of machinery equipment, veterinary preparations, devices of veterinary medicine, transportation vehicles, and also temporary use of facilities (objects) in order to carry out necessary veterinary-sanitary measures, including in particular, safe destruction of animal carcasses and accompanying items seized for disease control purposes;
- 2) Allocation of special tasks to relevant persons other than those referred to in paragraph 1 of this Article, and to other relevant State bodies in order to carry out necessary veterinary-sanitary measures.

Article 44. End of an Outbreak of Especially Dangerous Disease

(1) An outbreak of especially dangerous animal disease of the OIE List shall be considered terminated when:

- 1) The conditions specified in the relevant rule book have been met; or, if no rule book exists, the conditions, prescribed by relevant international standards, guidelines and recommendations, have been met;

2) If no such international standards, guidelines, or recommendations exist, if the period from the recovery or death of the last affected animal the longest incubation period for especially dangerous disease has elapsed.

(2) The Chairman of the State Emergency Anti-Epizootic Commission under the Cabinet of Ministers of Ukraine shall announce in official newspapers the end of the quarantine, which had been imposed due to an outbreak of especially dangerous animal disease of the OIE List.

(3) The Chief State Inspector of Veterinary Medicine of Ukraine shall immediately inform the relevant international organizations and the Veterinary Administrations of neighboring countries and affected trading partners of the end of the outbreak of especially dangerous animal disease of the OIE List .

Article 45. Tasks of the Bodies of the Interior during an Outbreak of Animal Disease

(1) During an animal disease outbreak, on the basis of the statement of state inspector of veterinary medicine or authorized doctor of veterinary medicine, the bodies of the interior shall be obliged to assist the latter in implementation of measures to restrict circulation of animals, impose a prohibition on movement of animals and people within an infected zone, and in the implementation of other quarantine measures specified by this Law.

(2) In order to fulfill the tasks referred to in paragraph 1 of this Article, the veterinary militia shall establish quarantine veterinary-militia posts in accordance with a decision of the relevant local state emergency anti-epizootic commission .If necessary the personnel of the structural units of the central body of executive power on emergency issues and protection of population from consequences of Chornobyl disaster may be involved in fulfilment of the tasks.

(3) During animal quarantine, declared due to an outbreak of especially dangerous disease of the OIE List, the central body of executive power on the issues of the interior must, pursuant to the decision of the Cabinet of Ministers, provide assistance in containing, controlling, and eliminating such disease.

Article 46. Animal Quarantine (Quarantine Restrictions) for an Outbreak of a Disease Other Than Especially Dangerous Diseases

(3) Upon suspicion of detection of a notifiable disease, which is not an especially dangerous disease that requires animal quarantine (quarantine restrictions), the chief state inspector of veterinary medicine of the relevant territory shall issue an instruction imposing animal quarantine:

1) Immediately after confirmation of the outbreak of a quarantine disease;

2) In the case that, at the end of 24 hours after receiving information on the suspicion of the outbreak of a quarantine disease, the suspicion has not been ruled out.

(4) Instruction of the relevant chief state inspector of veterinary medicine imposing animal quarantine shall identify the boundaries of infected and buffer zones and, if necessary, a surveillance zone, veterinary-sanitary measures, which will be applied in these zones during animal quarantine (quarantine restrictions) and expected time of their duration.

(5) The chief state inspector of veterinary medicine of the next higher administrative-territorial unit and the local body of executive power and/or the bodies of the local self-governance of the relevant administrative-territorial unit and of the next higher level shall be immediately informed of the decision imposing animal quarantine (quarantine restrictions). In case of suspicion of the outbreak of zoonosis, the latter shall immediately be reported to the relevant chief state sanitary doctor.

(6) The relevant chief state inspector of veterinary medicine, by his instruction imposing animal quarantine (quarantine restrictions) may establish prohibition on movement of animals, transportation vehicles, persons, and other objects that may be factors for transmission of the pathogenic agent into, out of, and within infected and buffer zones and, if necessary, in the surveillance zone.

(7) Implementation of the quarantine measures specified in the instruction of the relevant chief state inspector of veterinary medicine imposing animal quarantine (quarantine restrictions) shall be compulsory for all persons staying in the quarantine zone.

(8) Local bodies of executive power and/or bodies of local self-governance of the relevant administrative-territorial unit shall be responsible for non-implementation of measures of animal quarantine (quarantine restrictions). State bodies and institutions shall be obliged to support to the implementation of quarantine measures.

(9) Instruction of the relevant chief state inspector of veterinary medicine imposing animal quarantine (quarantine restrictions) shall be effective until the local state emergency anti-epizootic commission issues a decision imposing animal quarantine (quarantine restrictions), but not longer than 72 hours.

(10) During the first 48 hours of animal quarantine (quarantine restrictions), the local state emergency anti-epizootic commission under local body of executive power must start its operation. The State Emergency Anti-Epizootic Commission under the Cabinet of Ministers of Ukraine, shall also start its operation upon the proposal of the Chief State Inspector of Veterinary Medicine of Ukraine, if the nature of quarantine disease is such that the risk of rapid or extensive spread of the disease is high, or if the quarantine zone includes the territory (or part of the territory) of several oblasts, or exceeds the boundaries of the Autonomous Republic of Crimea.

(11) Upon proposal of the chief state inspector of veterinary medicine, local state emergency anti-epizootic commission must within 24 hours issue a decision imposing animal quarantine (quarantine restrictions).

(12) The decision of the relevant local state emergency anti-epizootic commission imposing animal quarantine (quarantine restrictions) shall specify:

- 1) The name of the quarantine disease(s), for which animal quarantine has been imposed;
- 2) If known, the circumstances that caused the occurrence or an outbreak of the quarantine disease;
- 3) Boundaries of the quarantine zone, including the data on infected, buffer, and, if necessary, surveillance zones;
- 4) Special veterinary-sanitary measures applicable in infected, buffer, and, if necessary, surveillance zones that are aimed at containing and eliminating quarantine disease;
- 5) The movement restrictions placed on animals, transportation vehicles, and persons;
- 6) Any instructions for mandatory involvement of veterinary medicine specialists to the implementation of quarantine measures, and their duties during animal quarantine.

(13) In the first 24 hours after a decision is issued to impose animal quarantine (quarantine restrictions), the local state emergency anti-epizootic commission shall take all measures necessary to inform persons within the territory of the quarantine zone about it, and the relevant local bodies of executive power and bodies of local self-governance of adjacent administrative-territorial units. Notification on imposition of animal quarantine (quarantine restrictions) shall be published in an official newspaper circulated in the territory of the relevant administrative-territorial unit. The local

state emergency anti-epizootic commission may employ television and radio-broadcasting media to provide for prompt notification to persons with regard to imposition of animal quarantine (quarantine restrictions).

(14) Persons guilty of violation of quarantine measures shall be held liable according to legislation.

Article 47. Guarantees of the Rights of Legal Entities and Natural Persons during Animal Quarantine (Quarantine Restrictions)

(1) Persons, who have suffered property damage (losses) as a result of imposition of animal quarantine (quarantine restrictions), or due to the implementation of procedures and works to eliminate and prevent animal diseases, shall be reimbursed from the funds of the State Budget pursuant to the procedure and in the amount, prescribed by the Cabinet of Ministers of Ukraine.

(2) Persons, involved into the implementation of works and rendering of services in course of quarantine measures, and persons, whose property was used to prevent spread or eliminate animal disease, for which animal quarantine (quarantine restrictions) has been imposed, shall have the right for remuneration for the works done and services rendered, pursuant to the procedure and in the amount, prescribed by the Cabinet of Ministers of Ukraine. Damage caused to life and health of a natural person involved into the implementation of works and rendering of services in course of quarantine measures, and associated with the implementation of works (rendering of services) shall be fully compensated from the funds of the State Budget of Ukraine pursuant to the procedure, prescribed by the Cabinet of Ministers of Ukraine.

SECTION VIII. REGULATION OF THE PRODUCTION AND CIRCULATION OF NON-EDIBLE PRODUCTS OF ANIMAL ORIGIN

Article 48. Facilities Required to Obtain an Operating Permit from the central body of executive power on veterinary medicine issues

(1) It shall be prohibited for the following facilities (objects) to carry out activities on production and circulation without obtaining an operating permit from the relevant state body of veterinary medicine:

- 1) Facilities (objects) for processing non-edible products of animal origin;
- 2) Animal breeding centers (enterprises / associations engaged in breeding activities; selection, selection and production, selection and hybrid centers, horse race tracks, assessment stations for pedigree animals) ;
- 3) Facilities (objects) for producing, mixing and preparing feed additives, premixes and feed;
- 4) Facilities (objects) for production and circulation of veterinary preparations.

(2) Operating permit that is valid for one year shall be issued upon submission to the relevant state body of veterinary medicine of an application for such permit accompanied by necessary information, provided an on-site inspection confirms compliance of the above facilities (objects) with relevant veterinary-sanitary measures, technical regulations, and provisions of this Law.

(3) Procedure for issuing and renewal of the operating permit and a list of documents to be presented with the application for obtaining an operating permit shall be prescribed by the the central body of executive power on veterinary medicine issues and may include design and construction

requirements, availability of qualified staff, and continuous operation of safety and quality control system. The central body of executive power on veterinary medicine issues shall prescribe relevant technical regulations and veterinary-sanitary measures for each type of facility (object) referred to in paragraph 1 of this Article. Procedures for verification of compliance with such veterinary-sanitary measures and technical regulations shall be prescribed in normative-legal acts, issued by the central body of executive power on veterinary medicine issues pursuant to this Law.

(4) All facilities (objects), for which the central body of executive power on veterinary medicine issues issues operating permits, shall be subject to state veterinary-sanitary control and supervision.

(5) Operators (owners) of the relevant facilities (objects), for which the central body of executive power on veterinary medicine issues issued an operating permit, shall effect payment to state institutions of veterinary medicine for obtaining the operating permit, carrying out state veterinary-sanitary control and supervision by state inspectors of veterinary medicine.

(6) Any person, who is engaged in producing, mixing, or preparing feed, and is using meat-and-bone meal and other products from ruminants, which may cause animal disease - bovine spongiform encephalopathy or other transmissible spongiform encephalopathy (TSE), must have a separate facility (object) with a separate operating permit for production of feed containing such materials to avoid cross contamination of feed intended for ruminants with the products from ruminants, identified above, and minimize the risk of unintentional inclusion of such products into feed for ruminants.

Article 49. Identification Control Number for Facilities, Which Obtained an Operating Permit

(1) Facilities (objects) that obtain an operating permit from the central body of executive power on veterinary medicine issues shall be issued a control number for identification of such facilities (objects).

(2) The central body of executive power on veterinary medicine issues shall issue a control number for identification of facilities (objects) (hereinafter: identification control number) and enter it into the relevant Register of facilities (objects).

