

THE LAW OF UKRAINE

**“ON INTRODUCTION OF CHANGES TO THE LAW OF UKRAINE “ON VETERINARY MEDICINE””**

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, No. 8, p. 62, 2003, No. 16, p.126, No. 27, p. 209, 2005, N 9, page 180; 2006, No. 14, page 116) that shall read:

**THE LAW OF UKRAINE  
“ON VETERINARY MEDICINE”**

Section I. GENERAL PROVISIONS

Article 1. Definitions of Basic Terms

The terms used herein shall have the following meanings:

“Risk research” shall mean the process which includes identification of hazards, assessment of animal disease risk, risk management, and risk communication;

”Arbitration research” shall mean laboratory analyses conducted in response to an appeal by a person against the results of previous laboratory analyses;

”Safety of objects of veterinary-sanitary control and supervision” shall mean assurance that the objects of veterinary-sanitary control and supervision will not cause harm to human and animal 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.

”Buffer zone” shall mean 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;

”Veterinary Administration” shall mean the State service of veterinary medicine having authority in the whole country for coordination, organization and implementation of veterinary-sanitary measures and an inspection 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 inspection of their application;

”Veterinary pharmacy” shall mean an establishment of veterinary medicine - a pharmacy, a pharmaceutical station, a pharmaceutical stall, that circulates veterinary preparations and provides consultations on issues of veterinary preparations administration;

“Veterinary note” shall mean a single-use document issued by a state inspector of veterinary medicine or a licensed doctor of veterinary medicine, which document attests the veterinary-sanitary state of animals, products of animal origin, reproductive material, biological products and feed of animal and plant origin, including a mandatory indication of results of laboratory tests and the veterinary-sanitary status of the territory (facility) of origin and, for animals, a record of vaccination and diagnostic research;

Veterinary documents shall mean documents of an authorization nature, which include an international veterinary certificate, a veterinary affidavit, a veterinary card, a veterinary note and a veterinary-sanitary passport for animals issued by state inspectors of veterinary medicine and authorized or licensed doctors of veterinary medicine, attesting the veterinary-sanitary state of animals, quality and safety of products of animal origin, reproductive material, biological products, pathological material and feed;

“Veterinary immune-biological means” shall mean such means as are obtained with the use of biological agents through biotechnology, the therapeutic and/or diagnostic effect of which means is aimed at correction (stimulation, modulation) as well as at diagnosis of the immunity system and detection of pathogenic agents causing infectious animal diseases;

Veterinary card shall mean a document issued by a state doctor of veterinary medicine or an authorized doctor of veterinary medicine, with a record of the veterinary-sanitary state of a farm, diagnostics, vaccination, medical treatments and other anti-epizootic procedures for a specific animal, which supplements the animal passport;

“Veterinary medicinal means” shall mean substances or combination of substances intended for medical treatment and prophylaxis of animal diseases, or for restoring, correcting, or modifying physiological functions, metabolic processes in animals as well as substances;

“Veterinary medicine” shall mean a sphere of science and practical knowledge on physiology and animal diseases, their prophylaxis, diagnostics, medical treatment, determination of safety of products of animal origin, and in the agricultural food market shall mean of products of plant origin as well, activity aimed at preservation of health and productivity of animals, prevention of animal diseases and protection of humans from zoonosis and prion diseases;

“Veterinary practice” shall mean 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;

“Veterinary preparations” shall mean veterinary medicinal means, veterinary immune-biological means, antiseptics, disinfectants, insectoacaricides, deratizides, diagnosticums that are used in veterinary medicine and animal-raising sector;

“Veterinary affidavit” shall mean a one-use document issued by a state inspector of veterinary medicine, attesting the veterinary-sanitary state of the consignment of animals, products of animal origin, reproductive material, biological products, feed of animal origin and plant origin, including a compulsory indication of results of laboratory tests and the veterinary-sanitary status of the territory (facility) of origin and, for animals, the record of vaccination and diagnostic research;

“Veterinary-sanitary expertise” shall mean a set of necessary laboratory and special studies (virus, bacteriological, chemico-toxicology, pathology-anatomy, histology, parasitology, radiology studies), conducted by specialists of the state service of veterinary medicine or authorized doctors of veterinary medicine with regard to safety of products of animal origin and, on agricultural food markets, of products of plant origin, reproductive material, biological products, veterinary preparations,

substances, feed additives, premixes and feed, including research of production technology and technological equipment for compliance with veterinary-sanitary measures;

“Veterinary-sanitary and epizootic welfare” shall mean ensuring protection of human and animal life and health from hazards associated with animal diseases, including zoonosis, as well as ensuring optimum conditions for animal life, which prevent animal diseases and harmful effect of environmental factors on animal health and productivity;

“Veterinary-sanitary measures” shall mean any measures, including enforcement of laws, regulations and other normative-legal acts, books of rules, requirements and procedures, including, in particular, anti-epizootic measures, determination of end product criteria, processes and production methods, testing, inspection, certification, and approval procedures, quarantine treatments, including relevant requirements associated with transportation of objects of veterinary-sanitary control and supervision, in implementation of provisions on relevant statistical methods, sampling procedures and methods of animal disease risk assessment, that are applied to:

- a) 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;
- b) Protect human and animal life and health from risks arising from contaminants, toxins or disease-causing organisms in products of animal origin or feed;
- c) Protect human life or health from risks resulting from diseases carried by animals or products produced thereof;

“Veterinary-sanitary state” shall mean the presence or absence of a notifiable disease and/or the level of contaminants relative to the maximum allowed level;

“Veterinary-sanitary status” shall mean 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;

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

“Random veterinary-sanitary control” shall mean periodic verification of safety of commodities by means of extended control that is conducted by the state service of veterinary medicine;

Conclusion of the state veterinary-sanitary expertise (expert conclusion) shall mean a document issued by the state or authorized laboratory of veterinary medicine, attesting the safety of products of animal origin, reproductive material, biological products, veterinary preparations, substances, feed additives, premixes and feed. The expert conclusion validity term shall not exceed 1 month;

“Ruling” shall mean an informational-methodological document issued by the Chief State Inspectors of Veterinary Medicine of Ukraine, the Autonomous Crimean Republic, the oblasts, cities of Kyiv and Sevastopol, cities, rayons, regional services of the state veterinary-sanitary control and supervision on the state border and transport, or by their deputies;

“Finished feed” shall mean feed of animal and plant origin containing feed additives for non-food-producing animals, including fish and birds;

“State Department of Veterinary Medicine with the State Inspectorate of Veterinary Medicine (the “Department”)” shall

mean a state body of public administration that carries out functions of the administration of veterinary medicine of Ukraine;

“State service of veterinary medicine of Ukraine” shall mean a system of state bodies for administration of veterinary medicine and state institutions of veterinary medicine;

“State veterinary-sanitary control” shall mean functions performed by state inspectors of veterinary medicine and/or authorized doctors of veterinary medicine, which consist of continuously ensuring fulfillment of veterinary-sanitary measures and technical regulations established by current law;

“State veterinary-sanitary supervision” shall mean functions performed by state inspectors of veterinary medicine and/or authorized doctors of veterinary medicine, which consist of periodic verification of the adherence to the requirements of current law in the sphere of veterinary medicine;

“State inspector of veterinary medicine” shall mean a doctor of veterinary medicine employed by the State service of veterinary medicine or authorized by the Department or if this is a doctor from a foreign country, its Veterinary Administration, to perform inspections of commodities, facilities (objects), devices of veterinary medicine and accompanying items with the purpose of protecting public 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;

“State doctor of veterinary medicine” shall mean a doctor of veterinary medicine employed by state bodies or state institutions of veterinary medicine;

“State bodies of veterinary medicine” shall mean the Department and territorial bodies, the Regional Service of State Veterinary and Sanitary Control and Supervision at the State border of Ukraine and Transport;

“State institutions of veterinary medicine” shall mean institutions of veterinary medicine, carrying out prophylactic, diagnostic, medical treatment and other anti-epizootic measures, laboratory research as to safety of commodities, 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;

“Permit for importation” shall mean an authorization document that is issued by the Department and that grants a right to import commodities into the territory of Ukraine;

“Mandate” shall mean a written authorization, by which Chief State Inspectors of Veterinary Medicine of Ukraine, Autonomous Crimean Republic, the oblasts, cities of Kyiv and Sevastopol, 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;

“Exploitation permit” shall mean an authorization document, which is issued by a relevant Chief State Inspector of Veterinary Medicine to an operator of facilities (objects) on the basis of an inspection whether such facilities (objects) comply with veterinary and sanitary measures and technical regulations, and which document permits the operator of facilities (objects) to engage in business activities in accordance with this Law;

“Export facilities (objects)” shall mean facilities used for production of the objects of state veterinary-sanitary control or supervision, for which the Department 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 and have an applicable exploitation

permit;

“Contaminants” shall mean any biological substance, including microorganisms and their parts, or a chemical substance (including pesticides, toxins), residues of veterinary preparations, including hormones, sedatives and thyreostatic substances, antibiotics, other veterinary preparations, salts of non-organic substances, organic and radioactive substances, and breakdown products thereof, or other substances, which are contained (got or developed) in products of animal origin, feed that may be harmful to human and animal health;

“National Control Program” shall mean a program developed by the Department and implemented by the state service of veterinary medicine, or , if this relates to 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;

“Interested trading partners” shall mean 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;

“Establishment of veterinary medicine” shall mean an institution, enterprise, organization founded by a legal entity or a natural person (entrepreneur), who has qualification of a doctor of veterinary medicine that employs at least one doctor of veterinary medicine and carries out veterinary activity based on the license including veterinary practice, production of veterinary preparations, retail, wholesale trade in veterinary preparations, conducting disinfection, disinsection and deratization works;

“Devices of veterinary medicine” shall mean materials, equipment, instruments, specialized motor vehicles, and other mechanisms and tools intended for use in veterinary medicine;

“Means of animal care” shall mean methods that are intended for raising and taking care of animals that have no medical treatment or prophylaxis effect;

“Report on testing results” shall mean a document issued by the state or authorized laboratory of veterinary medicine containing a report on results of animal health testing and / or detecting of infectious or parasitic agents, their antibodies or results of pathologic or other testing. Recommendation and conclusions stated in the Report are compulsory for execution;

“Zone” shall mean a clearly defined part of the territory of a country with a defined veterinary-sanitary status;

“Zone free of the notifiable disease” shall mean 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;

“Zone of low prevalence of the notifiable disease” shall mean a zone covering all or a 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 countries effective surveillance, control (containment) or elimination measures are conducted;

“Surveillance zone” shall mean 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 the infected zone where rigorous surveillance measures are conducted;

“Zoonosis” shall mean such diseases as can be transmitted by animals to humans;

“Hazard identification” shall mean the process of detecting pathogenic agents that could potentially be introduced into the territory of Ukraine by importation of commodities and accompanying items;

“Infected zone” shall mean a zone, in which absence of animal disease has not been confirmed according to the requirements prescribed by the relevant international organizations;

“Quarantine zone” shall mean 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;

“Quarantine station (post)” shall mean a location (site), under the control of state bodies of veterinary medicine where groups of animals are kept in isolation, with no direct or indirect contact with other animals, which location is specially equipped to carry out observations for a specified length of time and, if appropriate, testing or medical treatment;

“Animal quarantine” shall mean 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 an animal disease and eliminating such animal disease according to laws, relevant veterinary-sanitary measures and normative-legal acts issued pursuant to this Law;

“Quarantine veterinary militia post” shall mean a temporary, specially equipped location at the border of a quarantine zone established according to the decision of the State Emergency Anti-Epizootic Committee to contain and prevent the spreading of a notifiable disease;

“Quantitative risk assessment” shall mean an assessment where the outputs of the assessment of risk may be expressed numerically;

“Feed” shall mean products of animal, plant, microbiological and chemical origin including finished feed and mixed feed, intended for animal feeding separately or in the mix, containing nutritive substances in digestible form and causing no adverse effect on animal health;

“Feed of plant origin” shall mean forage grain, feed concentrates, mixed feed, cake, shorts, root crops, tuber crops, hay, straw and other feed of plant origin;

“Feed of animal origin” shall mean meat-meal, bone-meal, meat-and-bone meal, fish-meal, liver-meal, blood-meal, feather-meal, fat, live fish for feeding, milk and milk products, meat and other products of animal origin intended for animal feeding, based on animal protein;

“Feed additives” shall mean 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 improve 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 wastes on the environment, improve the production of animal products, improve the productivity or welfare of animals, by means of affecting their gastro-intestinal flora or digestibility of feed;

