

Draft

The Law of Ukraine „ON INTRODUCTION OF CHANGES TO THE LAW “ On Veterinary Medicine”

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SECTION I - GENERAL PROVISIONS

Article 1: Definitions of Basic Terms

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

- 1) **Risk analysis** – the process composed of *hazard identification, animal disease risk assessment, risk management, and risk communication*.
- 2) **Arbitration analysis** – laboratory analyses conducted in response to an appeal by a person against the results of previous laboratory analyses;
- 3) **Buffer zone** – a zone established within, and along the border of, an *infected zone* using measures based on the epizootic characteristics of the *animal disease* under consideration to prevent spread of the causative pathogenic agent into a country or zone free of such *animal disease*. These measures may include, but are not limited to, vaccination of *animals*;
- 4) **Veterinary Administration** – the governmental veterinary service having authority in the whole country for implementing *veterinary-sanitary measures* and verification of the conformity of *commodities* with the requirements specified by a country of destination, issuance of *international veterinary certificates* in accordance with the recommendations and guidelines of the *relevant international organisations*, and supervising or auditing their application;
- 5) **Veterinary card** – a document, issued by a *state veterinary doctor*, with a record of treatments, vaccinations, and other veterinary procedures for a specific *animal*, which supplements an *animal* passport;
- 6) **Veterinary laboratory** (laboratory of veterinary medicine) – an equipped laboratory, accredited by the national accreditation body or a comparable accreditation body of a foreign country, that is staffed by technically competent personnel under the control of a specialist in veterinary diagnostic analysis, who is responsible for the validity of the results;
- 7) **Veterinary medicine** – a sphere of science and practical knowledge on *animal diseases*, their prevention, diagnostics, medical treatment, determination of veterinary-sanitary safety of products of *animal* origin, activity aimed at protection of health and productivity of *animals*, prevention of *animal diseases* and protection of humans from *zoonoses*;
- 8) **Veterinary affidavit** – a document of single use issued by a *state inspector of veterinary medicine* or *authorised veterinarian*, confirming the *veterinary-sanitary state* of *commodities, feed of plant origin, and accompanying items*, including obligatory attestation of the *veterinary-sanitary status* of the territory (facility) of origin and, for *animals*, the record of vaccination and diagnostic analysis;

- 9) **Veterinary establishment** – legal entity that employs at least one doctor of veterinary medicine or a physical person – entrepreneur, which has the qualification of a doctor of veterinary medicine, which obtained a license for veterinary practice, including rendering of services related to prophylactics, diagnostics and treatment of *animal diseases* and *maladies*;
- 10) **Veterinary documents** – *international veterinary certificate, veterinary affidavit, veterinary card*, and information notes issued by a *state inspector of veterinary medicine* attesting to the *veterinary-sanitary state of commodities, feed and accompanying items*;
- 11) **Veterinary immunological products** – products (means) intended for correcting the active or passive immunity of *animals* or to diagnose the state of immunity of *animals*;
- 12) **Veterinary medicinal products (means)** – any substance or *combination* of substances intended for treating or preventing disease in animals, and any substance or combination of substances administered to animals in order to make a medical diagnosis or for restoring, correcting, or modifying physiological functions in animals;
- 13) **Veterinary preparations** – *veterinary medicinal products (means), veterinary immunological products*, antiseptics, disinfectants, and arachnicides used in veterinary medicine and livestock rearing;
- 14) **Veterinary services** – the *state veterinary bodies* and the *state institutions of veterinary medicine*;
- 15) **Veterinary-sanitary testing** – a set of necessary laboratory *examination* special analysis carried on by veterinary specialists from state veterinary institutions with regard to determining the safety of *non-edible products of animal origin* for use as *feed*, for further processing, and for other uses;
- 16) **Veterinary-sanitary and epizootic welfare** – ensuring protection of human and *animal* life and health from hazards associated with *animal diseases*, optimum conditions for *animal* life to prevent *animal diseases* and harmful effect of environmental factors on their health and productivity, and ensure prevention of *animal diseases*, including *zoonoses*;
- 17) **Veterinary-sanitary state** – the presence or absence of *notifiable disease* and/or the level of *contaminants* relative to maximum allowed levels;
- 18) **Veterinary-sanitary status** – the status of a country or a territory (facility) with respect to *animal disease*, determined according to the criteria specified by the *relevant international organisations*;
- 19) **Veterinary-sanitary measure** – any measure, including all relevant laws, decrees, regulations, rule books, requirements and procedures including in particular *anti-epizootic measures*; end product criteria; processes and production methods; testing, inspection, certification, and approval procedures; quarantine treatments including relevant requirements associated with the transport of *animals*, or with the materials necessary for their survival during transport; and provisions on relevant statistical methods, sampling procedures and methods of *animal disease risk assessment*, that are applied to:
 1. Protect *animal* life or health from *risks* arising from the entry, establishment or spread of *animal diseases*, *animal* disease-carrying organisms or *animal* disease-causing organisms; or
 2. Protect *animal* life or health from *risks* arising from *contaminants*, toxins or *animal* disease-causing organisms in *feed*; or
 3. Protect human life or health from *risks* arising from *zoonoses* carried by *animals* and other *commodities* and *accompanying items*.