Article 50. Suspension or Revocation of an Operating Permit

(1) Should it be revealed during state veterinary-sanitary control and supervision that facilities (objects), which obtained an operating permit, violate relevant veterinary-sanitary measures or technical regulations, the state inspector of veterinary medicine shall issue a written directive to correct the violation. Should the level of severity of the violation create an immediate threat to animal health, the state inspector of veterinary medicine shall issue a directive for immediate repair of the violation, or prohibition of use of relevant equipment, and submit a report, along with any necessary materials and documentation, to the relevant chief state inspector of veterinary medicine or his/her deputy.

(2) The relevant chief state inspector of veterinary medicine or his/her deputy, who obtained the report of the state inspector of veterinary medicine on the violations of this law, may issue a decision to suspend the operating permit for the facility (object).

(3) The duration of suspension of an operating permit shall not be longer than three months. In case the above violations are not corrected within the time-period, prescribed in the directive of the chief state inspector of veterinary medicine on correcting the violations, or within the time-period of suspension of the operating permit, the central body of executive power on veterinary medicine issues shall revoke the operating permit and remove the facilities (objects) from the Register.

Article 51. Registration of Facilities (Objects) That Use Non-Edible Products of Animal Origin

- (1) Operators of facilities, other than those listed in Article 48 of this Law that use non-edible products of animal origin (for purposes of agricultural production, industry, pharmacology and surgery etc.), which may carry or transmit animal diseases, must register said facilities (objects) with the central body of executive power on veterinary medicine issues.
- (2) The central body of executive power on veterinary medicine issues shall maintain a register of facilities (objects) that use non-edible products of animal origin.
- (3) The chief state inspector of veterinary medicine of Ukraine shall determine the facilities (objects) that use non-edible products of animal origin for purposes of agricultural production, industry, pharmacology and surgery etc., which are subject to paragraph 1 of this Article, and the procedure for registering said facilities with the central body of executive power on veterinary medicine issues.

Article 52. Approved Export Facilities (Objects) for Non-Edible Products of Animal Origin

- (1) Legal entities, which obtained an operating permit from the central body of executive power on veterinary medicine issues and intend to export non-edible products of animal origin to countries that have specific requirements for facilities (objects) producing, processing or storing such products, or other similar requirements, may request verification of such specific requirements from the central body of executive power on veterinary medicine issues.
- (2) The central body of executive power on veterinary medicine issues shall make a decision on approval of the facility (hereinafter: approved export facility) after official verification by the state bodies of veterinary medicine that the facility fulfils the requirements prescribed by the legislation of the country of destination.
- (3) Any products intended for export, which are produced at an approved export facility (object), shall be marked according to the requirements of the country of destination. If possible, such marking shall also include the identification control number, referred to in Article 49 of this Law.
- (4) The central body of executive power on veterinary medicine issues shall maintain a register of approved export facilities. The register shall be published in electronic and written form.
- (5) Procedure for carrying out official verification of the fulfillment of all the requirements, prescribed by the country of destination, to which the operators of approved export facilities (objects) intend to export non-edible products of animal origin, procedure for approving export facilities (objects), registration and removal from the register as well as procedure with regard to the amount of fee for carrying out official verification of the fulfillment of the requirements of the country of destination, shall be prescribed by the central body of executive power on veterinary medicine issues.

Article 53. Removal of Approved Export Facilities (Objects) from the Register of Approved Export Facilities (Objects)

- (6) If during state veterinary-sanitary control and supervision, the state inspector of veterinary medicine reveals that an approved export facility (object) fails to fulfill the requirements of a country of destination, the state inspector of veterinary medicine shall collect necessary evidence of the violation of the above-mentioned requirements. The relevant chief state inspector of veterinary medicine or his/her deputy shall review the evidence and make a decision on whether to remove such facility (object) from the register of approved export facilities (objects).
- (7) The person, who is an operator of the approved export facility (object) may lodge an appeal for a decision on removal (temporal or permanent) of such facility (object) from the Register of approved

export facilities (objects) with the central body of executive power on veterinary medicine issues in accordance with the procedure, specified in Article 34 of this Law.

(8) In case of making a decision on removal (temporal or permanent) of approved export facilities (objects) from the relevant Register, the central body of executive power on veterinary medicine issues shall immediately notify the competent authority of the country of destination.

(9) The competent authority of any country of destination, for which the central body of executive power on veterinary medicine issues has conducted official verification of fulfillment by the operators of facilities (objects) of prescribed requirements, shall have unhindered access to approved export facilities (objects) for inspection purposes. The competent authority of the country of destination shall be obliged to notify the central body of executive power on veterinary medicine issues at least 48 hours in advance of the above inspection.

(10) If as a result of inspecting approved export facilities (objects) to verify fulfillment of prescribed requirements, the competent authority of a country of destination concludes that such facilities (objects) fail to fulfill prescribed requirements, the central body of executive power on veterinary medicine issues shall suspend or withdraw its decision on approval of the facility (object) for exporting non-edible products of animal origin to the relevant country of destination in accordance with the instructions of the above competent authority of the country of destination. The decision on suspension or withdrawal of the approval of the facility (object) for exporting non-edible products of animal origin to the relevant country of destination shall be sent to the operator of the facility with the report by the competent authority of the country of destination identifying the violations of prescribed requirements.

Article 54. Production and Circulation of Non-Edible Products of Animal Origin

(1) State inspectors of veterinary medicine shall conduct state veterinary-sanitary control and supervision of production, processing and circulation of non-edible products of animal origin, including extended veterinary-sanitary control on the basis of professional judgment of the state inspector of veterinary medicine or within the framework of the program for random veterinary-sanitary control.

(2) It shall be prohibited to sell non-edible products of animal origin, feed of animal origin in bulk, devices of veterinary medicine and means of animal care in places not established for such.

(3) Veterinary-sanitary state of non-edible products of animal origin and feed of animal origin shall be certified by the relevant veterinary document.

Article 55. Circulation of Leather Raw Materials

(1) Circulation of raw cattle, sheep, and goat hides and skins shall be allowed only after prior verification for anthrax. The rules for such verification, rules for storage of raw hides and skins, which have not been subjected to verification, procedures for treatment of raw hides and skins found to be infected with anthrax, and rules for marking raw hides and skins free from anthrax shall be prescribed in normative-legal acts of the central body of executive power on veterinary medicine issues issued pursuant to this Law.

(2) Operators circulating raw hides and skins must keep records on the origin of purchased raw hides and skins, and keep such records for three years. The central body of executive power on veterinary medicine issues shall establish requirements for keeping such record.

(3) Unprocessed waste from raw hides and skins that have not been chemically treated shall be destroyed in accordance with the rules on security and in the procedure specified in the relevant rule book.

Article 56. Requirements to Record Keeping at the Facilities (Objects) Processing Non-Edible Products of Animal Origin

(1) Operators of facilities (objects) processing non-edible products of animal origin must keep and save relevant records enabling traceability of their purchases of raw materials and sales of their products during three last years.

(2) The records, referred to in paragraph 1 of this Article, shall be provided to the state inspector of veterinary medicine upon request.

Article 57. Obligations of Persons Carrying Out Activities on Production and Circulation of Non-Edible Products of Animal Origin

(3) Operators of facilities (objects) for production or circulation of non-edible products of animal origin, reproductive material, feed additives, premixes, and feed, shall be obliged to fulfill the requirements of veterinary-sanitary measures, hygiene and other specific requirements regarding premises, machinery and equipment, prescribed in relevant technical regulations, rule books, and the provisions of this Law.

(4) Operators of facilities, used for production or circulation of non-edible products of animal origin, veterinary preparations, feed additives, premixes, feed and reproductive material, shall:

1) Ensure unhindered access of state inspectors of veterinary medicine to such facilities (objects) during normal working hours with the purpose of exercising state veterinary-sanitary control and supervision;

2) Allow the taking of samples of the objects of state veterinary-sanitary control and supervision, as well as samples of other materials and substances within such facilities (objects);

3) Upon request of the state inspector of veterinary medicine, provide all documents necessary for the purpose of exercising state veterinary-sanitary control and supervision;

4) Keep records, according to serial numbers, when applicable, on the purchase and use of non-edible products of animal origin, veterinary preparations, feed additives, premixes, feed and reproductive material.

Operators of facilities (objects) for production or circulation of non-edible products of animal origin, veterinary preparations, feed additives, premixes, feed and reproductive material shall be obliged to ensure that their products are free of, or do not carry pathogenic agents of animal diseases.

SECTION IX. SCIENTIFIC SUPPORT TO VETERINARY MEDICINE, STATE PHARMACOLOGY COMMISSION OF VETERINARY MEDICINE, STATE AND AUTHORIZED LABORATORIES.

Article 58. Scientific Support to Veterinary Medicine

(1) Scientific support to veterinary medicine shall be provided by relevant scientific institutions of the National Academy of Sciences of Ukraine, other scientific institutions and faculties of veterinary medicine of higher educational establishments.

- (2) Activities, pertaining to scientific support to veterinary medicine, shall be coordinated by the departments of veterinary medicine of Ukrainian Academy of Agrarian Sciences jointly with the scientific-methodic council of the central body of executive power on veterinary medicine issues.
- (3) The central body of executive power on veterinary medicine issues shall act as a client for scientific-research works in the sphere of veterinary medicine.
- (4) With the aim to resolve the operative problems of veterinary medicine, implement innovation projects requested by the central body of executive power on veterinary medicine issues, scientific-implementation centers of veterinary medicine shall be created, as well as other structural units that are not prohibited by legislation, whose activities shall be defined by the central body of executive power on veterinary medicine issues jointly with the Ukrainian Academy of Agrarian Sciences.
- (5) Scientific support, referred to in paragraph one of this Article, including relevant scientific research in the sphere of veterinary medicine, as defined by the central body of executive power on veterinary medicine issues, and practical implementation of scientific developments shall be financed from the State Budget of Ukraine and other sources that are not prohibited by legislation.

Article 59. State Pharmacology Commission of Veterinary Medicine

- (1) The State Pharmacology Commission of Veterinary Medicine shall be an expert-advisory body on issues of regulation of the safe and efficient application of veterinary preparations, feed additives, premixes and finished feed, as well as their registration.
- (2) The State Pharmacology Commission of Veterinary Medicine shall recommend, and the Head of the central body of executive power on veterinary medicine issues shall adopt the following:
 - 1) State registration of veterinary preparations, feed additives, premixes and finished feed;
 - 2) Maximum allowed levels of residue amounts of veterinary preparations and other contaminants in feed additives and feed;
 - 3) Annual program for carrying out random veterinary-sanitary control of feed for animals;
 - 4) Annual plan for monitoring residue amounts of veterinary preparations and other contaminants in animals, products of animal origin and feed;
 - 5) List of veterinary preparations, which shall be dispensed under the prescription and the rules of prescription issuance;
 - 6) Requirements to clinical and pre-clinical tests for veterinary preparations.
- (3) The State Pharmacology Commission of Veterinary Medicine shall operate under the central body of executive power on veterinary medicine issues.
- (4) The State Pharmacology Commission of Veterinary Medicine shall operate on the basis of the Regulations adopted by the Cabinet of Ministers of Ukraine.