“Laboratory of veterinary medicine” shall mean 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;

“Medicated feed” shall mean any mixture of veterinary medicinal means, including vitamins, amino acids, microelements or medicated premixes and feed, which mixture is manufactured under control of a specialist of veterinary medicine and is ready for circulation and is intended for animal feeding without prior treatment for prophylaxis and medical treatment purposes;

“Licensed doctor of veterinary medicine” shall mean 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;

“Maximum residue limit (maximum allowed residue level)” shall mean maximum allowed content of an active substance of veterinary preparations and their metabolites (conversion products in live systems) and toxicants in products of animal origin and feed, which, if exceeded, may negatively affect human and animal health;

“International veterinary certificate” shall mean a certificate of the form and with the content as are recommended by the relevant international organizations, issued in the exporting country in conformity with the guidelines of the relevant international organizations, attesting animal health and/or compliance with human health requirements, which are fulfilled by exported commodities;

“International standards, guidelines and recommendations” shall mean standards, guidelines, and recommendations that are developed and adopted by the OIE and other international organizations engaged in the development of recommendations, guidelines and standards with regard to protection of human and animal life and health from animal diseases;

“Minimum quality indicators” shall mean organoleptic, chemical, biological and physical indicators that have to be met by the relevant object in order for it to be deemed acceptable for use as intended;

“Monitoring” shall mean a system and procedure of surveillance of the veterinary-sanitary state of the objects of veterinary-sanitary control and supervision;

“Emergency epizootic circumstances” shall mean the epizootic state of a country, the confirmed or suspected presence of a notifiable disease in a country of origin or transit that may cause immediate and irreparable damage to the health of certain animals throughout Ukraine or in a part of Ukraine, if commodities and accompanying items, which may carry a notifiable disease, are imported;

“Good Manufacturing Practice (for veterinary preparations, feed additives, premixes, and finished feed)” shall mean 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 may be 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 the event that relevant international standards, guidelines or recommendations do not exist, or they do not ensure the necessary level of protection, veterinary-sanitary measures shall be based on objective scientific criteria, including on the basis of risk assessment research according to the technique, developed by relevant international organizations;

“Appropriate level of animal and related human health protection” shall mean the level of protection deemed sufficient by

the State for the determination of veterinary-sanitary measures to protect human and animal health and life from an adverse effect that the veterinary-sanitary measure is designed to address;

“Maladies” shall mean the condition of animals other than diseases that requires care or medical treatment by a specialist of veterinary medicine;

“Non-edible products of animal origin” shall mean raw materials of animal origin not normally used for human consumption, but that are used for pharmaceutical, surgical, agricultural, and industrial purposes;

“Objects of state veterinary-sanitary control and supervision” shall mean commodities, facilities (objects), devices of veterinary medicine, means of animal care and accompanying items;

“Circulation” shall mean moving (transporting) or storing, and any other actions related to the change of ownership or possession right, including, selling, exchanging or granting;

“Operator of facilities” shall mean a natural person or a legal entity that carries out activities, envisaged by this Law, using facilities (objects), for which the person/entity has the right of ownership, possession (use);

“Especially dangerous diseases on the OIE List” shall mean 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 human or animal health and which may significantly affect international trade in animals and products of animal origin;

“Risk assessment” shall mean 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;

“Consignment” shall mean any defined quantity of a commodity with the same name and properties, which is produced within a time period defined by the producer, 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;

“Series” shall mean defined by producer quantity of veterinary preparations, feed additives, premixes, feed with the same name and properties, which are produced during one technological cycle, under the same conditions in the same facilities (objects);

“Pathological material” shall mean samples taken from live or dead animals, which contain or may contain pathologic changes, agents causing infectious or parasitic diseases and which are intended for sending to the laboratory of veterinary medicine;

“Withdrawal period” shall mean 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 to ensure that such products do not contain residues of the preparation in quantities exceeding the established levels;

“Risk communication” shall mean the interactive exchange of information on risk among risk assessors, risk managers, interested trading partners, and other interested parties;

“Facilities (objects)” shall mean any building, collection of buildings, premises, structures or area, including 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;

“Premixes” shall mean mixtures of feed additives or mixtures of one or several feed additives, including vitamins, amino acids and minerals, with feed of animal origin or feed of plant origin or water, which are produced according to special technology using high-technology-equipment and used as carriers, not intended for direct feeding of animals;

“Border state inspector of veterinary medicine” shall mean a 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;

“Border inspection posts” shall mean premises located at the entry/exit points at the state border of Ukraine and designated customs offices, 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;

“Directive” shall mean a written demand of State Inspectors of Veterinary Medicine of Ukraine, Autonomous Crimean Republic, the oblasts, cities of Kyiv and Sevastopol, cities, rayons, regional Services of State Veterinary-Sanitary Control and Supervision at the State Border and Transport, which demand is provided to legal entities and natural persons, with the aim to terminate revealed violation of law on veterinary medicine issues and eliminate its consequences. The latter shall be compulsory for execution;

“Products of animal origin” shall mean 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;

“Products of animal origin intended for agricultural or industrial use” shall mean products of animal origin, except those intended for human consumption, pharmaceutical or surgical purposes and feed of animal origin;

“Products of animal origin for human consumption” shall mean 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;

“Products of animal origin intended for pharmaceutical or surgical use” shall mean animal organs, tissues and organic fluids intended for the production of pharmaceutical preparations or surgical devices;

“Anti-epizootic measures” shall mean organizational-economic and veterinary-sanitary activities, including prophylactic and diagnostic activities, aimed at prevention, detection, and elimination of transmissible animal diseases;

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;

“Regional Service of State Veterinary and Sanitary Control and Supervision at the State Border of Ukraine and Transport of the State Department of Veterinary Medicine with the State Inspectorate of Veterinary Medicine (hereinafter, the “regional services”) shall mean a state institution of veterinary medicine, which carries out state veterinary-sanitary control and supervision at the relevant regional level with an aim of protecting 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;

“Registration certificate” shall mean a document which attests the state registration of veterinary preparations, feed additives, premixes and finished feed and their use in the animal-raising sector;

“Reproductive material” shall mean semen, zygotes, fertilized fish eggs, incubate eggs, fertilized ova, embryos, and other biological material that is designated for reproduction;

“Reference laboratory” shall mean a laboratory, authorized by the Department, which is involved as a "third party" in the course of resolution of disputable issues of the results of laboratory research;

“Risk” shall mean a likelihood of the occurrence of an adverse event and the likely magnitude of its consequences during a specified time period;

“Market” shall mean a specially allocated and equipped place for the rendering of services concerned with the selling of products;

“Instruction” shall mean a legal act, issued by the Chief State Inspectors of Veterinary Medicine of Ukraine, Autonomous Crimean Republic, the oblasts, cities of Kyiv and Sevastopol, cities, rayons, regional services of state veterinary-sanitary control and supervision on the state border and transport, or their deputies, to resolve internal organizational/commercial issues;

“Extended veterinary-sanitary control” shall mean process of verification of safety of commodities on the basis of laboratory research conclusions conducted by the state service of veterinary medicine;

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

“Outbreak of a disease” shall mean 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 animals or animals suspected as being diseased;

“Veterinary medicine specialists” shall mean doctors and medical assistance, which have relevant diploma and carry out activities of prophylaxis, recovery, diagnostics, and medical treatment of animals, veterinary-sanitary testing, or other veterinary activities;

“Standard” shall mean 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 shall not contain requirements as to safety of goods prescribed by veterinary-sanitary measures, and may include or be entirely devoted to requirements for symbols, packaging, marking and labeling of a commodity or a process as well as requirements for terminology that is used in respect of a process, commodity or service;

“Standard border veterinary-sanitary control” shall mean the process, whereby border state inspectors of veterinary medicine verify the safety of objects of veterinary-sanitary control and supervision on the basis of review of accompanying

documents, visual examination of a consignment when the latter is imported into the territory of Ukraine, exported out of the territory of Ukraine and shipped through the territory of Ukraine (transit);

“Stamping-out” shall mean a set of anti-epizootic 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, if need be, those animals in other herds that may have had direct or indirect contact with the animals from the 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 the spreading 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.

“Substance” shall mean any matter of organic or inorganic origin or their mixture that may be used for production of veterinary preparations or feed additives, specifically:

- a) of animal origin, e.g., parts of organs and animal secretions, toxins, extracts, blood products;
- b) of plant origin, e.g., plants, parts of plants, plant secretions, extracts;
- c) of chemical origin, e.g., naturally occurring chemical elements and/or chemical products obtained by chemical reaction or synthesis;
- d) biotechnology products.

“Accompanying items” shall mean 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;

“Animals” shall mean mammals, poultry, birds, bees, insects, fish, crustaceans, mollusks; frogs, amphibians, and reptiles;

“Territorial bodies” shall mean bodies of state executive power created by the Department as chief offices of veterinary medicine in the Autonomous Crimean Republic, the oblasts, cities of Kyiv and Sevastopol, and as offices in cities and rayons to perform the functions of the Department in a certain territory;

“Technical regulation” shall mean a law of Ukraine or a normative-legal act adopted by the Cabinet of Ministers of Ukraine, which lays down characteristics of products or their related processes or production methods, as well as the requirements for services, including applicable provisions, with which compliance is compulsory; it may include requirements to terminology, symbols, packaging, marking or labeling, which apply to a certain commodity, process or a production method;

“Commodities” shall mean animals, products of animal origin, reproductive material, biological products, pathological material, veterinary preparations, substances, feed additives, premixes and feed;

“Authorized laboratory” shall mean 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, pathological material, veterinary preparations, substances, feed additives, premixes, feed, etc. according to special methods and procedures defined by national or international standards, guidelines and recommendations;

“Authorized (official) doctor of veterinary medicine” shall mean a doctor of veterinary medicine, who has been authorized by the Department to perform certain functions of state veterinary-sanitary control and supervision;

“Risk management” shall mean a process of identifying, selecting, and implementing measures that are applied with the

aim to reduce the level of risk;

“Notifiable disease” shall mean an animal disease on the list approved by the Department, and which disease, as soon as detected or suspected, must be immediately reported to the state inspector of veterinary medicine or an authorized doctor of veterinary medicine;

“Animal diseases” shall mean the clinical, immunological and/or histopathological manifestations of pathogenic agents;

“Micro-organism strains” shall mean genetically homogeneous populations of micro-organisms within a species, which have certain stable specific morphological features and biological properties;

“Qualitative risk assessment” shall mean 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 such qualitative terms as 'high', 'medium', 'low' or 'negligible';

“Quality of objects of veterinary-sanitary control and supervision” shall mean 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

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

This Law shall not extend onto products of animal origin for human consumption in the process of production and internal circulation of such products within the country.

## 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:

To reduce or eliminate the risks with regard to the occurrence of zoonosis and diseases of the population;

To protect the territory of Ukraine from the entry of animal diseases from the territories of other countries or from quarantine zones;

To protect animals and the population from animal diseases by applying prophylactic, diagnostic, and medical treatment measures;

To take measures to prevent transmission of animal diseases through commodities, means of animal care and accompanying items;

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;

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;

To monitor feed and water for ensuring their suitability for consumption and impossibility of transmitting animal diseases;

To ensure the proper, appropriate, effective, and safe use of veterinary preparations;

To protect the environment from negative effects associated with production and circulation of animals;

To protect animal welfare by means of ensuring the humane attitude toward animals throughout their life span;

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 research;

To implement state veterinary-sanitary control and supervision during the process of production and circulation of products of animal origin, and in agricultural product markets – of plant origin as well, veterinary preparations, substances, feed additives, premixes, feed, microorganism strains, reproductive and pathologic material, and to implement state veterinary-sanitary supervision during circulation of the devices of veterinary medicine and means of animal care;

To implement a national program of monitoring residue amounts of veterinary preparations and other contaminants in animals, products of animal origin and feed;

To implement standard border veterinary-sanitary control and/or extended veterinary-sanitary control of the objects of state veterinary-sanitary control and supervision;

To control the movement of the objects of state veterinary-sanitary control and supervision within Ukraine;

To facilitate the implementation of an animal identification system;

To facilitate continuing education and upgrading of the qualification of specialists of veterinary medicine;

To facilitate the practical introduction and wide application of the achievements of scientific and practical veterinary medicine;

and

To develop, implement and apply veterinary-sanitary measures.

## 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 agency of executive power for agricultural policy affairs, the State Department of Veterinary Medicine with the State Inspectorate of Veterinary Medicine and its territorial bodies.