- 20) **Relevant international organisations** – the World Animal Health Organisation and other international organisations in which *international standards, guidelines, and recommendations* associated with protection of *animal* health and the safety of *commodities* are developed;
- 21) **Finished feed** – *feed* of *animal* and plant origin for non-food-producing *animals*, including fish and birds;
- 22) **Department** – the veterinary administration of Ukraine titled the State Department of Veterinary Medicine of Ukraine;
- 23) **State control programme** – a programme which is developed by the *Department* and implemented by the *veterinary service*, or in the case of a foreign country, its *Veterinary Administration*, for the purpose of controlling (i.e., containing and/or eradicating) an *animal disease* by specific measures applied throughout the country or within a *zone* or *zones* of the country;
- 24) **State veterinary-sanitary control** – functions (activities) performed by *state inspectors of veterinary medicine* and *authorised veterinarians* that consist of continuously ensuring fulfilment of *veterinary-sanitary measures* established by current legislation;
- 25) **State veterinary-sanitary supervision** – functions (activities) performed by *state inspectors of veterinary medicine* that consist of periodic checking to verify adherence to the requirements of current legislation in the sphere of *veterinary medicine*;
- 26) **State inspector of veterinary medicine** – a doctor of veterinary medicine employed by the state *veterinary services* or an *authorised veterinarian* that is authorized by the *Department* or in the case of a foreign country, its *Veterinary Administration*, to perform inspections of *commodities, feed of plant origin, and accompanying items* with the purpose of protecting public and/or animal health and, when appropriate, 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*;
- 27) **State veterinary doctor** – a doctor of veterinary medicine employed by a state body or *state institution of veterinary medicine*;
- 28) **State veterinary bodies** – the *Department, territorial bodies, and regional services*;
- 29) **State institutions of veterinary medicine** – scientific-research and scientific-control institutes, state laboratories of veterinary medicine, state hospitals of veterinary medicine, and other institutions, funded by the State and authorized to perform certain functions pursuant to this Law;
- 30) **Export facility (object)** – a *facility (object)* used for the production of *objects subject to state veterinary-sanitary control or supervision* for which the *Department* has verified its compliance with the requirements established by a country of destination for such *facility (object)* to allow export of the above objects to such country;
- 31) **Contaminants** – pesticides, toxins, hormones, sedatives, thyreostatics, antibiotics, other veterinary preparations, salts of non-organic substances, radioactive substances, decayed products or other substances that can be harmful to *animal* health;
- 32) **Interested trading partners** – states and other subjects of international law that are participants of multilateral and bilateral agreements, of which Ukraine is also a participant, governing the application of *veterinary-sanitary measures*, and members of *relevant international organisations* of which Ukraine is also a member;
- 33) **Devices of veterinary medicine** – materials, equipment, instruments, specialized motor vehicles, and other mechanisms and tools designed for *veterinary medicine*;