Article 60. State and Authorized Laboratories

- (1) Laboratory diagnostics of animal diseases and evaluation of the veterinary-sanitary state of products of animal origin, non-edible products of animal origin, feed additives, premixes, feed, soil, water for animals, shall be conducted by the State Scientific-Research Institute of Laboratory Diagnostics and Veterinary-Sanitary Testing, created on the basis of the Central State Laboratory of Veterinary Medicine (hereinafter - Institute of Laboratory Diagnostics), the Republican Laboratory of

the Autonomous Republic of Crimea, the oblast, regional, inter-oblast, city, rayon, inter-rayon state laboratories of veterinary medicine and other laboratories, authorized to conduct necessary analysis according to the procedures established by the central body of executive power on veterinary medicine issues. Analysis shall be conducted according to the recommendations, guidelines and standards of the relevant international or national organizations.

- (2) National Reference-Laboratories of Laboratory Diagnostics and Control of Residual Amounts of Contaminants shall be created on the basis of the Institute of Laboratory Diagnostics.
- (3) Laboratories of other institutions of veterinary medicine, scientific-research institutes, higher education establishments, and other legal entities may also carry out laboratory analysis pursuant to the authorities provided by the central body of executive power on veterinary medicine issues.
- (4) In order to work with the pathogens of especially dangerous diseases of the OIE List laboratories must receive a special permit from the central body of executive power on veterinary medicine issues.
- (5) After conducting an appropriate laboratory analysis, an expert conclusion (laboratory report, protocol etc.) shall be issued. The latter shall stipulate the results of laboratory analysis and their evaluation.
- (6) The Institute of Laboratory Diagnostics shall be responsible for conducting laboratory diagnostics and/or identification of animal diseases, veterinary-sanitary testing in the country, provide for methodic support to state and authorized laboratories of veterinary medicine, and exercise control of the implementation of laboratory analysis.
- (7) In case of an appeal of disputable issues, resulting from the conclusions of laboratory diagnostics and veterinary-sanitary testing, the Institute of Laboratory Diagnostics shall conduct an arbitration analysis. Results of arbitration analysis shall be final. Procedure for carrying out arbitration analysis shall be prescribed by the central body of executive power on veterinary medicine issues.
- (8) Laboratories in the markets shall be structural units of relevant state institutions of veterinary medicine that shall operate on the basis of the regulations, adopted by the central body of executive power on veterinary medicine issues. Owners or the authorized administrations of the markets shall be obliged to provide, free of charge, the premises for laboratory uses and create appropriate conditions for their operation.
- (9) The Institute of Laboratory Diagnostics and state laboratories of veterinary medicine may be legal entities, operating on the basis of the regulations, approved by the central body of executive power on veterinary medicine issues.
- (10) All laboratories, referred to in this Article, shall be subject to accreditation by the National Accreditation Agency of Ukraine or an accreditation body of a foreign country in accordance with relevant national or international legislation.
- (11) It shall be prohibited to interfere into the activities of specialists of state laboratories of veterinary medicine in course of the implementation by the latter of laboratory diagnostics and veterinary-sanitary testing.
- (12) Veterinary documents shall be issued under condition of compulsory analysis of the products of animal origin, non-edible products of animal origin, feed additives, premixes and feed in the state institutions of veterinary medicine.

SECTION IX. REGULATION OF PRODUCTION AND CIRCULATION OF VETERINARY PREPARATIONS, SUBSTANCES, AND DEVICES OF VETERINARY MEDICINE

Article 61. State Registration of Veterinary Preparations

- (1) Veterinary preparations shall be subject to registration prior to their circulation and use in Ukraine. The maximum term of validity of such registration shall be five years.
- (2) It shall be prohibited to register (re-register) veterinary preparations that may cause damage to veterinary-sanitary and epizootic welfare or health of animal or human.
- (3) In order to effect the registration of veterinary preparations, a person (hereinafter- applicant) shall submit an application with relevant accompanying documents, the list of which shall be prescribed by the central body of executive power on veterinary medicine issues, to one of the state scientific-research control institutes, authorized by the central body of executive power on veterinary medicine issues. The applicant shall be liable according to legislation for providing invalid information in the registration dossier. Regulations on state registration of veterinary preparations shall be developed and approved by the central body of executive power on veterinary medicine issues
- (4) State scientific-research control institute of veterinary preparations and feed additives or/and the State scientific-control institute of bio-technologies and micro-organism strains shall perform evaluation (testing) of submitted documents, organize the implementation of necessary analysis and perform other measures, which are necessary to verify information and data, stipulated in the documents, and also prepare expert conclusions for consideration of the State Pharmacology Commission of Veterinary Medicine.
- (5) The State Pharmacology Commission of Veterinary Medicine shall consider expert conclusions and provide the central body of executive power on veterinary medicine issues with recommendations on state registration of the relevant veterinary preparations.
- (6) The central body of executive power on veterinary medicine issues shall make a decision to register a veterinary preparation or deny the latter. The time-period for registration shall not exceed 210 days from the date of receipt of an application, complete set of documents, and effecting relevant payments.
- (7) Registration of a veterinary preparation may be denied if the verification of the particulars and documents submitted reveals that:
 - 1) The applicant failed to prove the quality, safety and efficacy of the veterinary preparation in an appropriate manner;
 - 2) Safety and welfare of animals and/or safety of consumers have not been confirmed in an appropriate manner in course of tests of the veterinary preparations;
 - 3) The withdrawal period recommended by the applicant is not sufficient to ensure that products of animal origin intended for human consumption, derived from animals, which had been subjected to medical treatment with this preparation, do not contain residues that may present threat to consumer health or are insufficiently justified;
 - 4) Application of the veterinary preparation presented for registration is prohibited by current legislation.

- (8) A decision to deny state registration of a veterinary preparation shall be transmitted to the applicant with an exhaustive explanation of the reasons. The applicant may appeal this decision in court according to the procedure prescribed by legislation..
- (9) A decision to register veterinary preparation shall be transmitted to the applicant, along with a registration certificate. The registration certificate shall include the name of the veterinary preparation, information about the producer and the person who has ownership right for the preparation, registration number of the preparation, the term of validity of the registration. It shall be mandatory to attach brief characteristics of the preparation, guidelines for use, and a marking in Ukrainian language to the registration certificate.
- (10) Upon making a decision to register the preparation for circulation and use in Ukraine, it shall be entered into the Register of Veterinary Preparations maintained by the central body of executive power on veterinary medicine issues. The register entry shall include the veterinary preparation name, information on the producer and the person who has ownership right for the preparation, registration number of the preparation, the term of validity of the registration certificate and other information required pursuant to legislation.
- (11) After registration of domestic veterinary immune-biological means, the applicant must deposit microorganism strains (cultures) used in production of such immune-biological means with the National Center for Microorganism Strains. The National Center for Microorganism Strains, for which its regulations shall be adopted by the Cabinet of Ministers of Ukraine, shall be responsible for storage and maintenance of microorganism strains that have been deposited.
- (12) The person, to whom registration certificate for veterinary preparation has been issued, shall provide for collection and processing of information about all adverse reactions to the veterinary preparation, for which the registration certificate has been issued. Such information shall be submitted to the central body of executive power on veterinary medicine issues or its designated institutions in the form and procedure prescribed by the central body of executive power on veterinary medicine issues.
- (13) A package of registration materials shall be submitted for re-registration 3 months before the the expiration of the registration certificate.

Article 62. Streamlined State Registration of Veterinary Preparations

- (1) State registration on the basis of an application for streamlined registration may be applied for some veterinary preparations.
- (2) Veterinary preparations, for which streamlined registration may be applied, shall be the preparations that are significantly similar and contain the same amount of the same active substance in the same form, with appropriate analysis confirming their identity regarding bio-availability and bio-equivalence, and also the fact that their therapeutic effect is essentially the same as of the patented preparations (brand preparation) already registered in Ukraine and in other countries specified by the central body of executive power on veterinary medicine issues as those having the same criteria for registration of such veterinary preparations.
- (3) If the veterinary preparation, for which an applicant submitted an application for streamlined registration has been filed, is to be used for different medical treatment purposes, in different amount, or in different methods, compared to a similar preparation that is already present in the market of Ukraine, the results of the own pharmacological-toxicological and/or clinical analysis shall be attached to the application.

(4) A decision to register veterinary preparations according to simplified procedure shall be issued within 90 days from receipt of a complete package of registration documents, and effecting relevant payment.

(5) The central body of executive power on veterinary medicine issues shall prescribe the procedure and the list of documents, which shall be submitted for obtaining a decision on simplified registration procedure.

Article 63. Suspension or Cancellation of Registration of Veterinary Preparations

(1) The registration of a veterinary preparation shall be suspended if:

- 1) The veterinary preparation does not comply with the requirements specified in its registration dossier;
- 2) Registration has been conducted on the basis of incomplete or untrue data;
- 3) The holder of the registration certificate no longer complies with prescribed requirements.

(2) The registration of a veterinary preparation shall be cancelled, should it be revealed that the veterinary preparation is not efficient under prescribed conditions for its use, or is not safe for animal or human health when present in products of animal origin at levels in excess of maximum residue limits.

(3) Should a veterinary preparation be found unsafe, in addition to the provision of paragraph 2 of this Article, the central body of executive power on veterinary medicine issues shall issue an instruction to prohibit circulation of such preparation and its withdrawal from circulation.

(4) The central body of executive power on veterinary medicine issues shall prescribe the procedure for suspension or renewal of registration, and for cancellation of registration of a veterinary preparation.

(5) In the event of suspension or cancellation of the registration of a veterinary preparation, the holder of the registration certificate for the veterinary preparation in question may appeal such decision according to legislation.

Article 64. Production of Veterinary Preparations

(1) Veterinary preparations not registered in Ukraine shall be not allowed for serial production.

(2) Persons producing veterinary preparations must obtain a license for carrying out such activity according to legislation.

(3) A license for production of veterinary preparations shall be issued if the following are available:

- 1) relevant production facilities (objects);
- 2) qualified staff;
- 3) quality control for the preparations that are produced;
- 4) observance of Good Manufacturing Practices;
- 5) observance of other requirements prescribed by the central body of executive power on veterinary medicine issues.

- (4) Substances, packaging materials, and other resources for production of veterinary preparations shall be allowed for use by the central body of executive power on veterinary medicine issues on the basis of testing, conducted by authorized state institutions of veterinary medicine with the aim to verify their quality and safety.
- (5) The producer shall be obliged to conduct quality control for each lot (series) of veterinary preparations in accordance with prescribed requirements.
- (6) Any lot (series) of veterinary preparations, which as a result of control in the process of production fails to comply with prescribed quality requirements, shall be subject to processing, utilization and/or destruction. Processing, utilization and/or destruction of such preparations shall be conducted by the owner or an authorized representative of the owner in accordance with the procedure prescribed in the relevant normative-legal act issued pursuant to this Law.
- (7) General requirements for the conditions of production of veterinary preparations shall be established by the central body of executive power on veterinary medicine issues and controlled by authorized state institutions of veterinary medicine.