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

Competence of the Cabinet of Ministers of Ukraine shall include:

Ensuring implementation of state policies in the sphere of veterinary medicine;

Development and implementation of the relevant national programs;

Organization of implementation of veterinary-sanitary measures, aimed at ensuring veterinary-sanitary and epizootic welfare, protection of the territory of Ukraine against the entry of pathogenic agents of animal diseases from other countries or from quarantine zones, ensuring of safety of products of animal origin, imposition of the animal quarantine, protection of the environment against potential negative effects associated with animal raising;

Ensuring of financing and logistic support of the state service of veterinary medicine;

Implementation of State policies as to licensing in the sphere of veterinary medicine;

Conclusion of international agreements;

Discharge of other authorities pursuant to law.

#### Article 6. Powers of the Central Agency of Executive Power for Agricultural Policy Affairs in the Sphere of Veterinary Medicine

The central agency of executive power for agricultural policy affairs shall:

Ensure implementation of state policies in the sphere of veterinary medicine and protect the territory of Ukraine from introduction of animal diseases from other countries or from quarantine zones;

Direct and coordinate 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;

Ensure implementation of state policies in the sphere of veterinary medicine, application of veterinary-sanitary control and supervision over the safety of products of animal origin;

Solving other issues in the area of veterinary medicine pursuant to law.

#### Article 7. State Bodies of Veterinary Medicine and their Officials

1. The State Department of Veterinary Medicine with the State Inspectorate of Veterinary Medicine shall be a governmental body of state management, which acts within the structure of the central agency of executive power for agricultural policy affairs and implements state policies in the sphere of veterinary medicine.

2. In order to fulfill its assigned tasks the Department shall create relevant territorial bodies, regional services and state institutions.

3. The Department, its territorial bodies shall constitute an integral system of state bodies of veterinary medicine.

4. The Chairman of the Department, his/her deputies, and heads of offices of the State Department of Veterinary Medicine with the State Inspectorate of Veterinary Medicine, who have been assigned with the functions of conducting state veterinary-sanitary control and supervision, shall be concurrently, *ex officio*, the Chief State Inspector of Veterinary Medicine of Ukraine and his/her deputies, respectively.

5. The heads of territorial bodies of the Autonomous Crimean Republic, oblasts, cities of Kyiv and Sevastopol, 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 service of veterinary medicine and regional services shall be, concurrently, *ex officio*, 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 Department shall develop, review and adopt veterinary-sanitary measures, including measures on prophylaxis, medical treatment, diagnostics, and elimination of notifiable diseases.

7. The following shall be within the competence of the state bodies of veterinary medicine:

- 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;
- 2) 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;
- 3) 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 the course of export, import and transit of objects of veterinary-sanitary control and supervision;
- 4) Implementation of state veterinary-sanitary supervision of the activities of authorized (official) doctors of veterinary medicine with regard to implementation of veterinary-sanitary measures;
- 5) Carrying out of extended veterinary-sanitary control on the basis of professional evaluation of the state inspector of veterinary medicine and/or within the framework of the program for random veterinary-sanitary control in order to verify safety of commodities;
- 6) Carrying out of standard veterinary-sanitary border control of commodities and/or, if necessary, random or extended control;
- 7) Coordination and organization of the implementation of veterinary-sanitary measures;
- 8) Determining the veterinary-sanitary status of Ukraine and particular zones within its territory, and the veterinary-sanitary state of facilities (objects) in Ukraine;
- 9) Organizing, jointly with the bodies of health care, the state sanitary-epidemiological service, structural units of the central agency of executive power on emergency issues the protection of the population from zoonosis and timely exchange of information on such animal diseases;
- 10) Issuance of veterinary documents and verification of their authenticity;
- 11) Organizing ante-mortem inspection of animals and veterinary-sanitary testing of non-edible products of animal origin;
- 12) Issuance of operating permits for facilities (objects) used for production, processing, storage and circulation of products of animal origin, veterinary preparations, substances, feed additives, premixes, feed of animal origin, finished feed, reproductive material and keeping the register of such facilities (objects);
- 13) Suspending an operating permit or restricting the activities of 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, as well as vehicles, which are used for transportation thereof, in case their operators violate veterinary-sanitary measures;

- 14) Carrying out of 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 the allocation of land plots for all above-mentioned types of construction and water supply for animals;
- 15) 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 agricultural product markets, - of plant origin as well;
- 16) Organization of laboratory-diagnostic (bacteriological, virus, chemic-toxicology, pathology-anatomy, histology, parasitology, radiology) and other studies in order to diagnose animal diseases and evaluate the safety of products of animal origin, feed additives, premixes, feed, reproductive material, biological products and water for animals;
- 17) Carrying out state veterinary-sanitary supervision over collection, utilization and destroying of perished animals and waste of animal origin;
- 18) Analyzing causes of animal diseases, maladies, and murrain, development of recommendations on their prophylaxis;
- 19) Providing insurance bodies with the conclusions as to diseased animals forcedly slaughtered, perished or destroyed;
- 20) Coordinating the activities of specialists of veterinary medicine, regardless of their subordination;
- 21) Organization of measures concerned with disinfection, disinsection and disinfestation at the 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, as well as vehicles, which are used for transportation thereof;

8. The powers of the Department 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 of 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 research (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 research 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 recorded onto 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 recorded onto the OIE List, or other notifiable diseases from certain countries or quarantine zones due to confirmed of such 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 and staff number of the state service of veterinary medicine;
- 15) Drafting and adopting of veterinary-sanitary measures, normative-legal acts on veterinary medicine issues within its competence;
- 16) Establishment of maximum permitted levels of residual quantities of veterinary preparations, feed additives and other contaminants in feed and biological material.
- 17) Ensuring of implementation of state policies in the sphere of veterinary medicine and protecting the territory of Ukraine from introduction of pathogens of especially dangerous diseases recorded onto the OIE List from the territories of other countries or from quarantine zones;
- 18) Coordination of 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 of implementation of state policies in the sphere of veterinary medicine, application of veterinary-sanitary control and supervision over the safety of products of animal origin.

9. Normative-legal acts of the Department issued within limits of its competence shall be binding on state bodies, legal entities (both Ukrainian resident and foreign), citizens of Ukraine, foreign nationals and persons without citizenship who reside/stay in the territory of Ukraine.

Article 8. 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 Department on issues specified by this Law. The heads of these subdivisions shall be appointed to and dismissed from their offices upon consent of the Department.
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 Department and its territorial bodies.

Article 9. Subdivisions of Veterinary Militia on Quarantine Veterinary Measures Enforcement

1. A subdivision of veterinary militia dealing with the accomplishment of quarantine veterinary measures within the Ministry of Internal Affairs of Ukraine and relevant subdivisions of its main offices and offices in the Autonomous Crimean Republic, the oblasts, cities of Kyiv and Sevastopol, 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 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. The subdivision of veterinary militia on quarantine veterinary measures enforcement of the Ministry of Internal Affairs of Ukraine and relevant subdivisions of the relevant main offices and offices in the Autonomous Crimean Republic, the oblasts, cities of Kyiv and Sevastopol, city and rayon offices and units shall be functionally subordinated to the Department and its territorial bodies.
3. Subdivisions of veterinary militia on quarantine veterinary measures enforcement shall be financed from budgetary funds allocated to the Department and its territorial bodies for carrying out anti-epizootic measures.
4. The Cabinet of Ministers of Ukraine shall approve regulations on subdivisions of veterinary militia dealing with the accomplishment of quarantine veterinary measures.

Section III. STATE VETERINARY-SANITARY CONTROL AND SUPERVISION

Article 10. 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, upon consent from the Department, may be conducted by the subdivisions of veterinary medicine of these bodies.

#### Article 11. 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, in the course of transportation of objects of state veterinary-sanitary control and supervision, whether veterinary-sanitary measures are complied with and whether relevant accompanying veterinary documents are available;
  - 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 law 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) Submit proposals as to suspension, renewal or annulment (cancellation) of operating permits;
  - 8) Inspect and, if necessary, issue instructions or directives with regard to disinfection of transportation vehicles, which are moving through quarantine zones for notifiable diseases;
  - 9) Conduct standard border veterinary-sanitary control of the objects of state veterinary-sanitary control and supervision, which are being moved as transit;
  - 10) 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;
  - 11) 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 law.

#### Article 12. 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 Crimean Republic, the oblasts, cities of Kyiv and Sevastopol, 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 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 13. 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, within working hours, have unhindered access to facilities (objects), which are used for production, processing and circulation of commodities, veterinary preparations, feed additives, premixes and feed;
  - 2) In the event of an outbreak of a notifiable disease, have, at any time, unhindered access to the facilities (objects) engaged in production or circulation of commodities, if such facilities (objects) are located within a quarantine zone to verify their veterinary-sanitary state and/or commodities, and/or to implement necessary measures imposed during the animal quarantine;
  - 3) Obtain information necessary to determine the veterinary-sanitary state of, and ensuring safety of, goods, 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 on binding veterinary-sanitary measures (including animal slaughter, forced animal slaughter, neutralization, utilization or destruction of goods, compliance with 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 levels);

- 6) Prohibit export, import, transit and other circulation of commodities and means of animal care, which do not comply with veterinary-sanitary measures and/or technical regulations;
- 7) Issue orders, instructions and directives on withdrawing from circulation commodities and means of animal care, which do not comply with veterinary-sanitary measures and/or technical regulations;
- 8) Issue instructions and directives on the suspension, termination, renewal and annulment (cancellation) of operating permits and veterinary documents;
- 9) If need be, set up commissions 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 law, economic activities of legal entities or natural persons, in case the latter violate veterinary-sanitary measures, established by law, 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 law.

2. State inspectors of veterinary medicine implementing state veterinary-sanitary supervision shall be obliged to:

- 1) Immediately, upon detection or suspicion of an outbreak of an especially dangerous disease recorded onto the OIE List, or any other notifiable disease, or mass-scale poisoning of animals, - notify the relevant bodies of executive power on the necessity of establishing a special regime of operation of the facilities (objects), and undertaking measures aimed to combat animal diseases.
- 2) Inform licensing bodies in the sphere of veterinary medicine on violations of licensing conditions by licensees.
- 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 14. 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, foreign citizens, and persons without citizenship residing/staying in the territory of Ukraine shall be obliged to assist the latter in the course of discharge of 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.

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 15. 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. 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.
3. The system for registration of animal facilities (objects), the animal identification system and procedures for maintenance of the recording of data on animal movements must enable the clear identification of animals and traceability of their facilities (objects) of origin, movement, and circulation.
4. Loading, unloading or reloading of animals into a transportation vehicle shall be allowed only in those places that have facilities in compliance with veterinary- sanitary measures.
5. Circulation of animals that have a notifiable disease or are suspected of potentially having such disease shall be prohibited. Any movements of the animals may be performed only upon permission of the relevant state inspector of veterinary medicine.
6. Movements of unidentified animals or animals that are not accompanied by relevant identification, veterinary or other accompanying documents shall be prohibited.

#### Article 16. State Veterinary-Sanitary Control and Supervision at Markets

1. State veterinary-sanitary control and supervision shall be conducted at any market where trading in live animals and products of animal origin is organized.
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 revealed violations are corrected and shall levy a penalty.

#### Article 17. 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 which are engaged in the production or circulation of veterinary preparations; inspection of entities for ensuring their compliance with licensing requirements; certification as to compliance with requirements of adequate production practices, adequate distribution practices, adequate laboratory practices, 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 shall be developed and adopted by the Department.
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 specialists of the state institutions of veterinary medicine, authorized by the Department. 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 grounds of probability that veterinary preparations, substances and devices of veterinary medicine do not comply with prescribed requirements.
4. State institutions of veterinary medicine, authorized by the Department, 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 harm to human and animal health.
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 maximally levels of residues, authorized institutions of veterinary medicine shall inform their conclusions to the Department and the relevant chief state inspector of veterinary medicine for taking necessary measures, pursuant to law, in order to prevent placing such products into circulation.
6. State control of veterinary preparations shall include an research of safe residue amount of such preparations, and side effects of the application of veterinary preparations. This work shall be carried out by national reference laboratories that deal with controlling of residue amounts of veterinary preparations and feed additives within the State Scientific and Research Institute of Biotechnology and Microorganism Strains and the State Scientific-Control Institute of Biotechnology and Microorganism Strains.
7. The National Agency for Veterinary Preparations and Feed Additives, which functions on the basis of the State Scientific and Research Controlling Institute of Biotechnology and Microorganism Strains, shall carry out expert examinations and/or identifications of veterinary preparations and feed additives with a view of their further State registration, and the National Agency for Veterinary Immunobiological Preparations, which functions on the basis of the State Scientific-Control Institute of Biotechnology and Microorganism Strains, shall carry out expert examinations and/or identification of veterinary immunobiological preparations. The State Scientific-Research Institute of Laboratory Diagnostics and Veterinary-Sanitary Testing and other scientific and research institutions may be involved in the above activities.