- 34) **Means of animal care** – means and substances for breeding and taking care of *animals* that have no medical or prophylactic effect;
- 35) **Zone** – a clearly defined part of the territory of a State with a distinct *veterinary-sanitary status*;
- 36) **Zone of low prevalence of notifiable disease** – a *zone*, whether all of a country, part of a country, or several countries or parts thereof, as identified by the competent authorities, in which a *animal disease* occurs at low levels and which is subject to effective surveillance, control (containment), or eradication measures;
- 37) **Surveillance zone** – a *zone* established within, and along the border of, a *zone* free of *notifiable disease* separating the zone that is free of *notifiable disease* from an *infected zone* where there is an intensified degree of surveillance;
- 38) **Zone free of notifiable disease** – a *zone* in which the absence of the *animal disease* under consideration has been demonstrated by meeting the requirements for free status as specified by the *relevant international organisations*. Within the *zone* and at its borders, appropriate control (containment) measures shall be effectively applied for *commodities* and other objects that may carry the relevant *animal disease*, including means of transport;
- 39) **Zoonoses** – diseases that can be transmitted by vertebrate *animals* to humans;
- 40) **Hazard identification** – the process of identifying the pathogenic agents that could potentially be introduced into the territory of Ukraine by importation of *commodities* and *accompanying items*;
- 41) **Infected zone** – a *zone* in which the absence of the *animal disease* under consideration has not been demonstrated by meeting the requirements specified by the *relevant international organisations*;
- 42) **Animal quarantine** – a special legal regime that is implemented in an *infected zone* and surrounding *buffer* and, when appropriate, *surveillance zones* with the objective of containing an *outbreak* of *animal disease* and eradicating such *animal disease* according to relevant *veterinary-sanitary measures* laws and sub-legal acts issued pursuant to this Law;
- 43) **Quarantine zone** – a zone that includes an *infected zone* and *buffer zone*, and may include a *surveillance zone*, within which *animal quarantine* is being implemented;
- 44) **Quarantine station (post)** – a specially equipped premises (site), under the control of the *state veterinary bodies* where a group of *animals* is maintained in isolation, with no direct or indirect contact with other *animals*, in order to undergo observation for a specified length of time and, if appropriate, testing and treatment;
- 45) **Quarantine veterinary-militia post** – a temporary, specially equipped premises at the border of a *quarantine zone* established according to the decision of the State Emergency Anti-Epizootic Committee to contain and prevent spread of a *notifiable disease*;
- 46) **Quantitative risk assessment** – an assessment where the outputs of the assessment of *risk* are expressed numerically;
- 47) **Feed** – *finished feed* and *feed of plant* and *animal origin*;
- 48) **Feed of plant origin** – forage grain, *feed* concentrates, mixed *feed*, cake, shorts, root crops, tuber crops, hay, straw and other *feed* of plant origin;