Article 65. Circulation of Veterinary Preparations

- (8) The placing into circulation of a veterinary preparation by a producer and/or seller (supplier) shall be understood to be a guarantee of safety of the preparation according to its intended use and fulfillment of prescribed purity (quality) requirements for such preparation, and/or its compliance with other compulsory requirements established by relevant technical regulations and/or the terms of registration.
- (9) Circulation of veterinary preparations that are not registered in Ukraine shall be prohibited.
- (10) Veterinary preparations that are in circulation shall be accompanied by complete, legible, and understandable instructions for consumers with marking in Ukrainian language. Veterinary preparations must also have a registration number indelibly painted or otherwise marked on the packaging.
- (11) It shall be prohibited to sell veterinary preparations with an expired “use-by” date. Prolongation of the shelf life of veterinary preparations shall be prohibited.
- (12) Veterinary preparations and substances that are in circulation shall be subject to random control for compliance with the terms of their registration and relevant technical regulations. Veterinary preparations and substances that do not comply with the requirements of this Law shall be subjected to the provisions of Article 72 of this Law.
- (13) It shall be prohibited to use veterinary preparations in the way or for purposes that do not comply with their intended use.
- (14) Veterinary preparations, which suppress the function of the endocrine glands, in particular having thyreostatic, estrogenic, androgenic, gestagenic effect, as well as antibiotics and hormones, shall be applied for medical treatment and other purposes, taking into account that the maximum residue limit of such preparations in raw materials of animal origin must not exceed established maximum limits.

Veterinary immune-biological preparations shall be dispensed to the establishments of veterinary medicine or licensed doctors of veterinary medicine exclusively.

Article 66. Licensing of Wholesale Trade in Veterinary Preparations

(15) All persons (economic entities) engaged in trade in veterinary preparations at the level of wholesale lots (hereinafter - wholesale enterprises) shall obtain from the central body of executive power on veterinary medicine issues, or an authorized body, a license for the right to carry out business activity in the sphere of wholesale trade in veterinary preparations.

(16) Wholesale enterprises engaged in wholesale trade in veterinary preparations may sell such preparations only to registered wholesale enterprises, licensed establishments of veterinary medicine, and veterinary pharmacies.

(17) Persons engaged in wholesale trade in veterinary preparations must keep records on their purchase, import, export, and sales.

(18) Materials, referred to in paragraph 3 of this Article, must be submitted periodically to the central body of executive power on veterinary medicine issues or to the institutions, authorized by the central body of executive power on veterinary medicine issues, and, upon request, shall be immediately provided to the state inspector of veterinary medicine for review.

(5) The central body of executive power on veterinary medicine issues shall prescribe the procedure and requirements for licensing of the activity on wholesale trade in veterinary preparations, the specific form and content of the records (reporting) on purchase and circulation of veterinary preparations, and the periodicity and procedures for submitting such records to the central body of executive power on veterinary medicine issues or to the institutions, authorized by the latter.

Article 67. Licensing of Retail Trade in Veterinary Preparations

(1) Licensed establishments of veterinary medicine shall have the right to carry out retail trade in veterinary preparations and medicated feed, under condition that such preparations are necessary for the course of medical treatment of an animal, which belongs to their client.

(2) Veterinary pharmacies may carry out retail trade in veterinary preparations only after obtaining a license for such activity, issued by the central body of executive power on veterinary medicine issues or the body, authorized by the latter.

(3) Licensed establishments of veterinary medicine and licensed veterinary pharmacies shall keep records on purchases and sales of particular veterinary preparations, which shall be submitted to the central body of executive power on veterinary medicine issues or to the establishments, authorized by the latter, in the form and according to the procedure prescribed by the central body of executive power on veterinary medicine issues.

(4) If the results of state veterinary-sanitary control and supervision of the activities of the establishments of veterinary medicine and veterinary pharmacies reveal violations of the requirements and conditions for retail trade or storage of veterinary preparations, devices of veterinary medicine, or violations associated with keeping the appropriate records, or if the records referred to in paragraph 3 of this Article are not submitted to the central body of executive power on veterinary medicine issues as required, the relevant chief state inspector of veterinary medicine shall issue an instruction to suspend or prohibit sale of such preparations until the deficiencies are corrected.

(5) Should an establishment of veterinary medicine, within a year, repeat the violations referred to in paragraph four of this Article, or retail trade in such preparations be suspended or prohibited twice within two years, the central body of executive power on veterinary medicine issues or the body

authorized by the latter (as licensing body) shall revoke the license of this establishment of veterinary medicine. Establishment of veterinary medicine, whose license has been revoked, may, pursuant to established procedure, apply to obtain a new license not earlier than one year after issuance of a decision on its revocation.

(6) The decision to revoke a license or suspend the right to sell veterinary preparations may be appealed according to the procedure established by legislation.

(7) The central body of executive power on veterinary medicine issues shall prescribe the licensing conditions for carrying out activity of retail trade in veterinary preparations, the procedure for issuance of such licenses, special form and content of the records referred to in paragraph 3 of this Article, as well as the procedure for submitting such records to the central body of executive power on veterinary medicine issues, procedures for exercising control over compliance with established requirements, and procedure for suspending and revoking the license or the right for retail trade in veterinary preparations.

Article 68. Retail Trade in Veterinary Preparations

- (1) Retail trade in veterinary preparations shall be carried out only by licensed doctors of veterinary medicine, licensed establishments of veterinary medicine, and licensed veterinary pharmacies.
- (2) Licensed doctors of veterinary medicine and establishments of veterinary medicine shall issue prescriptions and sell medicinal means (preparations) only to the animal owners or keepers within the course of medical treatment of animals or for prophylaxis of animal maladies and diseases.
- (3) Licensed doctor of veterinary medicine, who issues a prescription for a veterinary preparation, shall be obliged to provide animal owners or keepers with prescription and its copy that must be kept by the owners (keepers) together with the records, referred to in Article 71 of this Law.
- (4) Licensed doctors of veterinary medicine, licensed establishments of veterinary medicine and licensed veterinary pharmacies must sell veterinary preparations, which require a prescription, only if such prescription is available, and must save prescription copies for each sold veterinary preparation during three years from the date of sale.
- (5) The prescription referred to in paragraph 3 of this Article shall include, in addition to the name of the veterinary preparation and guidelines for its use, the date of issuance of the prescription, the name, address, phone number, license number and signature of a licensed doctor of veterinary medicine, as well as the name and address of the animal owner (keeper), for which veterinary preparation is prescribed.

Article 69. Veterinary Preparations that Require a Prescription for Their Sale and Use

1. It shall be prohibited to carry out retail sale of the following veterinary preparations without a prescription from a licensed doctor of veterinary medicine or from a doctor of veterinary medicine, employed by state institution of veterinary medicine:

- 1) Veterinary medicinal means, use and circulation of which shall be restricted according to international agreements, agreed upon by the Verkhovna Rada as mandatory;
- 2) Veterinary medicinal means, application of which requires special preventive measures or which shall be applied only under control of the state doctor of veterinary medicine or licensed doctor of veterinary medicine so as to avoid an undesired risk for animals, persons administering the preparation to animals, consumers of products of animal origin, derived from animals that were subjected to medical treatment with the relevant veterinary medicinal means, or for the environment;

3) Veterinary medical means intended for medical treatment application of which requires preliminary diagnostics or may bring on processes preventing further diagnostic and therapeutic measures;

4) Veterinary immune-biological means.

2. The central body of executive power on veterinary medicine issues shall prescribe the list of veterinary preparations, referred to in paragraph one of this Article, and the rules for issuing prescriptions.

Article 70. Import of Veterinary Preparations for Special Purposes

1. Veterinary preparations, which are not registered for circulation and use in Ukraine, may be brought into the territory of Ukraine for the purposes of:

- 5) Registration in Ukraine;
- 6) Displaying at exhibitions, fairs and conferences;
- 7) Scientific research.

2. In case veterinary preparations are imported for purposes specified in paragraph 1 of this Article, amount of such preparations shall be limited to what is necessary to achieve defined purposes, and their circulation in Ukraine shall be prohibited.

3. In case of calamity, natural disaster, or outbreaks of animal disease, which may result in the infection of a large number of animals with animal disease, the central body of executive power on veterinary medicine issues may, pursuant to established procedure, issue a single use import permit for a specific veterinary preparation that is not registered for circulation and use in Ukraine, under condition of availability of documents confirming the circulation and application of this preparation in the country, from which such is imported.

Article 71. Record Keeping of Use of Veterinary Preparations and Medicated Feed by Food-producing Animal Owners (Keepers)

(6) Owners (keepers) of food-producing animals shall be obliged to keep records on purchases and use of veterinary medicinal means, veterinary immune-biological means and medicated feed according to each animal for the life span of the animal and, upon request, provide such records to state inspector of veterinary medicine or authorized doctor of veterinary medicine. In case of transfer of food-producing animal, the previous owner (keeper) shall provide such records to the new owner (keeper).

The mentioned records shall include the date of purchase, the name of veterinary medicinal or immune-biological means or medicated feed, the amount of purchased products, the name and address of the establishment of veterinary medicine or veterinary pharmacy, where medicinal or immune-biological means or medicated feed were sold, and information on the animals treated thereby.

2. The records referred to in paragraph 1 of this Article may be inscribed in the form of copies of the prescriptions for the veterinary medicinal means or veterinary immune-biological means and invoices for such means or medicated feed from a veterinary pharmacy or establishment of veterinary medicine, with a specification of the animal or animals treated thereby.

Article 72. Utilization and Destruction of Veterinary Preparations

- (1) Veterinary preparations, which in the process of implementation of state control and supervision are found incompliant with the requirements of this Law, as well as those with an expired shelf life, must be withdrawn from circulation, utilized and destroyed.
- (2) Utilization and destruction of veterinary preparations shall be conducted according to the rules, prescribed by the central body of executive power on veterinary medicine issues, and in compliance with other requirements of legislation.

Article 73. Circulation of Means of Animal Care

- (1) Means of animal care may be circulated and used in Ukraine provided they:
 - 1) Are not harmful to animal health;
 - 2) Are not capable of being harmful to human health when used according to the guidelines provided by the producer of such means;
 - 3) Do not impair the veterinary-sanitary and epizootic welfare of Ukraine.

Article 74. Regulating Circulation of Devices of Veterinary Medicine

New devices of veterinary medicine, for which national standards or technical regulations do not exist, and for which an ISO/IEC standard does not exist, shall be submitted to the central body of executive power on veterinary medicine issues prior to their circulation for compulsory testing of their ability to achieve the relevant effect, for which such devices are designed.