#### Article 18. 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 the event of export, import and transit of objects of state veterinary-sanitary control and supervision by all types of transport.
3. Veterinary-sanitary control 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 in 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 Department, 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 19. State Veterinary and Sanitary Control and Supervision for Hunting

1. The hunting season within a defined territory shall be opened upon confirmation by competent 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. The state inspector of veterinary medicine shall consider such reports if necessary after inspecting carcasses and, based on his/her professional judgment, shall take samples of animal tissue for research in the relevant laboratory of veterinary medicine.

### Section IV. PRINCIPLES FOR DEVELOPING, APPROVING AND APPLYING VETERINARY-SANITARY MEASURES

#### Article 20. Objectives of Veterinary-Sanitary Measures

The Department, jointly with other bodies of state management in the sphere of veterinary medicine, shall undertake appropriate and necessary veterinary-sanitary measures with the aim to achieve the following objectives:

1. Protecting 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. Protecting 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. Protecting human life or health from the risks resulting from diseases, which are carried by animals or products, manufactured thereof.



#### Article 21. Appropriate Level of Animal and Related Human Health Protection

1. The Department, 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 the following:
  - 1) The presence of animal diseases in Ukraine and implementation of the national programs designed to combat such animal diseases;
  - 2) Forecast economic estimates of losses by the animal-raising sector of Ukraine, associated with the introduction of animal disease pathogens, which are absent 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 22. Developing, Revising and Adopting Veterinary-Sanitary Measures

1. Veterinary-sanitary measures shall be developed, reviewed, revised and adopted by the Department based on the following:
  - 1) Pursuant to item 4 of this paragraph, all veterinary-sanitary measures shall be based on scientific principles and scientific justifications, including relevant processes and methods of production, 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 that 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 research according to the methodology of relevant international organizations.
  - 4) When scientific justifications needed for risk research are insufficient, or in emergency circumstances, veterinary-sanitary measures shall be developed on the basis of information obtained from the relevant international organizations, or the veterinary-sanitary measures applied by interested trading partners.
2. In the course of developing, revising and adopting veterinary-sanitary measures applicable to imported commodities, the Department shall take into account Ukraine's veterinary-sanitary status relative to that of the country of origin of commodities.
3. In the course of developing, revising and adopting veterinary-sanitary measures, arbitrary or unjustifiable discrimination shall be prohibited between interested trading partners, which are bringing commodities into the territory of Ukraine if 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. In the course of developing, revising and adopting veterinary-sanitary measures, relevant measures, which are applied in another country, shall be considered equivalent to those that are applied and accepted in Ukraine, if the other country proves in an objective manner that its measures achieve the same or higher level of protection of human and animal health and life relative to those required by Ukraine.
5. All veterinary-sanitary measures, including those that have been adopted in emergency epizootic 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 other persons in order to make sure that such measures achieve, but do not exceed, the appropriate level of animal and related human health protection.
6. All veterinary-sanitary measures adopted in emergency circumstances shall be reviewed and updated no later than within six months of the date of adoption or the last date of revising as referred to in paragraph 5 of this Article, in order to make sure that such measures achieve, but do not exceed, the appropriate level of animal and related human health protection.
7. The Department shall prepare and adopt a procedure for development and revision of veterinary-sanitary measures, which shall be applied pursuant to this Article.

#### Article 23. Conducting of the Risk Analysis

1. Risk research conducted by the specialists of the state service of veterinary medicine, which shall be defined by the Department, 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 research;
  - 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) Assessment of the animal disease risk, including a probability of harm to animals and humans and possible consequences;
  - 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. In the event that 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 research document, referred to in paragraph 1 of this Article, shall be made available to all interested persons in writing and/or electronic form.

#### Article 24. 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 must not limit trade more 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 Department.

#### Article 25. Notifying of Proposed Veterinary-Sanitary Measures

1. Except as provided in paragraphs 5 through 8 of this Article, whenever there are no relevant international standards, or proposed veterinary-sanitary measures do not conform to international standards, the Department shall take the following actions:
  - 1) A notice shall be immediately published in mass media publications in such form as to enable all interested parties to become acquainted with the content of proposed measures;
  - 2) When a proposed veterinary-sanitary measure is expected to significantly affect the exporting opportunities of other countries, the Department shall prepare a relevant notification, which shall be sent by the Centre for Processing Inquiries and Providing Notifications Regarding Veterinary-Sanitary Measures (hereinafter, the “Enquiry and Notification Centre”) to interested trading partners.
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 accordance with requirements of 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. When requested in writing by a person or interested trading partners, the Department 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 Department 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. In the event that emergency epizootic circumstances arise, and a veterinary-sanitary measure is adopted, a notice on its application shall be published in mass media.

6. If there are grounds to expect that the emergency veterinary-sanitary measure referred to in paragraph 5 of this Article significantly affects the exporting opportunities of other countries, the Department shall immediately send a notification through the Enquiry and Notification Centre to interested trading partners. The notification shall be prepared in accordance with requirements of 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 a written request, the Department shall provide the text of the emergency veterinary-sanitary measure to interested trading partners and persons.

8. The Department shall review written comments about the emergency veterinary-sanitary measure received from interested persons and trading partners, and upon a written request, discuss and take them into account when considering the revision of the emergency veterinary-sanitary measure.

9. The Department 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 26. Publishing and Applying Veterinary-Sanitary Measures

After adoption, all veterinary-sanitary measures and amendments thereto shall be published in the relevant official publication and made available on the web site of the Department. 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 immediately, veterinary-sanitary measures shall come into force no sooner than in six months from the date of the publication.

#### Article 27. Principles for Applying Veterinary-Sanitary Measures

The Department 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 20 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 28. Equivalence Agreements for Veterinary-Sanitary Measures

The Department 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 29. 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) The necessary level of qualification for staff members of the foreign Veterinary Administration, including the level of their professional education, necessary experience, and competence to make solid professional decisions;
- 4) Independence of employees of the foreign Veterinary Administration from any commercial, financial, administrative, political and other pressures, which may affect their judgments and decisions;
- 5) Impartiality of the foreign Veterinary Administration, as well as impartiality of its employees, in particular in the course of rendering of services;
- 6) Integrity of employees 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 law 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:
  - a. Planning and management of activities, including international veterinary certification activities;
  - b. Prevention and control of animal disease outbreaks;
  - c. Epizootic surveillance and zoning of the territory of the country pursuant to the veterinary-sanitary status;
  - d. Inspection and sampling techniques;
  - e. Diagnostic research for animal diseases;
  - f. Development, production, registration and control of biological products, used for the diagnostics of animal diseases and for production of veterinary preparations;
  - g. Treatments intended to destroy pathogenic agents in products of animal origin;
  - h. Minimum qualification level (education and professional training) for laboratory specialists and those officials authorized to inspect commodities and issue international veterinary certificates;
  - i. Use of international standards, guidelines, and recommendations when issuing international veterinary certificates;
  - j. Use of international standards, guidelines, and recommendations in course of application of measures to control animal disease outbreaks;
  - k. 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 an animal disease, which were issued by the officials of the foreign Veterinary Administration for import consignment of commodities, but were invalidated by laboratory research (testing) of samples from such shipment;
  - 11) Existence of the State system for identification and registration of animals;
  - 12) Other criteria recommended by the relevant international organizations.
2. All criteria 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. If a foreign country requests 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 30. Control, Inspection, and Approval Procedures

1. The Department shall ensure the fulfillment of all procedures of verification and requirements of veterinary-sanitary measures, specifically:
  - 1) that such procedures conform to the standards, recommendations, and guidelines of the relevant international organizations;
  - 2) that such procedures are executed expeditiously, without unjustifiable delay and in accordance with the procedure which is not less favorable for imported commodities than for domestic commodities;
  - 3) that sampling requirements for control, inspection, and approval procedures are limited to what is necessary and reasonable;
  - 4) that the applicant requesting the conduct of control, inspection and approval procedures must be immediately informed of any deficiencies in the application so as to avoid a 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) that the expected time for completing such procedures shall be communicated to the applicant upon his/her request;
  - 6) that the results of the procedure shall be immediately transmitted to the applicant in written form and in a complete volume;
  - 7) that such procedures shall be applied equally to the objects of state veterinary-sanitary control and supervision of foreign and domestic origin;
  - 8) that 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) that confidentiality of provided information shall be protected in order to ensure the commercial interests of the applicants;
  - 10) that 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 approximate costs of services rendered;

11) that the sampling procedures and requirements associated with the use of particular facilities for carrying out control, inspection, and decision 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) that 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.

2. The Department may prescribe requirements for facilities (objects), production processes, storage conditions and other requirements for goods that are imported into Ukraine. Such requirements must not exceed similar requirements that are prescribed for domestic producers that produce and/or realize such goods.

3. The State Service of Veterinary Medicine of Ukraine may verify compliance with requirements for facilities (objects), production processes, storage conditions and other requirements in countries, from which goods are imported (hereinafter referred to, as “facilities (objects) for importation into Ukraine”). Specialists from the State Service of Veterinary Medicine, who are authorized by the Department, must have unhindered access to the facilities (objects) for importation into Ukraine for purposes of inspection for verifying their compliance with the requirements specified in Part 2 of this Article. The Department shall be obligated to notify the relevant competent service in the importer’s country about the said inspection at least 48 hours prior to such inspection.

4. It shall be prohibited to import goods from the facilities (objects) for importation into Ukraine, in the course of inspection of which the relevant service has revealed failures to comply with the prescribed requirements.

5. The Department shall maintain a registry on facilities (objects) for importation of goods into Ukraine.

6. Procedures for inspection of compliance with the requirements specified in Part 2 of this Article as well as procedures for registration and removal from the registry on facilities (objects) for importation into Ukraine shall be laid down by the Department.

#### Article 31. Documentation of Veterinary-Sanitary Measures

1. The Chief State Inspector of Veterinary Medicine of Ukraine shall appoint a group of the officials in the Department, 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 request of the above persons, which shall include :

1) Approved or proposed veterinary-sanitary measures;

2) Control, inspection, and approval procedures;

3) Procedures for animal disease risk assessment, criteria 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 or international agreements regarding veterinary-sanitary measures and the texts of such agreements.

#### Article 32. Issuance of Respective Veterinary Documents

1. Veterinary documents for movement of animals, products of animal origin and other objects of state veterinary-sanitary

control and supervision shall be obtained in order to protect the territory of Ukraine against transmission of animal diseases from the territory of other countries and quarantine zones and to protect the public against diseases common for animals and people as well as to prevent the existence of residual quantities of veterinary preparations and contaminating substances in products of animal origin and fodder.

2. Objects of state veterinary-sanitary control and supervision shall be accompanied by the following veterinary documents:

- 1) international veterinary certificates (for CIS countries – veterinary affidavits in forms No. 1, No. 2, No. 3) – in case of movement outside Ukraine;
- 2) veterinary affidavits (for Ukraine – forms No. 1 and No. 2) – in case of movement outside the territory of the Autonomous Crimean Republic, the oblasts, cities of Kyiv and Sevastopol, rayons and cities;
- 3) veterinary notes – in case of movement within a rayon.

Veterinary documents shall also include veterinary cards and/or veterinary-sanitary passports for animals.

3. The right to issue international veterinary certificates, veterinary affidavits, veterinary notes, veterinary cards and/or veterinary-sanitary passports for animals shall be vested with relevant state inspectors of veterinary medicine and authorized doctors of veterinary medicine: 1) departments of veterinary medicine in the Autonomous Crimean Republic, oblasts, cities of Kyiv and Sevastopol, cities of the oblast level, rayons; 2) state institutions of veterinary medicine;

3) regional services of state veterinary-sanitary control and supervision at the State border and transport.

4. Veterinary notes and veterinary-sanitary passports for animals may be also issued by licensed doctors of veterinary medicine.

5. Relevant veterinary documents shall be issued on a paid basis pursuant to Article 99 of this Law.

6. A decision to issue or refuse to issue veterinary documents shall be passed not later than within one month from the date, on which documents submitted for review were received.