- 49) **Feed of animal origin** – *animal* products based on *animal* protein, including, *inter alia*, meat-meal, bone-meal, liver-meal, fish-meal, blood-meal, feather-meal, pork fat, live fish for feeding, milk and milk products and other products of *animal* origin intended for *animal* feeding;
- 50) **Feed additives** – substances, micro-organisms or preparations, other than *feed* material and *premises*, which are not normally consumed as *feed* by itself but are intentionally added to *feed* or water in order to favourably affect the characteristics of *feed* or animal products, favourably affect the colour of ornamental fish and birds, satisfy the nutritional needs of animals, favourably affect the environmental consequences of animal production, affect animal production, performance or welfare, particularly by affecting the gastro-intestinal flora or digestibility of *feed*, or have a coccidiostatic or histomonostatic effect;
- 51) **Licensed veterinary doctor** – a doctor of veterinary medicine that is employed full-time with a veterinary establishment or a physical person –entrepreneur, which has the qualifications of a doctor of veterinary medicine, and which obtained a license according to current legislation to carry out certain types of activities in the sphere of *veterinary medicine*;
- 52) **Medicated feed** – any *feed* which contains *veterinary medicinal products (means)*;
- 53) **International veterinary certificate** – a certificate of the form and with the content recommended by the *relevant international organisations*, issued in the exporting country in conformity with the guidelines of the *relevant international organisations*, describing the *animal* health and/or related human health requirements which are fulfilled by exported *commodities*;
- 54) **International standards, guidelines and recommendations** – standards, guidelines, and recommendations that are developed and adopted by the World Animal Health Organization and other international organizations involved in development of standards, guidelines, and recommendations related to protection of animal and human life and health from animal disease;
- 55) **Minimum quality specifications** – prescribed quality characteristics, specified in terms of organoleptic, chemical, biological and physical characteristics of an object as such, that must be met by the relevant object in order for it to be deemed acceptable for its intended use;
- 56) **Monitoring** – a system and procedure of observation and verification of the *veterinary-sanitary state* of an *object subject to state veterinary-sanitary control*;
- 57) **Urgent circumstances** – occur when the confirmed or suspected presence of a *notifiable disease* in an country of origin or transit can cause immediate irreparable damage to the health of susceptible *animals* throughout Ukraine or in a part of Ukraine if *commodities, feed of plant origin, or accompanying items* that may carry this *notifiable disease* are imported;
- 58) **Good Manufacturing Practice (for veterinary preparations, premises, feed additives, and finished feed)** – a system, covering all aspects of the production process, for ensuring that goods (such as *veterinary preparations, premises, feed additives, and finished feed*) are consistently produced and controlled according to quality standards in order to minimize safety and other risks involved in production of goods that cannot be eliminated through testing the final product. Such practices are based on *international standards, guidelines and recommendations* and are practices which are necessary to ensure that goods comply with relevant veterinary-sanitary measures, technical regulations, and other requirements specified in this Law;
- 59) **Appropriate level of animal and related human health protection** – the level of protection deemed appropriate by the State when developing *veterinary-sanitary measures* to protect *animal* and human health and life from an adverse effect that the *veterinary-sanitary measure* is designed to address;
- 60) **Maladies** – conditions of *animals* other than *animal diseases* that require care or treatment by a doctor of veterinary medicine;

- 61) ***Non-edible products of animal origin*** – raw *materials* of *animal* origin not normally used for human consumption but that are used for pharmaceutical, surgical, agricultural, and industrial purposes;
- 62) ***Objects subject to state veterinary-sanitary control and supervision*** – *commodities, feed of plant origin, veterinary preparations,*
- 63) ***Circulation*** – moving (transporting) or storing, and any actions related to the transfer of *proprietary* or possession right, including, selling, exchanging or granting;
- 64) ***Operator of facilities*** – person who carries out activities, envisaged by this law, using *facilities (objects)*, which the *person* owns (i.e., is the owner) or for which this person has the right of ownership, possession (usage);
- 65) ***Animal disease risk assessment*** – the evaluation of the likelihood and the biological and economic consequences of introduction, establishment, or spread of a pathogenic agent within the territory of Ukraine;
- 66) ***Pathological material*** – samples taken from live or dead animals, which contain or may contain infectious or parasitic agents, that are intended for delivery to a veterinary laboratory;
- 67) ***Withdrawal period*** – the period necessary between the last administration of a *veterinary medicinal product (means)* to *animals* under normal conditions of use and the production of animal products intended for human consumption from such animals, in order to ensure that such products intended for human consumption do not contain residues in quantities in excess of established limits;
- 68) ***Risk communication*** – the interactive exchange of information on *risk* among *risk* assessors, *risk* managers, *interested trading partners*, and other interested parties;
- 69) ***Facility (object)*** – any building, collection of buildings, premises, structures or area, including the equipment therein or thereon, used for *animal* breeding, raising, training, competition, keeping, displaying (viewing), tendering, selling, slaughtering or harvesting of *animals*; for destroying *animal* carcasses and other parts of *animals*; for producing and *circulating non-edible products of animal origin, reproductive material, feed, feed additives, and veterinary preparations*;
- 70) ***Premixes*** – mixtures of *feed additives* or mixtures of one or more *feed additives* with *feed of plant origin* or *feed of animal origin* or water used as carriers, not intended for direct feeding of *animals*;
- 71) ***State border inspector of veterinary medicine*** – an appropriately qualified *state inspector of veterinary medicine* authorised by the *Department* to inspect import, transit and export consignments of *commodities* and *feed of plant origin*, and permit their entry or exit depending on their *veterinary-sanitary state* and issue *international veterinary certificates*;
- 72) ***Border inspection posts*** – premises located at the entry points of the state border of Ukraine, including *entry* points at the highways, railway stations, airports, sea and river ports, where veterinary-sanitary control of consignments that cross the state border of Ukraine is conducted;
- 73) ***Products of animal origin*** – animal products *intended* for human consumption, *feed of animal origin, products of animal origin for pharmaceutical and surgical use, and products of animal origin for agricultural and industrial use*;