SECTION XI. REQUIREMENTS TO PRODUCTION OF FEED ADDITIVES, PREMIXES AND FEED FOR ANIMALS

Article 75. Registration of Feed Additives, Premixes, and Finished Feed

- (1) Feed additives, premixes and finished feed shall be allowed for circulation and use in Ukraine only after their state registration.
- (2) It shall be prohibited to register (re-register) feed additives, premixes and finished feed that:
 - 1) Cause damage to the veterinary-sanitary and epizootic welfare of Ukraine;
 - 2) Have an unfavorable effect on animal health, human health, and the environment;
 - 3) Are presented in a manner which may mislead the users/ consumers;
 - 4) Harm the consumer by impairing the characteristic peculiarities of products of animal origin, or make an erroneous impression on the consumer about characteristic peculiarities of the products of animal origin.
- (3) In order to conduct state registration of feed additives, premixes, and finished feed, the person (hereinafter- application) shall submit an application along with the relevant accompanying documents, list of which shall be prescribed by the central body of executive power on veterinary medicine issues, to the state scientific-research control institute, authorized by the latter. The applicant shall be responsible for validity of information presented in the registration dossier. The applicant applying for registration of feed additives, premixes and finished feed shall indicate in

the documents accompanying the application any information that he/she wishes to keep confidential. Regulations on state registration of feed additives, premixes and finished feed shall be developed and approved by the central body of executive power on veterinary medicine issues.

(4) State scientific-research control institute of veterinary preparations and feed additives shall conduct an evaluation (testing) of submitted documents, organize the implementation of necessary analysis and perform other measures necessary to verify information and data, stipulated in the documents, and also prepare expert conclusions for consideration of the State Pharmacology Commission of Veterinary Medicine

(5) The State Pharmacology Commission of Veterinary Medicine shall consider expert conclusions and provide the central body of executive power on veterinary medicine issues with the recommendations regarding state registration of the relevant feed additives, premixes and finished feed.

(6) The central body of executive power on veterinary medicine issues shall make a decision to approve or deny registration of feed additives, premixes and finished feed. The term of registration must not exceed 90 days from the date of receipt of the application, complete set of documents, and effecting relevant payments.

(7) After a decision is made to register feed additives, premixes and finished feed, the latter shall be entered into the register of feed additives, premixes and finished feed, which shall be maintained by the central body of executive power on veterinary medicine issues.

(8) In case a decision is made to deny registration, such decision and an exhaustive explanation of reasons for denial shall be transmitted to the applicant. The applicant may appeal the decision in court according to the procedure prescribed by legislation.

9) Registration of feed additives, premixes and finished feed shall be confirmed by issuance of a registration certificate whose validity term may not exceed 5 years. The registration certificate shall stipulate the name of feed additives, premixes and finished feed, information on the producer and the person who has ownership right for the latter, registration number, and the term of validity of the registration.

(10) Annexes to the registration certificate shall contain information with regard to:

1) the purpose for feed additives, premixes and finished feed, and, if necessary, quality indicators;

2) all specific conditions or restrictions on storage and application of feed additives, premixes and finished feed, monitoring requirements for producers with regard to negative impact during circulation and use of the latter, and categories of animal species for which feed additives, premixes and finished feed or medicated feed shall be used;

3) all specific requirements in addition to those specified in paragraph 10 of this Article with regard to marking of feed additives, premixes and finished feed, which shall be necessary to fulfill the requirements and restrictions, prescribed in item 3 of this paragraph;

4) maximum allowed levels of residue amounts for veterinary medicinal or immune-biological means, which are the components of feed additives, or for the metabolites of veterinary medicinal or immune-biological means in products of animal origin intended for agricultural or industrial use, when setting up of such levels is envisaged by current legislation, and international standards, guidelines and recommendations with regard to maximum allowed levels do not exist;

Annexes to the registration certificate shall also contain other information prescribed in relevant normative-legal act issued pursuant to this Law.

(11) Feed additives, premixes and finished feed being circulated in Ukraine shall comply with the following marking requirements and contain the following information clearly formulated in Ukrainian language, in a form that attracts attention and is indelible:

- 1) The specific name given upon registration;
- 2) The name or title, the address or registered place for carrying out the activity of the owner of registration certificate;
- 3) Qualitative and quantitative composition of components;
- 4) Guidelines for use and all recommendations regarding safe use and, if necessary, specific requirements, including animal species and categories, for which feed additives, premixes and finished feed are intended;
- 5) Registration number of the registration certificate issued by the central body of executive power on veterinary medicine issues;
- 6) Lot (series) number, date of manufacture, and the shelf-life.

(12) Feed additives, premixes and finished feed that are not registered for circulation in Ukraine may be brought into Ukraine on the basis of a single use permit for bringing in (entry) issued by the central body of executive power on veterinary medicine issues, but not subsequently circulated, only for the following purposes:

- 1) Registration in Ukraine
- 2) Displaying at fairs, exhibitions, and conferences;
- 3) Scientific and other purposes.

(13) The central body of executive power on veterinary medicine issues shall prescribe the procedure for registration of feed additives, premixes and finished feed. Registration shall be conducted, renewed, and revised only in compliance with the procedure prescribed by the central body of executive power on veterinary medicine issues.

Article 76. Production and Circulation of Feed Additives, Premixes and Finished Feed

(1) Production of feed additives, premixes and finished feed that are not registered for circulation in Ukraine shall be prohibited. During the production of feed additives, premixes and finished feed persons shall observe the requirements of Good Manufacturing Practices and other requirements prescribed by the central body of executive power on veterinary medicine issues.

(2) Persons producing feed additives, premixes and finished feed shall be obliged to keep detailed records with regard to suppliers, the date of receipt of materials for such production, including feed of animal origin and feed of plant origin, used in production, and also keep records with regard to all feed additives, premixes and finished feed sold during three years in accordance with the form and the guidelines prescribed by the central body of executive power on veterinary medicine issues.

(3) The placing into circulation of feed additives, premixes and finished feed by a producer and/or seller (supplier) shall be understood to be a declaration of their safety, and compliance with other mandatory requirements established by relevant technical regulations and the conditions of registration.

(4) Feed additives, premixes and finished feed in circulation shall be subject to random control for compliance with the conditions of their registration and relevant technical regulations. The central body of executive power on veterinary medicine issues shall authorize the relevant state institutes of veterinary medicine to exercise such control.

(5) It shall be prohibited to circulate feed additives, premixes and finished feed that do not comply with the conditions of their registration, and/or relevant technical regulations.

(6) In addition to the requirements specified in paragraph five of this Article, it shall be prohibited to circulate feed, including premixes and feed additives that are unsuitable. Feed additives, premixes and finished feed shall be deemed to be unsuitable if:

- 1) actual composition of components does not comply with the declaration on the marking;
- 2) they contain pathogenic microorganisms in the amount as to endanger animal health;
- 3) they contain contaminants in the amount in excess of maximum allowed levels;
- 4) the shelf-life has expired.

(7) Maximum allowed levels of contaminants and allowed amount of pathogenic microorganisms in feed shall be determined according to legislation.

(8) It shall be prohibited to feed ruminants with the feed containing animal protein from ruminants.

Article 77. Program for Monitoring Feed, Feed Additives and Premixes

(1) All feed, feed additives and premixes in circulation in Ukraine shall be control according to the state program for monitoring and surveillance that shall be designed and operated on the basis of risk assessment and implemented by the veterinary service of veterinary medicine with the aim to monitor suitability and compliance with relevant technical regulations.

(2) The results of analysis of samples of feed, feed additives and premixes within ten working days of the date of notification of the results of laboratory analysis, may be challenged by the owner of the above feed, feed additives and premixes, from which samples were taken, by requesting an arbitration analysis.

(3) The sampling frequency, facilities (objects) where samples are taken, the method of sampling and laboratory analysis in the state laboratories of veterinary medicine, measures to be taken when feed, feed additives and premixes are determined to be unsuitable or not complying with technical regulations, shall be specified according to normative-legal acts issued by the central body of executive power on veterinary medicine issues pursuant to this Law.

Article 79. Registration of Persons Circulating Feed of Animal Origin

(2) Persons circulating feed of animal origin shall be subject to registration with the central body of executive power on veterinary medicine issues.

(2) Persons referred in paragraph 1 of this Article shall be obliged to keep records on purchases and sales of feed of animal origin for three last years enabling traceability of such feed, and provide such information to state inspector of veterinary medicine upon request.

(3) Persons circulating feed, which contains animal protein from ruminants, shall maintain separate display and storage facilities (objects), and also separate transportation vehicles for transportation of such feed.

(4) The central body of executive power on veterinary medicine issues shall issue necessary normative-legal acts to implement the provisions of this Article.

Article 79. Use of Waste Food (Swill) for Feeding Animals

(1) In order to prevent the outbreaks of animal diseases caused by using feed produces from infected materials of animal origin as feed, it shall be prohibited to use as feed for animals waste food (swill) that was transported by vehicles, which took part in international transportation into infected or surveillance zones or from the latter without carrying out relevant veterinary-sanitary measures .

(2) Use of waste food from facilities (objects), which sell food products or are involved in the sphere of public catering, other than those referred to in paragraph 1 of this Article, for feeding animals intended for slaughter shall be allowed only under condition of prior thermal treatment of such waste food.

(3) Persons using waste food for feeding animals intended for slaughter shall be obliged to keep records for three years on the origin of the waste food and provide such information to state inspector of veterinary medicine upon request.

(4) Waste food shall be transported in containers and by such vehicles that preclude the threat of leakage or spillage, and which shall be thoroughly cleaned and disinfected after their use.

(5) Conditions for use of waste food, including procedure for collecting such and its thermal treatment, the type and vehicles of transportation, and the procedure for cleaning and disinfecting transportation vehicles and containers, and keeping of records shall be prescribed by the central body of executive power on veterinary medicine issues.

SECTION XII. REQUIREMENTS TO CARRYING OUT INTERNATIONAL TRADE

Article 80. Designated Border Inspection Posts

(1) The bringing (entry) into the territory of Ukraine, transit and bringing out (exit) of the territory of Ukraine of commodities shall be allowed only through designated border inspection posts, which have quarantine stations, and are designated for bringing in (entry) and bringing out (exit) of commodities (hereinafter: designated border inspection posts).

(2) The veterinary-sanitary, technical and working conditions at designated border inspection posts must be prescribed by the central body of executive power on veterinary medicine issues and be acceptable for the following purposes:

- 1) Conducting clinical visual examination of animals and taking of samples from such animals or of other commodities for diagnostic and laboratory analysis;
- 2) Isolating animals that have animal diseases or maladies, or animals suspected of having an animal disease;
- 3) Carrying out disinfection of vehicles used for transportation of commodities.

(3) All goods referred to in paragraph 1 of this Article that arrive at a border post other than a designated border inspection post shall be redirected to the nearest designated border inspection post.