7. Grounds for refusing to issue veterinary documents or annulling veterinary documents shall be as follows:

- 1) failure to comply with veterinary-sanitary measures contemplated by law; aggravation of an epizootic situation in a certain territory, at a facility (object);
- 3) impossibility to directly review an object of state veterinary-sanitary control and supervision;
- 2) absence of documentary confirmation of epizootic welfare in a locality of origin and the veterinary-sanitary state of objects; absence of required veterinary processing of animals, their quarantining, respective research and/or an expert conclusion.

8. Procedures for issuance of veterinary documents shall be laid down by the Department as confirmed with the specially authorized agency for affairs relating to the authorization system in the area of business activity.

## Section V. PROTECTION OF ANIMAL HEALTH

### Article 33. Notifiable Diseases

1. The list of notifiable diseases shall be determined by the Department and include:



- 1) All the especially dangerous diseases recorded onto 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 34. 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 those 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), the number of animals of each species, the name of the operator of facilities (objects), and, when necessary, the name of the owner of animals, their address, telephone number, and other information.

#### Article 35. 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 36. Rights of 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 products of animal origin, veterinary preparations, substances, feed additives, premixes, feed and reproductive material shall have the right to:

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

Department to perform certain functions.

#### Article 37. 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:

- 1) ensure that animals, which they are raising, keeping and/or circulating, do not have notifiable diseases;
- 2) 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;
- 3) 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 behavior of animals that is unnatural for them;
- 4) before moving animals from the facilities (objects), where they are kept,- obtain from the state inspector of veterinary medicine a permit for their movement;
- 5) 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;
- 6) fulfillment of the requirements of identification of animals, which they own, including cats and dogs and other small domestic pets, which shall be identified with the help of micro-chips;
- 7) 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 research 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 research;
- 8) 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;
- 9) facilitate state inspectors of veterinary medicine and authorized doctors of veterinary medicine in the course of discharge of official duties;
- 10) 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 research.

## Section VI. REGULATION of CIRCULATION OF ANIMALS AND REPRODUCTIVE MATERIAL

### Article 38. Permits for Events Featuring Animals

1. Persons conducting exhibitions, animal competitions, fairs, auctions, performances with traveling animals, 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, free of charge, upon fulfillment of the veterinary-sanitary requirements 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 the conduct of exhibitions shall be valid for a specified period of time but not more than 30 days.
5. The form and content of the application for a permit for an exhibition, accompanying information related to animals, which shall be required, the conditions that must be met by facilities (objects) shall be prescribed by the Department.
6. Grounds for refusing to issue a permit or for annulling a permit shall be as follows:
  - 1) failure to comply with veterinary-sanitary measures contemplated by law;
  - 2) aggravation of an epizootic situation in a certain territory, at a facility (object).

### Article 39. 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 through reproductive materials.
4. If there is a suspicion of infection of breeding animals with an animal disease that can be transmitted by reproductive materials, the operator of the facilities (objects) or the owner of the animals shall be obliged to provide samples of such material to a state laboratory of veterinary medicine or an authorized laboratory for laboratory research. 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 a request of the owner of the animal breeding centre or the owner of the animals, an arbitration research shall be

conducted to confirm the existence of the animal disease or to lift the suspicion of the animal disease in accordance with the procedure prescribed by the Department.

6. The Department shall establish the procedure for systematic monitoring.

#### Article 40. Circulation of Reproductive Material

It shall be prohibited to circulate semen for artificial insemination, fertilized ova, or embryos, if their biochemical, biophysical, or morphological properties, do not satisfy the basic conditions necessary for reproduction, or if they contain higher than permitted levels of bacteria or animal disease agents.

### Section VII. EMERGENCY ANTI-EPIZOOTIC COMMISSIONS AND ANIMAL QUARANTINE

#### Article 41. 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 competence 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 of the outbreaks of mass animal diseases and poisoning, and their elimination.
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 agricultural policy, the interior, economy, health protection, transport, emergency situations, and for affairs of protection of the population against consequences of the Chernobyl catastrophe finance, communication and informatization, forestry, state border protection, the customs service, foreign affairs, the security service, the state tax administration, as well as the Ukrainian Academy of Agricultural Sciences and officials of other bodies, non-government organizations and scientific institutions 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 Crimean Republic, oblast state administrations, state administrations of the cities of Kyiv and Sevastopol, city Radas, and rayon state administrations. In case of suspicion or confirmation of an outbreak of especially dangerous diseases recorded onto 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 commission under the Council of Ministers of the Autonomous Crimean Republic, state administrations of the oblasts, cities of Kyiv and Sevastopol, cities and rayons and city Radas shall be adopted by the Cabinet of Ministers of Ukraine.
8. Decisions of the State Emergency Anti-Epizootic Commission under the Cabinet of Ministers of Ukraine and local State Emergency Anti-Epizootic Commissions shall be binding on central agencies of executive power, bodies of local self-government and owners of goods.

#### Article 42. 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.

#### Article 43. Confirmation of an Outbreak of Especially Dangerous Diseases recorded onto the OIE List

1. In case of a suspicion of an outbreak of especially dangerous diseases included into the OIE List, the state inspector of veterinary medicine, which carries out supervision over 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 research.
2. Upon confirmation of an especially dangerous disease recorded onto the OIE List, the State Emergency Anti-Epizootic Commission under the Cabinet of Ministers of Ukraine or relevant local state emergency anti-epizootic commissions, local State administrations and bodies of local self-government shall determine the boundaries of infected and buffer zones, and if necessary, of the surveillance zone.
3. The State Emergency Anti-Epizootic Commission under the Cabinet of Ministers of Ukraine or relevant state emergency

anti-epizootic commissions shall order one or several measures prescribed in the relevant contingency plan or rule book, or in their absence - the implementation of one or several measures listed in Article 44 of this Law, according to the nature of especially dangerous diseases recorded onto the OIE List and the level of risk in the infected and buffer zones, and surveillance zone.

4. In the event of an especially dangerous disease recorded onto the OIE List, the State Emergency Anti-Epizootic Commission under the Cabinet of Ministers of Ukraine or relevant local state emergency anti-epizootic commissions shall publish in mass media such notices as 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 in order to restrict the movement of people, and perform disinfection, when appropriate.
6. After imposition of the animal quarantine for especially dangerous diseases recorded onto 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 recorded onto 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 recorded onto the OIE List.
7. The List of especially dangerous (quarantine) diseases shall be adopted by the Cabinet of Ministers of Ukraine.

#### Article 44. Veterinary-Sanitary Measures Applied During Animal Quarantine

1. The State Emergency Anti-Epizootic Commission under the Cabinet of Ministers of Ukraine or relevant local state emergency anti-epizootic commissions, local State administrations and bodies of local self-government 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 some of the following measures, deemed appropriate to contain, control and eliminate the notifiable disease:

- 1) Conduct thermometry, separate healthy animals from sick animals and perform diagnostic research;
- 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 and 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 products of animal origin;

10) Prohibition or restriction on 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 recorded onto the OIE List, and organization of the relevant control;

14) Disinfection, disinfestations, 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 such animals;

15) Reliable isolation of dogs and cats of known owners and extermination of stray cats and dogs in humane ways;

16) Surveillance of animals, including the taking of samples of blood or pathological material with the aim to conduct an research, and access to farm records in infected, buffer, and surveillance zones and in other facilities (objects) under surveillance outside such zones;

17) Involvement of employees of the bodies of internal affairs 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 recorded onto the OIE List.

2. All or some of the measures specified in paragraph one of this Article shall be applied during the period of the 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. A relevant chief state inspector of veterinary medicine, by his/her instruction, may impose quarantine restrictions and apply all or some of the measures, specified in paragraph one of this Article, but not longer than 72 hours.

5. Animals and other commodities out of the quarantine zone shall be exported and moved 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 45. Special Instructions during Quarantine

1. During an 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 imposed due to an outbreak of an especially dangerous animal disease recorded onto the OIE List, the Cabinet of Ministers of Ukraine, upon the proposal of the State Emergency Anti-Epizootic Commission under the Cabinet of Ministers of Ukraine, may 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 State bodies in order to undertake the necessary veterinary-sanitary measures.
3. In the event that especially dangerous animal diseases outbreak in the territory of Ukraine, which threaten to develop into a panzootic or cause considerable economic losses, the Cabinet of Ministers of Ukraine, upon a proposal from the central agency of executive power for agrarian policy as confirmed with central agencies of executive power for finances and economy, shall pass a decision to allocate required monies from the Reserve Fund of the State Budget for organizing and undertaking measures aimed to localize and eliminate such panzootic.

#### Article 46. Elimination of an Outbreak of Especially Dangerous Disease

1. The outbreak of an especially dangerous animal disease recorded onto the OIE List shall be considered regarded as eliminated:
  - 1) if conditions specified in the relevant book of rules have been met, or, if no such book of rules exists, conditions prescribed by relevant international standards, guidelines and recommendations, have been met;
  - 2) if no international standards, guidelines or recommendations exist - upon recovery or death of the last affected animal and the end of the longest incubation period of the especially dangerous disease.
2. The State Emergency Anti-Epizootic Commission under the Cabinet of Ministers of Ukraine and Local State Emergency Anti-Epizootic Commissions shall announce via official printed mass media about the end of the animal quarantine, which was imposed due to the outbreak of the especially dangerous animal disease recorded onto the OIE List.
3. The Chief State Inspector of Veterinary Medicine of Ukraine must immediately inform the relevant international organizations and the Veterinary Administrations of neighboring countries and trading partners, whose activities were affected by the outbreak of the especially dangerous animal disease recorded onto the OIE List, about the elimination of the outbreak.

#### Article 47. Tasks of Bodies of Internal Affairs during an Outbreak of an Animal Disease



1. During the outbreak of an animal disease, on the basis of the statement of a state inspector of veterinary medicine or an authorized doctor of veterinary medicine, bodies of internal affairs shall be obliged to assist them in the implementation of measures to restrict and prohibit circulation of animals, other goods and movement of 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. Quarantine veterinary militia posts shall be fitted out with participation of local state administrations and bodies of local self-government. When necessary the employees of structural units of the central agency of executive power on emergency issues and for affairs of protection of the population against consequences of the Chernobyl catastrophe may be involved to fulfill these tasks.
3. During the animal quarantine imposed due to the outbreak of an especially dangerous disease recorded onto the OIE List, the central agency of executive power for internal affairs shall, pursuant to a decision of the Cabinet of Ministers, provide assistance in containing, controlling, and eliminating such disease.

**Article 48. Animal Quarantine (Quarantine Restrictions) in case of an Outbreak of a Disease other than Especially Dangerous Diseases**

1. Upon suspicion of detection of a notifiable disease, which is not an especially dangerous disease that requires imposition of an animal quarantine (quarantine restrictions), the relevant chief state inspector of veterinary medicine shall issue an instruction imposing animal quarantine:
  - 1) Immediately after confirmation of the outbreak of a quarantine disease;
  - 2) In the event that, at the end of 24 hours after receiving information on the suspicion of the outbreak of a quarantine disease, it has not been ruled out.
2. The instruction of the relevant chief state inspector of veterinary medicine imposing an animal quarantine (quarantine restrictions) 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.
3. The chief state inspector of veterinary medicine of a higher level and the local body of executive power and/or the body of local self-government of the relevant territorial unit and of the next higher level shall be immediately informed of the decision imposing the animal quarantine (quarantine restrictions). In case of suspicion of the outbreak of zoonosis, the relevant chief state sanitary doctor shall be notified thereof immediately.
4. 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.
5. 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.

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

7. 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 the animal quarantine (quarantine restrictions), but not longer than 72 hours.

8. During the first 48 hours of animal quarantine (quarantine restrictions), the local state emergency anti-epizootic commission under local self-government body must start its operation. The State Emergency Anti-Epizootic Commission under the Cabinet of Ministers of Ukraine, shall 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 Crimean Republic.

9. Upon submission of the chief state inspector of veterinary medicine, the local State Emergency Anti-Epizootic Commission must within 24 hours issue a decision imposing the animal quarantine (quarantine restrictions).

10. 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.

11. In the first 24 hours after a decision is issued to impose the 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, and the local bodies of executive power and bodies of local self-government of adjacent administrative-territorial units. Notification on the imposition of the animal quarantine (quarantine restrictions) shall be published in an official printed publication circulated in the territory of the relevant administrative-territorial unit. The local State Emergency Anti-Epizootic Commission may involve television and radio-broadcasting media to provide for prompt notification to persons with regard to the imposition of the animal quarantine (quarantine restrictions).