- 74) **Products of animal origin intended for agricultural or industrial use** – products of *animal* origin, except those intended for food for human *consumption*, pharmaceutical or surgical purposes, and *feed of animal origin*;
- 75) **Products of animal origin intended for pharmaceutical or surgical use** – *animal* organs, tissues and organic fluids to be used in the preparation of pharmaceutical products or of surgical devices;
- 76) **Anti-epizootic measures** – *veterinary-sanitary measures, including* organisational, prophylactic, and diagnostic measures aimed at prevention, detection, and eradication of *notifiable diseases*;

- 77) **Preventive animal quarantine** – a system of *veterinary-sanitary measures* which apply before and/or after movement of *animals* to prevent introduction or spread of *animal disease*;
- 78) **Regional services** – the Regional Service of the State Department of Veterinary Medicine for State *Veterinary-Sanitary Control and Supervision* at the State Border and for Internal Transport, which is the body of state power carrying out *state veterinary-sanitary control and supervision* on a regional level with the purpose to protect the territory of Ukraine from introduction of *animal diseases* from the territories of other countries and to ensure the fulfilment of *veterinary-sanitary measures* by persons during international and domestic transportation of *objects subject to state veterinary-sanitary control and supervision*;
- 79) **Registration certificate** – a document allowing *circulation of veterinary preparations* feed additives, premixes and finished feed and their use in *animal* rearing;
- 80) **Reproductive material** – semen, zygotes, fertilized fish eggs, incubate eggs, fertilized ova, embryos, and other biological material that enables reproduction;
- 81) **Risk** – the likelihood of the occurrence and the likely magnitude of the consequences of an adverse event during a specified time period;
- 82) **Market** – a specially equipped and specially allocated location that is used for providing services to establish due conditions for *sale of animals, non-edible products of animal origin, finished feed, feed additives, premixes, means of animal care and devices of veterinary medicine*;
- 83) **Outbreak (of disease)** – an occurrence of a *notifiable disease in facility (object)*, including all buildings and all adjoining premises, where *animals* are present; or, an *outbreak* shall be considered as occurring in the part of the territory in which, taking local conditions into account, it cannot be guaranteed that both susceptible and non-susceptible *animals* have had no direct contact with affected or suspected cases in that area;
- 84) **Veterinary medicine specialists** – doctors of veterinary medicine and veterinary technicians that carry out preventive, recovery, diagnostic, and medical treatment activities for *animals*, perform *veterinary-sanitary testing of commodities*, or conduct other veterinary activities;
- 85) **Standard** – a document approved by a state power body, that provides, for common and repeated use, rules, guidelines, or characteristics for products, related processes or services with which compliance is not compulsory. It may also include or deal exclusively with symbols, packaging, marking, or labelling requirements as they apply to a product or process or with terminology requirements as applied to a product, process, or service. Safety requirements for *non-edible products of animal origin* shall not be prescribed in standards, but in *veterinary-sanitary measures*;