Article 81. Commodities and Other Products Prohibited for Entry into the Territory of Ukraine

- (1) It shall be prohibited for Ukraine's citizens, foreigners, and persons without citizenship, which reside/stay in the territory of Ukraine, to bring in non-edible products of animal origin for their own use.
- (2) It shall be prohibited to bring live pathogenic microorganisms (including bacteria, viruses, fungi, rickettsia, micro-plasmas, other pathogenic microbes) and pathological material containing pathogens of animal diseases into the territory of Ukraine, except for the purpose of conducting scientific research or for other allowed purposes.
- (3) It shall be allowed to bring microorganisms and pathological material containing pathogens of animal diseases into the territory of Ukraine on the basis of a permit for bringing (entry) into territory of Ukraine, issued by the central body of executive power on veterinary medicine issues in accordance with the provisions of Article 82 of this Law.
- (4) It shall be prohibited to bring veterinary preparations, feed additives, premixes and finished feed that are not registered in accordance with the provisions of this Law into the territory of Ukraine, except as prescribed in Article 70 and paragraph twelve of Article 75 of this Law.
- (5) This Article shall not apply to bringing in (bringing out) of microorganisms, which shall be under control of the relevant services of the Ministry of Health Protection of Ukraine.

Article 82. Permit for Bringing Commodities into the Territory of Ukraine

- (3) In cases specified in relevant veterinary-sanitary measures, commodities shall be brought into the territory of Ukraine on the basis of permits issued by the state bodies of veterinary medicine.
- (4) Procedure for submitting an application to obtain a permit for bringing (entry) into the territory of Ukraine, as well as requirements to the form and content of the application shall be prescribed by the central body of executive power on veterinary medicine issues. Under no circumstances shall the time-period of processing the application to obtain a permit for bringing (entry) goods into the territory of Ukraine take more than 30 calendar days.
- (5) A permit for bringing (entry) goods into the territory of Ukraine shall be issued if the following conditions are met:
 - 1) the bringing into the territory of Ukraine of commodities is not prohibited due to the veterinary-sanitary status in the country of origin or re-export;
 - 2) the risk associated with the bringing into the territory of Ukraine or transit of the commodities is acceptable in relation to the appropriate level of animal and related human health protection.
- (6) Factors to be considered for determination of risk, associated with bringing a commodity into the territory of Ukraine, shall include:
 - 1) Use of the commodity as intended;
 - 2) Geographic and other characteristics of Ukraine, the country of origin, and, when applicable, countries of transit that affect the ability of notifiable diseases to enter, establish, and spread;
 - 3) The existence of state control programs for animal diseases in Ukraine, the country of origin, and transit countries;

- 4) The existence of zones free of notifiable disease or zones of low prevalence of notifiable disease in the country of origin, when the risk of transmission of such disease does not exist or is minimal;
- 5) The effectiveness of the Veterinary Administration of the country of origin, which shall be defined pursuant to Article 28 of this Law;
- 6) The effectiveness of measures that the central body of executive power on veterinary medicine issues may require to be applied in the country of origin to reduce the risk associated with the bringing (entry) into the territory of Ukraine, including, pre-shipment prophylactic animal quarantine, specification of the facility (object) of origin, sampling and laboratory analysis for confirmation of freedom from notifiable diseases in the country of origin; If necessary, the veterinary administration of exporting country shall provide an appropriate access to facilities (objects) to conduct inspections, tests and other relevant procedures with regard to veterinary-sanitary measures associated with bringing out of live animals and products of animal origin;
- 7) In case of bringing animals into the territory of Ukraine, expected effectiveness of prophylactic animal quarantine for monitoring animal health shall be taken into account.

(5) The permit for bringing (entry) into the territory of Ukraine shall stipulate the veterinary-sanitary measures that must be conducted by the exporter prior to shipment and by the importer upon entry into the territory of Ukraine, as well as any declarations in addition to freedom from clinical indications of certain notifiable diseases that must be attested to in the international veterinary certificate. In case of bringing into the territory of Ukraine of live microorganisms and pathological material containing pathogens of animal diseases, the permit for bringing (entry) into the territory of Ukraine must include specification of veterinary-sanitary measures to be applied by the importer to prevent a spread of the pathogenic agent.

(6) The permit for bringing (entry) into the territory of Ukraine shall not be required for non-edible products of animal origin, should the latter be subjected to technical procedures, which precludes transmission of notifiable diseases.

(7) The decision to deny a permit for bringing (entry) into the territory of Ukraine shall be justified and be provided to the applicant without delay. The decision may be appealed according to the procedure established by legislation.

(8) The central body of executive power on veterinary medicine issues shall be obliged to provide a notification by making available on its web-site the list of commodities, according to their countries of origin, from which commodities may not be imported due to the veterinary-sanitary state of the country, and also inform interested state bodies about the imposition of prohibition on bringing (entry) into the territory of Ukraine of commodities, according to the veterinary-sanitary state of the country.

Article 83. Notification to State Inspectors of Veterinary Medicine about Bringing Live Animals into the Territory of Ukraine

(1) An importer or person responsible for shipping the consignment of animals, which require post-entry prophylactic animal quarantine, shall be obliged to inform the relevant regional service of veterinary medicine not later than three working days before the arrival of such consignment of animals.

- (2) Procedure and form of notification to the relevant regional service shall be prescribed by the central body of executive power on veterinary medicine issues.

Article 84. Requirements to Consignments of Commodities that are Brought into the Territory of Ukraine or Moved as Transit

- (1) Consignments of commodities that are brought into the territory of Ukraine must:
- 1) Be free of notifiable diseases in compliance with the requirements established by the OIE;
 - 2) Be accompanied by original international veterinary certificates signed by state inspector of veterinary medicine of the country of origin when so envisaged by current veterinary-sanitary measures;
 - 3) Be accompanied by a permit for bringing (entry) into the territory of Ukraine when so required by veterinary-sanitary measures;
 - 4) In the case of bringing live animal into the territory of Ukraine,- originate from countries or zones free from notifiable diseases or, when recommended by the OIE, - from the zones of low prevalence of notifiable diseases within the country of origin, and not be transported through the territory that is under restriction, as confirmed by relevant international organization or by the Veterinary Administration of the country of origin or transit.
- (2) Transit consignments of live animals shall meet the requirements specified in item 1 of paragraph 1 of this Article.
- (3) Transit consignments of non-edible products of animal origin and reproductive material shall be moved through the territory of Ukraine in accordance with prescribed general procedure for transit of other commodities.
- (4) List of commodities, stipulating their codes pursuant to Ukrainian Classificatory of Commodities of Foreign Economic Activities, which shall be subject to veterinary-sanitary measures when brought into the customs territory of Ukraine and brought out of the customs territory of Ukraine, shall be prescribed by the central body of executive power on veterinary medicine issues.

Article 85. Bringing Exotic Animals into the Territory of Ukraine

In order to bring exotic animals (those not normally present in Ukraine) into the territory of Ukraine the importer shall be obliged, when so required by relevant international agreements, to provide documents from the competent authority of the country of origin on issues of protection of natural resources, which confirm that this authority allows to bring such animals into the territory of Ukraine.

Article 86. Standard Border Veterinary-Sanitary Control

- (1) All import and transit objects of veterinary-sanitary control and supervision shall be subject to standard border veterinary-sanitary control in form of inspection, which shall be conducted by means of:
- 1) Verification of validity of the permit for bringing (entry) into the territory of Ukraine, which accompanies the consignment;

2) If an international veterinary certificate is required by veterinary-sanitary measures, verification that such certificate accompanying the consignment is complete and authentic, and that the commodities described in the international veterinary certificate are the commodities in the consignment;

3) Detection of indications of notifiable diseases in animals.

(2) Bringing of the consignment into the territory of Ukraine or its transit through the territory of Ukraine shall be allowed under following conditions:

1) The consignment is accompanied by a valid permit for bringing (entry) into the territory of Ukraine, when the permit for bringing (entry) into the territory of Ukraine is required by veterinary-sanitary measures;

2) International veterinary certificate is complete, authentic, and pertains to the commodities in the consignment, when international veterinary certificate is required by veterinary-sanitary measures;

3) No symptoms or other indications of notifiable diseases have been detected in the commodities;

4) At least one of the following conditions is met:

1. In case of transit consignments, if the customs seal applied by the customs authority of the country of shipment is not damaged;

2. The commodity is subject to a bilateral agreement regarding recognition of the equivalence of specific or general veterinary-sanitary measures between the country of origin and Ukraine;

3. The prior consignments of like commodities from the country of origin and/or particular facility (object) of origin were accompanied by valid international veterinary certificates;

4. The consignment presents a low level of risk to domestic animals based on the pre- and post-entry requirements for the commodities.

(3) In the case that standard veterinary-sanitary border control results in a conclusion that international veterinary certificate is incomplete, does not apply to the commodities in the consignment, or validity of the international veterinary certificate is doubted, the state border inspector of veterinary medicine shall implement the provisions of Article 89 of this Law.

(4) Extended veterinary-sanitary control of a consignment shall be conducted when the consignment is designated for such under the random veterinary-sanitary control program, or when the risk to animal or human health presented by a consignment is, based upon the professional judgment of the state border inspector of veterinary medicine, deemed to be high. When assessing the risk to animal and human health presented by the commodity in the consignment, the following shall be considered:

1) Results of standard border veterinary-sanitary control of commodities;

2) Existence of bilateral agreements regarding recognition of the equivalence of specific or general veterinary-sanitary measures between Ukraine and the country of origin;

3) The required pre- and/or post-entry veterinary-sanitary measures for the commodities as specified in the permit for bringing (entry) into the territory of Ukraine, if necessary;

4) Statistical data of the invalid international veterinary certificates attesting to freedom from animal diseases in consignments of like commodities from the country of origin and/or particular facility (object) of origin.

(5) Import consignments shall be considered as not require extended veterinary-sanitary control, if a certain number of prior consignments with like commodities from the relevant country of origin and/or particular facility (object) of origin were accompanied by valid international veterinary certificates and the results of standard border veterinary-sanitary control do not provide grounds for requiring an extended veterinary-sanitary control.

(6) Extended veterinary-sanitary control must be conducted in accordance with the provisions of Article 88 of this Law.

(7) The central body of executive power on veterinary medicine issues shall prescribe the number of prior consignments of like animals or like other commodities from a certain country of origin and/or facility (object) of origin, which were accompanied by valid international veterinary certificates that precludes the need for extended veterinary sanitary control.

Article 87. Random Veterinary-Sanitary Border Control

(1) Consignments of commodities that are brought into the territory of Ukraine, when so selected according to state random veterinary-sanitary control program, shall be subject to mandatory extended veterinary-sanitary border in accordance with the provisions of Article 88 of this Law.

(2) Mandatory extended veterinary-sanitary control shall be applied under the random veterinary-sanitary control program during a calendar year for specifically determined percentage of consignments of commodities classified into three categories: live animals; non-edible products of animal origin; and other commodities.