12. Persons guilty of violation of quarantine measures shall be held liable according to law.

#### Article 49. 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 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 50. Facilities Required to Obtain an Operating Permit from the Department

1. It shall be prohibited for the following facilities (objects) to carry out activities concerned with the 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, animal breeding enterprises / associations, selection, selection-technological and selection – hybrid centers; horse race tracks, animal breeding evaluation stations;
- 3) Facilities (objects) for production and circulation of veterinary preparations;
- 4) Facilities (objects) for producing, mixing and preparing feed additives, premixes and feed.

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 veterinary-sanitary measures, technical regulations, and provisions of this Law.

3. Issuance of operating permits shall be aimed to ensure a stable epizootic situation in Ukraine, adequate breeding of animals, production and circulation of safe non-edible products of animal origin, veterinary preparations, feed additives, pre-mixes and fodder. Procedures for issuing, suspending, revoking and renewing an operating permit as well as the form of and conditions for issuing an operating permit shall be laid down by the Cabinet of Ministers of Ukraine upon submission of the central agency of executive power for agricultural policy affairs and as confirmed with the specially authorized agency for affairs relating to the authorization system in the area of business activity. The list of documents required for obtaining an operating permit may also include design and construction requirements, availability of qualified staff, and continuous operation of safety and quality control system. The Department shall prescribe relevant technical regulations and veterinary-sanitary measures for each type of facility (object) referred to in paragraph 1 of this Article and procedures for verification of compliance with them.

4. All facilities (objects), for which the Department issues operating permits, shall be subject to state veterinary-sanitary control and supervision.
5. Operating permits shall be issued by the Department free of charge.
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 the cross contamination of feed intended for ruminants with the above referenced products from ruminants, and minimize the risk of unintentional inclusion of such products into feed for ruminants.

#### Article 51. Identification Control Number for Facilities, which obtained an Operating Permit

1. Facilities (objects) that obtain an operating permit from the Department shall be assigned a control number for identification (hereinafter referred to as, the “identification control number”).
2. The identification control number shall be recorded by the Department in the relevant Register of facilities (objects).

#### Article 52. 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 relevant technical regulations, the state inspector of veterinary medicine shall issue a written directive to correct the violation. Should the seriousness of this violation create an immediate threat to animal health, the state inspector of veterinary medicine shall issue a directive for immediate elimination of the violation or prohibition of use of specific equipment, and submit a report, along with any relevant 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 Department shall revoke the operating permit and remove the facilities (objects) from the Register.

#### Article 53. Registration of Facilities (Objects) that use Non-Edible Products of Animal Origin

1. Operators of facilities, except for those specified in Article 50 of this Law, that use non-edible products of animal origin (for purposes of agricultural production, industry, pharmacology, surgery etc.), which may carry or transmit animal diseases, must register said facilities (objects) with the Department.
2. The Department shall maintain a register of facilities (objects) that use non-edible products of animal origin.
3. The chief state inspector of veterinary medicine shall determine the facilities (objects) that use non-edible products of animal origin for purposes of agricultural production, industry, pharmacology, surgery etc., which are subject to paragraph 1 of

this Article, and the procedure for registering said facilities with the Department.

#### Article 54. Approval of Export Facilities (Objects) for Non-Edible Products of Animal Origin

1. Legal entities, which obtained an operating permit from the Department 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 the Department to verify compliance with such specific requirements.
2. The Department shall make a decision on approval of export facilities (hereinafter referred to, as the “approved export facilities (objects)”) after verification by the state bodies of veterinary medicine that the facilities (objects) comply with the requirements prescribed by the law of the country of destination.
3. Any products intended for export, which are produced at approved export facilities (objects), shall be marked according to the requirements of the country of destination. If it is possible, such marking shall include the identification control number referred to in Article 51 of this Law.
4. The Department shall maintain a register of approved export facilities, which shall be published in printed and electronic form.
5. Procedure for carrying out official verification of compliance with 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, shall be prescribed by the Department. The Department shall prescribe the procedure with regard to the amount of fee for carrying out the verification.

#### Article 55. Removal from the Register of Approved Export Facilities (Objects)

1. If in the course of 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).
2. The person, who is an operator of the approved export facilities (objects) may lodge an appeal against a decision on removal (temporary removal) from the Register of Approved Export Facilities (Objects) with the Department in accordance with the procedure specified in Article 36.
3. In the event that a decision on removal (temporary removal) of approved export facilities (objects) from the Register has been passed, the Department shall immediately notify the competent authority of the country of destination.
4. The competent authority of any country of destination, for which the Department has conducted the official verification of compliance by operators of facilities (objects) with the 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 Department at least 48 hours in advance of the above inspection.
5. If as a result of inspecting approved export facilities (objects) to verify compliance with the prescribed requirements, the

competent authority of a country of destination concludes that the requirements are not complied with, the Department shall suspend or withdraw its decision on approval of the facility (object) for exporting non-edible products of animal origin to the relevant country 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 export facilities (objects) 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 56. 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 the conduct of 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 57. Circulation of Leather Raw Materials

1. Raw cattle, sheep, and goat hides and skins shall be circulated 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 Department 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 Department shall prescribe requirements for record keeping.
3. Unprocessed waste from raw hides and skins that have not been chemically treated shall be destroyed in accordance with the safety rules and the procedure specified in the relevant rule book.

Article 58. 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 that enable to trace 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 59. Obligations of Persons Carrying Out Activities on Production and Circulation of Non-Edible Products of Animal Origin

1. 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 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.

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

- 1) Ensure unhindered access of state inspectors of veterinary medicine to such facilities (objects) during working hours with the purpose of exercising state veterinary-sanitary control and supervision;
- 2) Upon a request by state inspectors of veterinary medicine, to provide samples of objects of state veterinary-sanitary control and supervision, as well as samples of other materials and substances within such facilities (objects) free of charge;
- 3) Upon a 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 on the purchase and use of non-edible products of animal origin, veterinary preparations, feed additives, premixes, feed and reproductive material with indications of serial numbers of shipments.

3. 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, and 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 60. Scientific Support to Veterinary Medicine

1. Scientific support to veterinary medicine shall be provided by scientific institutions of the National Academy of Sciences of Ukraine, Ukrainian Academy of Agricultural Sciences, Ministry of Agricultural Policy 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 department of veterinary medicine of Ukrainian Academy of Agricultural Sciences jointly with the scientific-methodic council of the Department.
3. The Department shall act as a client for state 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 Department, scientific-implementation centers of veterinary medicine shall be created, as well as other structural units that are not prohibited by law, whose activities shall be defined by the Department jointly with the Ukrainian Academy of Agricultural 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 Department, and practical implementation of scientific developments shall be financed from the State Budget of Ukraine and other sources that are not prohibited by law.

Article 61. State Pharmacology Commission of Veterinary Medicine

1. The State Pharmacology Commission of Veterinary Medicine shall operate under the Department.
2. 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, and their registration.
3. The State Pharmacology Commission of Veterinary Medicine shall recommend, and the Chief State Inspector of Veterinary Medicine - Head of the Department 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 contaminating substances in feed additives and feed;
  - 3) Annual program for carrying out random veterinary-sanitary control of feed for animals;
  - 4) Annual plan for monitoring the availability of residue amounts of veterinary preparations and contaminating substances in animals, products of animal origin and feed;
  - 5) List of veterinary preparations, which shall be dispensed under the prescription and the rules of issuing prescriptions;
  - 6) Requirements to clinical and pre-clinical tests for veterinary preparations.
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 62. 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, as well as periodic control of quality and safety indicators shall be conducted by the State Scientific and Research Institute of Laboratory Diagnostics and Veterinary-Sanitary Examination and branches thereof in the Autonomous Crimean Republic, oblasts, as well as regional, inter-oblast, city, rayon, inter-rayon state laboratories of veterinary medicine and other laboratories, authorized to conduct necessary research according to the procedures established by the Department. Research shall be conducted according to the recommendations, guidelines and standards of the relevant international or domestic organizations.
2. The director, deputy directors, heads of units of the Institute of Laboratory Diagnostics and branches thereof in the Autonomous Crimean Republic, oblasts, regional, city state laboratories of veterinary medicine shall be state inspectors of veterinary medicine.
3. Laboratories of other institutions of veterinary medicine, scientific-research institutes, higher education establishments, and other legal entities may also carry out laboratory research pursuant to the authorities provided by the Department.
4. In order to work with the pathogens of especially dangerous diseases recorded onto the OIE List laboratories must receive a special permit from the Department.
5. After conducting appropriate laboratory research, an expert conclusion (laboratory report, protocol etc.) shall be issued.



The latter shall stipulate the results of laboratory research, their evaluation and recommendations which are compulsory for execution.

6. The Institute of Laboratory Diagnostics shall be responsible for conducting laboratory diagnostics and/or identification of animal diseases, veterinary-sanitary testing of products of animal origin and feed in Ukraine, provide for methodic support to state and authorized laboratories of veterinary medicine, and exercise control of the implementation of laboratory research. The reference-centers shall be established on the basis of Institute of Laboratory Diagnostics.

7. The Institute of Laboratory Diagnostics and other State laboratories of veterinary medicine may provide methodical support for and to departmental laboratories at facilities (objects) subject to control on the part of the State Service of Veterinary Medicine.

8. In case of disputes resulting from conclusions of laboratory diagnostics and veterinary-sanitary testing, the Institute of Laboratory Diagnostics shall conduct an arbitration research. Results of arbitration research shall be final. Procedures for carrying out arbitration research shall be prescribed by the Department.

9. Laboratories in the markets (agricultural product markets) shall be structural units of relevant state institutions of veterinary medicine that shall operate on the basis of the regulations, adopted by the Department.

10. The Institute of Laboratory Diagnostics and state laboratories of veterinary medicine may be legal entities, operating on the basis of the regulations, adopted by the Department.

11. 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 law.

12. 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.

13. Veterinary documents shall be issued under condition of compulsory research 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 63. 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 the 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 human or animal health.

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 Department, to one of the state scientific-research control institutes, authorized by the Department. The applicant shall be liable for untrue information submitted in the registration dossier in accordance with law. Regulations on state registration of veterinary preparations shall be prepared and adopted by the Cabinet of Ministers of Ukraine.

4. The National Agency of Veterinary Preparations and Feed Additives and / or the National Agency for Veterinary Immunobiological Preparations shall perform evaluation of submitted documents (testing), organize the implementation of necessary research and perform other measures aimed to verify information and data, stipulated in the documents, and also prepare expert conclusions for consideration of the State Pharmacology Commission of Veterinary Medicine within a time period that does not exceed 210 days from the date, on which the application and the full set of documents were received and the relevant payment was made.
5. The State Pharmacology Commission of Veterinary Medicine shall consider expert conclusions and provide the Department with recommendations on state registration of the relevant veterinary preparations.
6. On the basis of an application filed by an applicant and a decision of the State Pharmacology Commission of Veterinary Medicine and an estimate (expert examination) of the National Agency of Veterinary Preparations and Feed Additives and / or the National Agency for Veterinary Immunobiological Preparations, the Department shall pass a decision on the State registration of a veterinary preparation or a refusal to register a veterinary preparation.
7. The State registration of a veterinary preparation may be denied if the verification of the particulars and documents submitted reveals that:
  - 1) The applicant failed to duly prove the quality, safety and efficacy of the veterinary preparation or failed to submit a full set of documents;
  - 2) Safety and welfare of animals and/or consumers have not been duly confirmed in the course of tests of the veterinary preparations;
  - 3) The withdrawal period recommended by the applicant is not sufficient to ensure safety of products of animal origin intended for human consumption, derived from animals, which had been subjected to medical treatment with this preparation or is insufficiently justified;
  - 4) Application of the veterinary preparation presented for registration is prohibited by current law.
8. A decision to deny state registration of a veterinary preparation shall be transmitted to the applicant with an exhaustive explanation of the reasons for the denial. The applicant may appeal this decision in the court in accordance with the procedure established by law.
9. A decision to register veterinary preparation shall be transmitted to the applicant, along with a registration certificate. The time period for issuing the registration certificate by the Department must not exceed 30 days. 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, the term of validity of the registration. It shall be mandatory to attach brief characteristics of the preparation, an insert letter (guidelines for use), and a label in Ukrainian to the registration certificate.
10. Upon approval of the State registration of the preparation for circulation and use in Ukraine, it shall be entered into the Register of Veterinary Preparations maintained by the Department. 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, the term of validity of the registration certificate and other information required pursuant to current law.
11. After registration of domestic veterinary immune-biological means, the applicant must deposit microorganism strains (cultures) used in production and for control 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. Such information shall be submitted to the Department or its designated institutions in the form and procedure prescribed by the Department.