(3) Percentage of consignments referred to in paragraph 2 of this Article shall be determined on the basis of historical incidence of detection of notifiable diseases or other animal diseases in consignments of each category of commodities and other factors that affect the risks to animal life and health, associated with import consignments of commodities.

(4) Specifically determined percentage of consignments of commodities subject to extended veterinary-sanitary control shall be specified by the central body of executive power on veterinary medicine issues prior to the beginning of each calendar year.

Article 88. Extended Veterinary-Sanitary Control

(5) Should the state border inspector of veterinary medicine suspect that consignments of commodities, which are brought into the territory of Ukraine, or transit consignments of commodities do not fulfill necessary conditions for bringing into the territory of Ukraine or for transit, the following actions shall be taken:

1) The state border inspector of veterinary medicine shall immediately notify about it the Chief State Inspector of Veterinary Medicine of Ukraine, who in turn shall immediately notify the Veterinary Administration of the country of origin and of the country last transited through, if applicable, as well as the importer or the owner of the consignment.

2) The consignment shall be isolated at the quarantine station at the designated border inspection post and the state border inspector of veterinary medicine, if necessary, shall collect samples of

commodities according to the procedure specified in the relevant rule book, and dispatch such to an authorized laboratory equipped to conduct necessary analysis with the aim to confirm or rule out the suspicion.

3) Upon ruling out of the suspicion, the state border inspector of veterinary medicine shall issue a veterinary affidavit enabling movement of the consignment within the territory of Ukraine, the consignment shall be subject to further customs procedures, envisaged by legislation.

4) Upon confirmation of especially dangerous diseases of the OIE List in animals, the animals shall be slaughtered and the carcasses and any accompanying items shall be utilized or destroyed in a manner, guaranteeing that they will not be capable of transmitting the disease, at the expense of the owner or carrier. If the consignment contains commodities other than live animals, these commodities shall be utilized or destroyed in a manner, guaranteeing they will not be capable of transmitting the disease, at the expense of the owner or carrier.

5) Upon confirmation of an endemic notifiable disease subject to a state control program, or confirmation of infection with an animal disease that is capable of increasing the incidence of endemic animal disease in Ukraine, the consignment shall be:

1. Returned to the country of origin at the expense of the owner or carrier, provided such return does not endanger animal health;

2. With consent of the owner and observance of necessary veterinary-sanitary measures-subjected to technical processing to eliminate the pathogenic agent of animal disease;

3. Destroyed in accordance with the provisions of item 4 of paragraph 1 of this Article.

(2) The Chief state inspector of veterinary medicine shall immediately inform the Veterinary Administration of the country of origin, or the importer and/or owner of the consignment about confirmation or ruling out of suspicion of animal disease, and the actions subsequently taken.

Article 89. Procedures To Be Applied When International Veterinary Certificate is not Acceptable

(1) Should the state border inspector of veterinary medicine conclude that the international veterinary certificate accompanying a consignment of commodities is incomplete or fraudulent or otherwise falsified, or conclude that the commodities in a consignment are not those described in the accompanying international veterinary certificate, the consignment shall be held at the designated border inspection post, and the Chief State Inspector of Veterinary Medicine of Ukraine or his/her designated representative shall be notified.

(2) The Chief State Inspector of Veterinary Medicine of Ukraine or his/her designated representative shall immediately contact the Veterinary Administration of the country of origin for consultations and in order to jointly determine measures to be taken with regard to the consignment.

(3) Should the fact of unacceptable international veterinary certificate be confirmed, the consignment shall be returned to the country of shipment at the expense of the owner of the commodity or at the expense of the carrier.

Article 90. Restrictions on Bringing into the Territory of Ukraine and Transit due to an Outbreak of Especially Dangerous Disease of the OIE List in the Country of Origin or Transit

(3) An import or transit consignment of animals shall not be permitted entry, regardless of the availability of a permit for bringing (entry) into the territory of Ukraine or a permit for transit if:

1. The presence of especially dangerous disease of the OIE List, to which these animals are susceptible, has been confirmed in the country of origin in the zone where the animals originated;
2. The presence of especially dangerous disease of the OIE List, to which these animals are susceptible, has been confirmed in one or more transit countries in the territory or territories, through which the consignment of animals have been moved.

(2) In the above circumstances, the the central body of executive power on veterinary medicine issues must stop such consignment at the border, and, following the consultations with the Veterinary Administration of the country of origin, immediately return the consignment to the country of origin, and in the event of high risk - destroy the animals in such a manner as to minimize the risk of introduction or spread of especially dangerous disease of the OIE List, at the expense of the owner of the consignment.

Article 91. Quarantine Requirements for Animals That are Brought into the Territory of Ukraine

- (1) Animals that are brought into the territory of Ukraine except those intended for slaughter shall be subject to prophylactic animal quarantine with the aim to verify their health.
- (2) The length of prophylactic animal quarantine and the methods of diagnostic control and verification of the status of animal health shall be specified in the relevant rule books adopted by the central body of executive power on veterinary medicine issues in accordance with the OIE requirements. The places for prophylactic animal quarantine and the persons that will implement relevant procedures shall be specified and controlled by the state service of veterinary medicine.

Article 92. Procedures Applicable in Customs-Houses, Customs Warehouses and in Free Economic Zones

All commodities crossing the state border of Ukraine and arriving at customs warehouses, customs storage and free economic zones shall be subject to the same state veterinary-sanitary border control applied to the consignments that are imported.

Article 93. Documents Accompanying the Consignments of Commodities That are Brought out of the Territory of Ukraine

Consignments of commodities that are brought out of the territory of Ukraine must:

- 1) be accompanied by original international veterinary certificates signed and issued by state border inspector of veterinary medicine attesting to freedom from clinical indications of an animal disease, and containing other declarations pursuant to the requirements of the OIE and the country of destination;
- 2) when so required by the country of destination, be accompanied by the documents or have marking that indicates the facility (object) from which the commodities originate.

Article 94. Issuance of International Veterinary Certificates for Consignments of Commodities That are Brought out of Territory of Ukraine

- (1) Certificates for export consignments of commodities that must be accompanied by original international veterinary certificates attesting to compliance of the consignment with the requirements in the country of destination shall be issued not earlier than 72 hours prior to shipment of the consignment on the export transportation vehicle.

(2) Compliance with the certification requirements of the country of destination shall be determined on the basis of:

Veterinary affidavit issued prior to shipment and transporting the consignment within the territory of Ukraine, if the conditions of the veterinary affidavit are the same as those of the country of destination and, in the case of bringing the animals out of the territory of Ukraine - the date on said veterinary affidavit shall be no more than 72 hours prior to the final shipment on the export transportation vehicle;

In the event that a veterinary affidavit was not issued prior to shipment and transporting the consignment within the territory of Ukraine, or information in the veterinary affidavit do not comply with the requirements to such information of the country of destination, verification of fulfillment of the requirements of the country of destination shall be carried out by the state border inspector of veterinary medicine;

In the event of expiration of the veterinary affidavit, re-certification of the affidavit shall be carried out in accordance with the requirements of the country of destination.

(3) If the consignment complies with the requirements of the country of destination, state border inspector of veterinary medicine shall sign and issue an international veterinary certificate in accordance with the requirements of country of destination.

(4) Any consignment that is found to not comply with the requirements of the country of destination shall be denied an international veterinary certificate and not permitted to be brought out of Ukraine. The owner or person responsible for the consignment shall immediately take actions prescribed by the state border inspector of veterinary medicine in the relevant directive.

(5) International veterinary certificate shall be printed and serially numbered and conform to the standard form of a certificate, established by the relevant international organizations, or conform to the form and contents required by the country of destination.

Article 95. Measures to be Taken Due to a Threat of an Animal Disease

If there is a high risk of entry of a notifiable disease into the territory of Ukraine from the territory of a neighboring country, or its transmission through export or transit consignments, the Chief State Inspector of Veterinary Medicine of Ukraine may issue an instruction to impose in threatened area:

- 1) Control of movement of commodities in threatened border territories, including roads, bridges, and ferries;
- 2) Prohibition, restriction or regime of mandatory prior conditional permit for bringing into the customs territory of Ukraine, bringing out of the customs territory of Ukraine, or transit of commodities in relation to the risk associated with movement of commodities from/ or through such territories;
- 3) Mandatory disinfection of transportation vehicles crossing the border in threatened territories.

SECTION XIII. FINANCING AND LOGISTIC SUPPORT

Article 96. Financing and Logistic Support to the State Service of Veterinary Medicine

(1) Financing and logistic support to the state service of veterinary medicine shall be provided from the general and special funds of the State Budget of Ukraine.

(2) Contributions to the Office International Epizootic and other international organizations on veterinary medicine issues, to which Ukraine is a member, shall be made from the State Budget of Ukraine.

Article 97. Financing of Anti-Epizootic Measures and Ensuring the Implementation of National Long-Term Programs on Veterinary Medicine Issues

Measures on prophylaxis, containment, when appropriate elimination of animal diseases, laboratory-diagnostic and regular radiological analysis of commodities, logistic provision with specialized equipment and transport, other veterinary-sanitary measures identified by the Cabinet of Ministers of Ukraine and ensuring the implementation of national long-term programs on veterinary medicine issues, including national program for monitoring residue amounts of veterinary preparations and other contaminants in animals, products of animal origin and feed, shall be financed from the State Budget of Ukraine.

Article 98. Payment for Services Rendered by the State Service of Veterinary Medicine

(1) Payment for the implementation of measures on prophylaxis and elimination of animal diseases (except those envisaged by Article 97 of this Law), procedures for control, inspection, approval and provision of information, medical treatment of animals that have diseases and maladies, laboratory analysis, veterinary-sanitary testing of commodities, services provided for export/import transactions, and transportation of the objects of state veterinary-sanitary control and supervision within the territory of Ukraine shall be made at the expense of their owners (operators of facilities) according to tariffs. Payments must equal the costs of the services rendered.

(2) Payment for testing and tests with the aim of registration in Ukraine of veterinary preparations, feed additives, premixes and finished feed shall be made by the customer based on the price list, which shall be adopted pursuant to legislation.

(3) Payment for services of the specialists of veterinary medicine, engaged in veterinary practice, for carrying out mandatory or necessary anti-epizootic measures in accordance with the list and in the amount adopted by the Cabinet of Ministers of Ukraine shall be made from the funds of the State Budget and other sources not prohibited by legislation.

(4) Tariffs for veterinary services shall be approved according to the legislation on prices and pricing.

SECTION XIV. VETERINARY PRACTICE AND TRAINING, AND STATUS OF THE SPECIALISTS OF VETERINARY MEDICINE. INFORMATION SUPPORT TO THE STATE SERVICE OF VETERINARY MEDICINE

Article 99. Veterinary Practice

1. Legal entities or natural persons (Ukrainian citizens, foreigners, and persons without citizenship, which reside/stay in Ukraine) may engage in veterinary practice on the basis of a license that shall be issued pursuant to legislation.

2. State institutions of veterinary medicine (clinics, offices, points, pharmacies, warehouses, laboratories etc.), except for the State Scientific-Research Control Institute of Veterinary Preparations and Feed Additives, State Scientific-Control Institute of Bio-Technology and Microorganism Strains, Institute of Laboratory Diagnostics, zonal, inter-oblast, republican laboratory of the Autonomous Republic of Crimea, oblast state laboratories of veterinary medicine, state laboratories of veterinary medicine of the cities of Kyiv and Sebastopol, state laboratories of veterinary-sanitary testing in the markets, may be privatized in the procedure envisaged by legislation. Privatized objects may not change their profile within 10 years.

3. The self-supporting units may be established under the state institutions of veterinary medicine for providing veterinary services in contractual basis.

Article 100. Professional Training, Qualification Up-grades, Post-Graduate Education and Attestation of the Specialists of Veterinary Medicine

(1) Professional training of the specialists of veterinary medicine shall be provided only on a full-time basis.

(2) Qualification up-grades and post-graduate education of the specialists of veterinary medicine shall be provided:

- 1) For doctors of veterinary medicine, masters – in the higher educational establishments of post-graduate education and at the faculties of veterinary medicine of the higher educational establishments of the third and the fourth levels of accreditation;
- 2) For technicians of veterinary medicine – in veterinary and agricultural technical colleges, technical schools, higher educational establishments of the first and second or third and fourth levels of accreditation;
- 3) For PHDs, doctors of veterinary medicine – in the relevant sub-faculties of educational establishments of the third and the fourth levels of accreditation and in the departments of scientific-research institutes.

(3) Qualification up-grades and post-graduate education of the specialists of veterinary medicine may be provided by participation in seminars and training at the territory of Ukraine and abroad.

(4) Qualification up-grades for specialists of veterinary medicine shall be provided not less than once per five years.

(5) Payment for post-graduate education of the specialists of veterinary medicine during their qualification up-grades shall be made by their employer; and of the specialists working on the entrepreneurial basis – at their own expense.

(6) Specialists of veterinary medicine shall be subject to attestation according to the procedure established by legislation. Based on the results of the attestation, the following shall be determined: whether an employee meets the requirements of his/her office, the level of his/her qualification, the category and relevant salary.

(7) The central body of executive power on veterinary medicine issues shall adopt the regulations on post-graduate education and periodic qualification up-grades of specialists, as well as the procedure for attestation of the specialists of veterinary medicine.

Article 101. Measures of Legal and Social Protection, Logistic and Social Support of the Specialists of Veterinary Medicine

1. Specialists of veterinary medicine shall be provided with parcels of land for their use or ownership on general grounds in accordance with land legislation of Ukraine.

2. Bodies of state management, with facilitation from local bodies of executive power, enterprises, establishments and organizations of all types of ownership shall provide for creation of appropriate working and dwelling conditions for specialists of veterinary medicine, their medical and transportation servicing.

3. Specialists of veterinary medicine shall be provided with dwellings by means of:

1) Purchase and construction of dwellings provided for the time-period of employment (buildings, apartments), which shall be financed from general and special funds of the State Budget and other sources of funding that are not prohibited by legislation. Such dwellings may be transferred to specialists of veterinary medicine for both temporary and permanent use under conditions of payment or free of charge according to the procedure prescribed by the central body of executive power on veterinary medicine issues.

2) Purchase or construction of individual dwellings, on their own choice, at one of agricultural enterprises in the zone of servicing, financed from the State Budget funds, allocated on a reverse basis, as interest-free long-term loan for 25 years.

4. Amount of official salaries, procedure for determining qualification categories and increases, based on their job span, for the specialists of state institutions of veterinary medicine shall be prescribed by the Cabinet of Ministers of Ukraine.

5. Specialists of veterinary medicine shall have the right for a short working day and an additional paid vacation in cases prescribed by legislation.

6. Specialists of veterinary medicine shall receive doubled amount of their official salaries during their work in the zones of a notifiable disease outbreak.

7. Life and health of specialists of veterinary medicine shall be subject to compulsory insurance for cases of disability or professional illness obtained while performing their official duties, controlling zoonosis and direct treatments of animals, which shall be financed from the special fund of the State Budget of Ukraine.

8. In case of disability, professional illness or death related to performance of their official duties, a lump sum shall be paid to specialists of veterinary medicine or their successors according to the procedure, conditions and in the amount prescribed by the Cabinet of Ministers of Ukraine.

9. Specialists of veterinary medicine residing and working due to their profession in rural areas shall, pursuant to legislation, be granted with the right of free use of dwellings, heating and power supply, privileged loans for setting up their household business, construction of individual houses and purchasing cattle. Specialists of veterinary medicine – pensioners, who worked in rural areas and municipal type settlements, and resided there, shall preserve these rights.

10. In order to perform their official duties specialists of veterinary medicine of the state institutions shall be provided with specialized transportation vehicles. In case of using their own transportation vehicle to perform their official duties, the latter shall receive a specified amount of monetary compensation.

11. Expenses associated with social and legal protection of specialists of veterinary medicine shall be financed from general and special funds of the State Budget, allocated by the central body of executive power on veterinary medicine issues within the limits of legislation.

12. Chief State Inspectors of Veterinary Medicine of Ukraine, of the Autonomous Republic of Crimea, the oblasts, the cities of Kyiv and Sebastopol, cities, rayons, regional services of state veterinary-sanitary control and supervision on the state border and transport, their deputies, state inspectors of veterinary medicine of the central body of executive power on veterinary medicine issues and other officials of the state service of veterinary medicine shall have a priority right to receive dwellings and install private telephones.

13. Expenses of the Chief State Inspectors of Veterinary Medicine of Ukraine, of the Autonomous Republic of Crimea, the oblasts, the cities of Kyiv and Sebastopol, cities, rayons, regional services of state veterinary-sanitary control and supervision on the state border of Ukraine and transport, their deputies, state inspectors of veterinary medicine of the central body of executive power on veterinary medicine issues and other officials of the state service of veterinary medicine, for use of passenger transport when performing their official duties, shall be financed from the funds, envisaged to support operation of the state service of veterinary medicine in accordance with approved cost estimates. Procedure for reimbursement of expenses for use of passenger transport shall be prescribed by the Cabinet of Ministers of Ukraine.

14. Issues of social and legal protection, material (logistic) support to specialists of veterinary medicine, which serve in the military or in the bodies of the interior, state border guard, security service etc, shall be regulated by the relevant normative-legal acts.

Article 102. Information Support to the State Service of Veterinary Medicine

1. Information support to the state service of veterinary medicine shall be provided in order to develop veterinary-sanitary measures, to study, evaluate and forecast the situations, aimed at prevention, elimination and reduction of harmful effect of the factors on animal and human health, and also to provide information on these issues to executive power bodies, bodies of local governance, public organizations and citizens.

2. Information support to the state service of veterinary medicine shall be provided by the system of state, sectoral and operative reporting. The nature, amount, procedure and the time-period of supplying this information to the state bodies and institutions of veterinary medicine shall be prescribed by the central body of executive power on veterinary medicine issues.

Bodies of executive power, local self-governance, enterprises, institutions, organizations and citizens shall be obliged to provide the state bodies and institutions of veterinary medicine with such information free of charge.

SECTION XV. LIABILITY OF PERSONS FOR VIOLATIONS IN THE SPHERE OF VETERINARY MEDICINE

Article 103. Liability for Violations in the Sphere of Veterinary Medicine

(2) For violations in the sphere of veterinary medicine, natural persons and legal entities - subjects of entrepreneurial activities, whose activities are related to production and circulation of the objects of state veterinary-sanitary control and supervision, and also rendering of laboratory diagnostics services, and veterinary practice, shall be subject to penalties pursuant to legislation.

(2) Payment of penalties shall not release legal entities and natural persons from elimination of their violations and from reimbursement of damages caused thereby, in accordance with the procedure established by legislation.

Article 104. Bodies Authorized to Consider Cases of Violations in the Sphere of Veterinary Medicine

1. Cases of violations envisaged by this Law, shall be considered by the central body of executive power on veterinary medicine issues, its territorial bodies and regional services not later than within

two months of the date such violation took place, and if it is a continuing violation, within two months from the date of its detection.

2. The Chief state inspectors of veterinary medicine and their deputies shall have the right to impose penalties on behalf of the central body of executive power on veterinary medicine issues, its territorial bodies and regional services.
3. Upon request of the specialists of the state service of veterinary medicine, personnel of the bodies of the interior shall be involved in the implementation of measures on terminating the violations of legislation on veterinary medicine issues, in necessary cases.

Article 105. Decisions Made in Cases of Violations in the Sphere of Veterinary Medicine

- (1) Decisions on imposing penalties for violations in the sphere of veterinary medicine shall be formulated in relevant resolutions.
- (2) Legal entities and natural persons shall pay a penalty within one month of the date of receipt of the relevant resolution. Should the above time-period be violated, the penalty shall be collected in accordance with a court procedure.

Article 106. Appeals to Decisions Made in Cases of Violations in the Sphere of Veterinary Medicine

Decisions made in cases of violations in the sphere of veterinary medicine may be appealed in accordance with court procedure.

SECTION XVI. INTERNATIONAL COOPERATION

Article 107. International Cooperation in the Sphere of Veterinary Medicine

International cooperation in the sphere of veterinary medicine shall be provided for by:

- 1) Participation the activities of the OIE and other international organizations, ratification of international agreements and harmonization of veterinary-sanitary measures;
- 2) Harmonization of legislation in the sphere of veterinary medicine according to best international practices, unification of prophylactic and anti-epizootic measures, diagnostics methods for animal diseases, application of immune-biological, biological, plant, chemical, chemical-pharmaceutical and other veterinary preparations;
- 3) Establishing professional and scientific contacts and exchanging information on the veterinary-sanitary status of Ukraine.

Article 108. International Agreements

Should a current international agreement of Ukraine, mandatory nature of which has been approved by the Verkhovna Rada of Ukraine, prescribe the rules other than those stipulated by this Law, the rules of the international agreement shall be prevail.

SECTION XVII. FINAL PROVISIONS

This Law shall come into force from the date of its publication save for

- 1) Item 4 of Paragraph 3 of Article 64 and Paragraph 1 of Article 76 shall come into force on January 1, 2010;
- 2) Articles 31, 48-52 shall come into force on January 1, 2008 .
- 3) Paragraph 2 of Article 99 shall come into force on January 1, 2007;

2. Until the legislation is brought in compliance with the Law of Ukraine ““On Introduction of Changes to the Law of Ukraine “On Veterinary Medicine” , laws and other normative-legal acts shall be applied in those parts, which do not contradict this Law.

3. The Cabinet of Ministers of Ukraine shall within six month period :

Bring its normative-legal acts in compliance with this Law;

Ensure that other central bodies of executive power bring their normative-legal acts in compliance with this Law”.

Head of Verkhovna Rada of Ukraine

V. Litvin

Kyiv

December 22, 2005

№ 3276–IV