13. A package of registration documents shall be submitted for re-registration 3 months before the expiration of the registration certificate.

#### Article 64. Simplified State Registration of Veterinary Preparations

1. The State registration of certain veterinary preparations may be applied under simplified procedures.

2. Simplified registration shall apply in respect of preparations that are significantly similar and contain the same amount of the same active substance in the same form, with appropriate research confirming their identity regarding bio-availability and bio- equivalence, and also the fact that their therapeutic effect is essentially the same as of the brand preparation already registered in Ukraine and in other countries as well as in respect of preparations specified by the Department as those having the same criteria for registration of such veterinary preparations.

3. If the veterinary preparation, for which an application for Simplified 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 research shall be attached to the application.

4. An estimate (expert examination) of a possibility to register veterinary preparations according to simplified procedures shall be issued by the National Agency of Veterinary Preparations and Feed Additives or the National Agency for Veterinary Immunobiological Preparations within 90 days from receipt of a complete package of registration documents, and effecting the relevant payment.

5. The Department shall prescribe the procedure and the list of documents, which shall be submitted for obtaining a decision on Simplified registration procedure.

#### Article 65. 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 the registration dossier;
- 2) Registration has been conducted on the basis of incomplete or untrue data;
- 3) The holder of the registration certificate does not comply with requirements prescribed by law.

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

3. Should a veterinary preparation be found unsafe, in addition to the provision on the cancellation of the registration, the Department shall issue an instruction to prohibit circulation of such preparation and to withdraw it from circulation.

4. The Department shall prescribe the procedure for suspension or renewal of registration, and for cancellation of registration of a veterinary preparation.
5. In the event of cancellation of the State registration of a veterinary preparation, the holders of the registration certificate for the veterinary preparation may appeal such decision pursuant to law.

#### Article 66. Production of Veterinary Preparations

1. Activities associated with production of veterinary preparations shall be subject to licensing pursuant to law.
2. Serial production shall be carried out exceptionally carried out of those veterinary preparations that have been registered in Ukraine pursuant to procedures laid down by this Law.
3. The persons producing veterinary preparations shall observe requirements of Good Manufacturing Practices and other requirements prescribed by the Department;
4. Production of veterinary preparations, including packaging and other related activities, shall cover all stages of technological process;
5. Substances, packaging materials, and other resources for production of veterinary preparations shall be allowed by the Department for use on the basis of results of testing conducted by authorized state institutions of veterinary medicine with the aim to verify their quality and safety.
6. The producer shall be obliged to conduct quality control for each lot (series) of veterinary preparations in accordance with prescribed requirements and to issue quality certificate.
7. 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 veterinary 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.

#### Article 67. Circulation of Veterinary Preparations

1. 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.
2. Circulation of veterinary preparations that are not registered in Ukraine shall be prohibited. In exceptional instances, in the course of treatment of non-productive animals, a doctor of veterinary medicine may administer medical drugs in the event that registered similar veterinary preparations are absent.
3. 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.
4. It shall be prohibited to sell veterinary preparations which do not comply with requirements of normative documents and with an expired “use-by” date for veterinary preparations. Prolongation of the shelf life of veterinary preparations shall be

prohibited.

5. Veterinary preparations and substances that are in circulation shall be subject to random control for compliance with quality and technical regulations. Veterinary preparations and substances that do not comply with the requirements of this Law shall be subjected to the provisions of Article 73 of this Law.
6. It shall be prohibited to use veterinary preparations in the way or for purposes that do not comply with their designation.
7. 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 levels of such preparations in raw materials of animal origin may not exceed the established maximum levels.
8. Veterinary immune-biological preparations shall be sold to establishments of veterinary medicine or licensed doctors of veterinary medicine exclusively.

#### Article 68. Wholesale Trade in Veterinary Preparations

1. All economic entities engaged in trade in veterinary preparations at the level of wholesale lots (hereinafter - wholesale enterprises) shall obtain from the Department, or a body authorized by the Department, a license for the right to carry out entrepreneurial activity in the sphere of wholesale trade in veterinary preparations.
2. Enterprises engaged in wholesale trade in veterinary preparations may sell such preparations only to other wholesale enterprises, establishments of veterinary medicine, and veterinary pharmacies.
3. Persons engaged in wholesale trade in veterinary preparations must keep records on their purchases, import, export, and sales.
4. Materials, referred to in paragraph 3 of this Article, must be submitted periodically to the Department or to the institutions, authorized by the Department, and, upon request, shall be immediately provided to the state inspector of veterinary medicine in form and in accordance with the procedure established by the Department.

#### Article 69. Retail Sale of Veterinary Preparations

1. Retail sale of veterinary preparations shall be carried out only by establishments of veterinary medicine and veterinary pharmacies.
2. Establishments of veterinary medicine and veterinary pharmacies must keep records on purchases and sales of certain veterinary preparations and submit relevant reports in form and in accordance with the procedure established by the Department
3. 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 requirements and conditions for retail sale 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 2 of this Article are not submitted to the Department, 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.
4. Licensed doctors of veterinary medicine or doctors of veterinary medicine employed by state institutions of veterinary

medicine or establishments of veterinary medicine shall issue prescriptions for veterinary medicinal means (preparations) only to animal owners or keepers (within the course of medical treatment of animals or for prophylaxis of animal maladies and diseases)

5. A licensed doctor of veterinary medicine or a doctor of veterinary medicine employed by the state institutions of veterinary medicine who issue a prescription for veterinary preparations, they shall be obliged to provide animal owners or keepers with original prescription and its copy that must be kept by the owners (keepers) together with the records referred to in Article 71 of the this Law.
6. Establishments of veterinary medicine and veterinary pharmacies must sell veterinary preparations, whose sale and use require a prescription, only if such prescription is available, and must save prescription copies for each veterinary preparation sold during three years from the day of sale.
7. The prescription referred to in paragraph 5 of this Article shall include, in addition to the name of the veterinary preparation, contains 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 owner (owners) of animals, for which veterinary preparation is prescribed

#### Article 70. Veterinary Preparations that Require a Prescription for their Sale and Use

1. Establishments of veterinary medicine shall have a right to carry out retail sale of veterinary preparations and medicated feed provided that they are required within the course of medical treatment of animals owned by their clients.
2. 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 medicinal means which are intended for medical treatment requiring prior diagnostics or application of which may cause processes impeding further diagnostics or therapeutic measures
  - 4) Veterinary immune-biological means.
3. The Department shall prescribe the list of veterinary preparations, referred to in paragraph 2 of this Article, and the rules for issuing prescriptions.
4. Production, circulation and use in establishments of veterinary medicine, veterinary apothecaries and so on of narcotic substances, psychotropic substances and their precursors shall be governed by special legislation in this area.

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

1. 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 animal transfer, the previous owner (keeper) shall provide such records to the new owner (keeper).

Such records must contain 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 veterinary medicinal or veterinary 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. Import of Veterinary Preparations for Special Purposes

1. It shall be permitted to import veterinary preparations, which are not registered and have a permit for importation, imported into the territory of Ukraine for the purposes of:

- 1) State registration in Ukraine;
- 2) Displaying at exhibitions, fairs and conferences;
- 3) 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 Department 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 73. 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 Department, and in compliance with other requirements of law.

#### Article 74. Circulation of Means of Animal Care

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) Deteriorate the veterinary-sanitary and epizootic welfare in Ukraine.

#### Article 75. Regulating Circulation of Devices of Veterinary Medicine

New devices of veterinary medicine, for which domestic standards or technical regulations and an ISO/IEC standard do not exist, shall be submitted to the Department prior to their circulation for compulsory testing of their ability to achieve effects, for which such devices are designed.

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

#### Article 76. 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 status in Ukraine;
  - 2) Have an unfavorable effect on human health, animal 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-raising sector.
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 Department, to the state scientific-research control institute. The applicant shall be responsible for validity of information presented in the registration dossier pursuant to law. 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 laid down by the Cabinet of Ministers of Ukraine.
4. The National Agency of Veterinary Preparations and Feed Additives shall conduct an evaluation (expert examination) of submitted documents (testing), organize the necessary research and perform other measures aimed to verify information and data, stipulated in the documents, and also prepare expert conclusions for consideration of the State Pharmacology Commission of Veterinary Medicine within a time period does not exceed 90 days from the date of receipt of the application, the complete set of documents, and effecting of the relevant payment.



5. The State Pharmacology Commission of Veterinary Medicine shall consider expert conclusions and provide the Department with the recommendations regarding state registration of the relevant feed additives, premixes and finished feed.

6. The Department shall make a decision to register or deny the State registration of feed additives, premixes and finished feed. The State registration may be denied if as a result of verification of the data and documents submitted by the applicant it has been uncovered that the dossier is incomplete or the quality and safety of feed additives, premixes and finished feed are not duly confirmed or there are other characteristic features specified in Part 2 of this Article.

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 Department.

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 such decision in the court in accordance with the procedure established by law.

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 Department shall issue the registration certificate within 30 days. 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 Part 10 of this Article with regard to labeling 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 surgical use, when setting up of such levels is envisaged by current law, and there are no international standards, guidelines and recommendations with regard to maximum allowed levels;

Annexes to the registration certificate may 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 labeling requirements and contain the following information clearly formulated in Ukrainian language, in a form that attracts attention and is indelible:

- 4) The specific name given upon registration;
- 5) The name or title, the address or registered place for carrying out the activity of the owner of registration certificate;
- 6) Qualitative and quantitative composition of components;
- 7) Guidelines for use and all recommendations regarding safety and, if necessary, specific requirements, including animal

species and categories, for which feed additives, premixes and finished feed are intended;

8) Registration number of the registration certificate issued by the Department;

9) Lot (series) number, date of manufacture, and the shelf-life.

12. It shall be permitted to import veterinary preparations, which are not registered and have a permit for importation, into the territory of Ukraine for the purposes of:

1) State registration in Ukraine

2) Displaying at fairs, exhibitions, and conferences;

3) Scientific and other purposes.

13. The Department 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 Department.

#### Article 77. 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 if operating permit and / or license are not available. 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 Department.

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 components or ingredients 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 Department.

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 Department shall authorize the relevant state institutions 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 label;

2) they contain pathogenic microorganisms in the amount that may cause harm to animal health;

3) they contain contaminants in the amount in excess of maximum allowed levels;

4) they contain veterinary preparations and substances not allowed for use;

5) the shelf-life has expired.

7. Maximum allowed levels of contaminants and allowed amount of pathogenic microorganisms in feed shall be determined in accordance with current law of Ukraine.

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

#### Article 78. Program for Monitoring Feed, Feed Additives and Premixes

1. All feed, feed additives and premixes in circulation in Ukraine shall be subject to 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 research of samples of feed, feed additives and premixes within ten working days of the date of notification of the results of laboratory research, may be challenged by the owner of the above feed, feed additives and premixes, from which samples were taken, by requesting an arbitration research.
3. The sampling frequency, facilities (objects) where samples are taken, the method of sampling and laboratory research 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 Department pursuant to this Law.

#### Article 79. Registration of Persons Circulating Feed of Animal Origin

1. Persons circulating feed of animal origin shall be subject to registration with the Department.
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 Department shall issue necessary normative-legal acts to implement the provisions of this Article.

#### Article 80. Use of Waste Food for Feeding Animals

1. In order to prevent the outbreaks of animal diseases caused by using infected materials of animal origin as feed, it shall be prohibited to use as feed for animals waste food 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 possible 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 Department and controlled by its territorial bodies.

## SECTION XII. INTERNATIONAL TRADE REQUIREMENTS

### Article 81. Designated Border Inspection Posts

1. Importation of commodities into the territory of Ukraine, transit and exportation of commodities outside the territory of Ukraine shall be carried out exclusively 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 Department 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 research;
  - 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 consignments 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 82. 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 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 of animal diseases into the territory of Ukraine on the basis of a permit for importing into territory of Ukraine, issued by the Department in accordance with Article 83 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 this Law into the territory of Ukraine, except as prescribed in Article 72 and paragraph 12 of Article 76 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 83. Permits for Importing Commodities into the Territory of Ukraine

1. It shall be necessary to obtain permits in order to prevent importation into Ukraine of commodities that contain pathogenic agents causing animal diseases.
2. Permits for importation of commodities into the territory of Ukraine shall be issued on a condition that:
  - 1) results of the determination of efficiency of the foreign veterinary service in the country of origin of productive animals and reproductive material have been obtained;
  - 2) live micro-organisms and pathologic material that contains contain pathogenic agents of animal diseases have been imported;
  - 3) importation of other commodities has commenced.
3. A one-time permit for importation of veterinary preparations into the territory of Ukraine may be issued in instances as are stipulated in Article 72 of this Law.
4. Permits shall be issued by the Department on a free-of-charge basis within 30 days from the date, on which documents were received for review.
5. The grounds for denying issuance of a permit or revoking a permit shall be as follows:
  - 1) likelihood of brining of pathogenic agents of animal diseases into the territory of Ukraine;
  - 2) 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;
  - 3) 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. Procedures for issuance of permits for importation of commodities into the territory of Ukraine shall be laid down by the Cabinet of Ministers of Ukraine upon confirmation with the specially authorized agency for affairs relating to the authorization system in the area of business activity.
7. Factors to be considered for determination of risk, associated with bringing a commodity into the territory of Ukraine, shall be as follows:
  - 1) Use of the commodity as intended;
  - 2) Geographic and other characteristics of Ukraine, the country of origin and countries of transit that affect the ability of notifiable diseases to survive, establish, and spread;
  - 3) Existence of state control programs for animal diseases in Ukraine, the country of origin, and transit countries;
  - 4) Availability 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 notifiable 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 29 of this Law;
  - 6) The effectiveness of measures that the Department may require to be applied in the country of origin to reduce the risk associated with the importation into the territory of Ukraine, including, pre-shipment prophylactic animal quarantine, specification of the facility (object) of origin, sampling and laboratory research for confirmation of freedom from notifiable diseases in the country of origin; If necessary, the Department shall be provided with an appropriate access to facilities (objects) of exporting country to conduct inspections, tests and other relevant procedures with regard to veterinary-sanitary

measures associated with bringing in of live animals and products of animal origin;

7) Availability of the state system of animal identification and registration in the country of origin;

8) 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.

8. The permit for importing 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 of animal diseases, the permit for importing into the territory of Ukraine must include specification of veterinary-sanitary measures to be applied by the importer to prevent an uncontrolled spread of the pathogenic agent.

9. The permit for importing 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.

10. Denial of a permit for importing into the territory of Ukraine shall be justified and be provided to the applicant without delay. The applicant may appeal such decision in the court in accordance with the procedure established by law.

11. The Department 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 prohibition of importation into the territory of Ukraine of commodities, according to the veterinary-sanitary state of the country.

#### Article 84. Notification to State Inspectors of Veterinary Medicine about Importation of 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 Department.

#### Article 85. Requirements to Consignments of Commodities imported into the Territory of Ukraine or Moved as Transit

1. Consignments of commodities that are imported into the territory of Ukraine must:

1) Be free of notifiable diseases in compliance with the requirements of the OIE;

2) Be accompanied by original international veterinary certificates signed by state inspector of veterinary medicine of the country of origin when so required by current veterinary-sanitary measures;

3) Be accompanied by a permit for importing into the territory of Ukraine when so required by current 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.

- 5) Be identified in accordance with the law of the importing country;
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. The list of commodities with specification of their codes pursuant to the Ukrainian Classificatory of Commodities in Foreign Economic Activities, which shall be subject to veterinary-sanitary measures when imported into the customs territory of Ukraine and exported out of the customs territory of Ukraine, shall be prescribed by the Cabinet of Ministers of Ukraine .

#### Article 86. Importation of 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 out of the country of origin.

#### Article 87. Standard Border Veterinary-Sanitary Control

1. All objects of veterinary-sanitary control and supervision brought in or moved within the territory of Ukraine 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 importing into the territory of Ukraine, which accompanies the consignment;
  - 2) If an international veterinary certificate is required by current 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 contained in the consignment;
  - 3) Detection of indications of notifiable diseases in animals.
2. Importation of the consignment into the territory of Ukraine or its transit through the territory of Ukraine shall be carried out under following conditions:
  - 1) The consignment is accompanied by a valid permit for importing into the territory of Ukraine, when such permit is required by current 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 current 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:
    - a) In case of transit consignments, if the customs seal applied by the customs authority of the country of shipment is not damaged;
    - b) 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;

- c) The number of prior consignments of analogue commodities from the country of origin and/or particular facility (object) of origin were accompanied by valid international veterinary certificates;
- d) 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 gives grounds to come to 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 90 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, based upon the professional judgment of the state border inspector of veterinary medicine, the risk to animal or human health presented by a consignment is 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) Availability 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 importing 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 analogue 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 analogue 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 89 of this Law.
7. The Department shall prescribe the number of prior consignments of like animals or analogue 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 88. Random Veterinary-Sanitary Border Control

- 1. Consignments of commodities that are imported 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 89 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 Department prior to the beginning of each calendar year.

#### Article 89. Extended Veterinary-Sanitary Control

1. Should the state border inspector of veterinary medicine suspect that consignments of commodities, which are imported 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 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, 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 research 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 current law of Ukraine;

4) Upon confirmation of especially dangerous diseases recorded onto 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 of animals with a disease that is capable of increasing the incidence of endemic animal disease in Ukraine, the consignment shall be:

- a) Returned to the country of origin at the expense of the owner or carrier, provided such return does not endanger animal health;
- b) With consent of the owner and observance of necessary veterinary-sanitary measures-subjected to technical processing to eliminate the pathogenic agent of animal disease;
- c) Destroyed in accordance with the provisions of item 4 of paragraph 1 of this Article.

2. The Chief State Inspector of Veterinary Medicine of Ukraine shall immediately inform the Veterinary Administration of the country of origin and the importer and/or the owner of the consignment about confirmation or ruling out of suspicion of animal

disease, and the actions subsequently taken.

Article 90. Procedures to be Applied when the 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 or destroyed at the expense of the owner of the commodity or at the expense of the carrier.

Article 91. Restrictions on Bringing into the Territory of Ukraine and Transit due to an Outbreak of an Especially Dangerous Disease recorded onto the OIE List in the Country of Origin or Transit

1. No importation of an import or transit consignment of animals shall be permitted entry, regardless of the availability of a permit for importing into the territory of Ukraine or a permit for transit if:
  - 1) The presence of an especially dangerous disease recorded onto the OIE List, to which these animals are susceptible, has been confirmed in the country of origin or in the zone where the animals originated;
  - 2) The presence of an especially dangerous disease recorded onto 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 Department 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 recorded onto the OIE List, at the expense of the owner of the consignment.

Article 92. Quarantine Requirements for Animals that are imported into the Territory of Ukraine

3. Animals that are imported into the territory of Ukraine except for 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 their health shall be specified in the relevant rule books adopted by the Department 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 93. Procedures that apply at Locations and Premises of Warehouses of Temporary Storage, Customs Licensed

Warehouses, in Special Customs Zones, Duty-Free Stores and other Places, where Goods and Motor Vehicles, which are subject to Customs Control, are or may be or where Activities, which are subject to control by Customs Authorities pursuant to law, are carried out

All goods, which come to locations and premises of warehouses of temporary storage, customs licensed warehouses, special customs zones, duty-free stores and other places, where goods and motor vehicles, which are subject to customs control, are or may be, or where activities, which are subject to control by customs authorities pursuant to law, are carried out, shall be also subject to mandatory State veterinary-sanitary control.

#### Article 94. 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 OIE requirements 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 95. 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 96. Measures to be taken in Connection with a Threat of an Animal Disease

If there is a high risk of entry of agents 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 a 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 97. 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.
4. 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 98. 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 research of commodities, logistic provision with specialized equipment and transport, establishment of the required reserve of biological, medicinal and disinfectant preparations and means, reimbursement for expenses of transportation and storage of veterinary preparations, 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, local budgets and other sources not prohibited by law.

#### Article 99. 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 mentioned in

Article 98 of this Law), procedures for control, inspection, approval and provision of information, medical treatment of animals that have diseases and maladies, laboratory research, veterinary-sanitary testing of commodities, issuance of relevant veterinary documents, 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.

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 applicant based on the price list approved pursuant to law.
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 of Ukraine and other sources not prohibited by law.
4. Tariffs for veterinary services shall be approved according to the law on prices and pricing.

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

##### Article 100. 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 the law of Ukraine.
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 and branches thereof in the Autonomous Crimean Republic, oblasts, as well as regional, zonal, inter-oblast, republican laboratory of state laboratories of veterinary medicine, state laboratories of veterinary medicine of the cities of Kyiv and Sevastopol, state laboratories of veterinary-sanitary testing in the markets, may be privatized in the procedure envisaged by law. Privatized objects may not change their profile within 10 years.
3. Issues relating to qualification up-grades, attestation and ethics of specialists of veterinary medicine that engage in veterinary practice shall be dealt with by a professional non-government organization authorized by the Department.

##### Article 101. 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 institutes 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 for specialists of veterinary medicine may be carried out by participation in seminars and internship programs in Ukraine and abroad taking into account their specialization.
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 state 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 law. 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 Department 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 102. 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 law 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 of Ukraine and other sources of funding that are not prohibited by law. Such dwellings may be transferred to specialists of veterinary medicine for temporary or permanent use according to the procedure prescribed by the Department.
  - 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 returnable 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 law.
6. Specialists of veterinary medicine shall receive doubled amount of their official salaries during their work in the quarantine zones of a notifiable disease outbreak.
7. Life and health of specialists of veterinary medicine at the cost of the special fund of the State Budget of Ukraine shall be subject to compulsory insurance for cases of disability or professional illness obtained while performing their official duties, controlling antropozoonosis diseases and direct treatments of animals, which shall be financed from.
8. In case of disability or professional illness, a lump sum shall be paid to specialists of veterinary medicine in amount of 3 to

5 annual salaries depending on disability.

9. In order to perform their official duties specialists of the state service of veterinary medicine 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.

10. 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 Department within the limits of current law.

11. Chief State Inspectors of Veterinary Medicine of Ukraine, of the Autonomous Crimean Republic, the oblasts, the cities of Kyiv and Sevastopol, 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 Department and other officials of the state service of veterinary medicine shall have a priority right to receive dwellings and install private telephones.

12. Expenses of the Chief State Inspectors of Veterinary Medicine of Ukraine, of the Autonomous Crimean Republic, the oblasts, the cities of Kyiv and Sevastopol, 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 Department 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.

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

#### Article 103. 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 study, evaluate and forecast situations, to develop veterinary-sanitary measures, 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, 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 Department. Bodies of executive power, local self-government, 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 104. Liability for Violations in the Sphere of Veterinary Medicine

1. For violations in the sphere of veterinary medicine, natural persons, legal entities and natural persons - subjects of

entrepreneurial activities, whose activities are related to raising (breeding) of animals, 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 current law.

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 law.

#### Article 105. 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 Department, 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 Department, its territorial bodies and regional services.

3. Upon request of the specialists of the state service of veterinary medicine, personnel of bodies of internal affairs, the security service, the prosecutor's office shall be involved in the implementation of measures on terminating the violations of law on veterinary medicine issues, in necessary cases.

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

Decisions on imposing penalties for violations in the sphere of veterinary medicine shall be formulated in relevant resolutions.

#### Article 107. 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 court.

### Section XVI. INTERNATIONAL COOPERATION

#### Article 108. International Cooperation in the Sphere of Veterinary Medicine

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

- 1) Participation in the activities of the OIE and other international organizations, ratification of international agreements and harmonization of veterinary-sanitary measures;
- 2) Harmonization of law in the sphere of veterinary medicine according to modern 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 109. 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 prevail.

#### Section XVII. FINAL PROVISIONS

1. This Law shall come into force from the date of its publication except for:

- 1) Articles 34, 51-55 which will come into force on January 1, 2008;
- 2) paragraph 3 of Article 66 and paragraph 1 of Article 77, which will come into force on January 1, 2010;
- 3) paragraph 2 of Article 100 and paragraph 3 of Article 102 which will come into force on January 1, 2008;

2. Until brought in compliance with this Law, laws and other normative-legal acts shall be applied to the extent consistent with this Law.

3. In Part 1 of Article 4 of the Law of Ukraine “On State Regulation of Imports of Agricultural Products” (Vidomosti of Verkhovna Rada of Ukraine, 1997, No. 44, page 281; 2005, No. 51, page 557), the words “mandatory certification (except for raw materials that are imported exclusively for production of goods that are subject to mandatory certification)” shall be deleted.

4. The Cabinet of Ministers of Ukraine shall within six months:

- 1) Bring its normative-legal acts in compliance with this Law;
- 2) Ensure that ministries, other central bodies of executive power bring their normative-legal acts in compliance with this Law”.

Victor Yushchenko  
President of Ukraine

Kyiv  
16 November 2006  
N 361-V