- 86) **Stamping-out** – carrying out under the authority of the relevant chief state inspector of veterinary medicine a set of measures including the killing of diseased or infected *animals* in the herd and, where appropriate, those in other herds which have been exposed to infection by direct or indirect *animal to animal* contact, of a kind likely to cause the transmission of the causal pathogen. All suspected *animals*, vaccinated or unvaccinated, are killed and their carcasses destroyed by burning or burial, or by any other method which will eliminate the spread of infection through the carcasses or products of the killed *animals*. It is also necessary to perform the cleansing and disinfection procedures recommended by the *relevant international organisations*;
- 87) **Substance** – any matter which may be used for production of *veterinary preparations* or *feed additives* of the following origin:
1. Human, e.g., human blood and its products;
 2. *Animal*, e.g., micro-organisms (microbiological products), whole *animals*, parts of organs, *animal* secretions, toxins, extracts, blood products;
 3. Vegetable, e.g., micro-organisms (microbiological products), plants, parts of plants, vegetable secretions, extracts;
 4. Chemical, e.g., elements, naturally occurring chemical materials, and chemical products obtained by chemical change or synthesis;
- 88) **Accompanying items** – items that may carry or transmit *animal disease* to other *animals* or humans, including straw, hay, tackle, and other items, that accompany or are used on *animals*;
- 89) **Animals** – mammals, birds, and bees; fish, crustaceans, molluscs; frogs, amphibians, and reptiles;
- 90) **Territorial bodies** – state bodies of the executive branch of power created by the *Department* in the form of the administrations of veterinary medicine in the Autonomous Republic of Crimea, oblasts, cities of Kyiv and Sevastopol, towns, and districts to perform the functions of the *Department* in a certain territory;
- 91) **Technical regulation** – a document, issued as a legal act, which lays down characteristics of products or their related processes and *production* methods, including applicable administrative provisions, with which compliance is compulsory. It may also include or deal exclusively with symbols, packaging, marking, or labelling requirements as they apply to a product or process or with terminology requirements as applied to a product, process or production method. *Technical regulations* for *facilities (objects)* shall include hygiene requirements for such *facilities (objects)*. Safety requirements for *non-edible products of animal origin* shall be prescribed in *veterinary-sanitary measures*;
- 92) **Commodities** – animals, non-edible products of animal origin, reproductive material, feed of animal origin, biological products and pathological material;
- 93) **Authorized laboratory** – an accredited veterinary laboratory authorized by the competent state bodies to test (to measure parameters and analyze), according to special methods and procedures defined in international standards, guidelines and recommendations, *non-edible products of animal origin, feed, feed additives, veterinary preparations, substances*;
- 94) **Authorised veterinarian** – a doctor of veterinary medicine that has been authorised by the *Department* to perform certain functions of *state veterinary-sanitary control*;
- 95) **Risk management** – the process of identifying, selecting, and implementing measures that can be applied to reduce the level of *risk*;
- 96) **Notifiable disease** – a disease from the list approved by the *Department*, and that, as soon as detected or suspected, must be immediately reported to a *state inspector of veterinary medicine* or *authorised veterinarian*;

- 97) **List A diseases** – transmissible *animal diseases* which have the potential for very serious and rapid spread, irrespective of national borders, which are of serious socio-economic or *animal* and/or related human health consequence and which are of major importance in the international trade of *animals* and *animal* products;
- 98) **Animal disease** – the clinical and/or histopathological manifestation of pathogenic agents;
- 99) **Micro-organism strains** – genetically homogeneous populations of micro-organisms within a species having certain stable specific morphological features and biological properties;
- 100) **Qualitative risk assessment** – an assessment where the outputs on the likelihood of the outcome or the magnitude of the consequences associated with the subject of a *risk* assessment are expressed in qualitative terms such as 'high', 'medium', 'low' or 'negligible'.
- 101) **HACCP (Hazard Analysis and Critical Control (containment) Points)** - a science based system which identifies, evaluates, and controls hazards which may result in products or means, such as *veterinary preparations* and *feed*, that are not safe for their intended use;

Article 2: Legislation on Veterinary Medicine

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

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

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

- 1) Protecting the population from *zoonoses*;
- 2) Protecting the territory of Ukraine from introduction of *animal disease* from the territories of other countries or from a *quarantine zone*;
- 3) Protecting *animals* and the population from *animal diseases* by applying preventive measures, conducting diagnostics, and providing medical treatment;
- 4) Ensuring that *commodities*, *feed of plant origin* and *finished feed* will not transmit or become a means of transmitting *animal disease*;
- 5) Establishing effective and efficient means for detecting, containing, controlling, and eradicating endemic *animal diseases* if possible, and eradicating exotic *animal diseases* that are introduced into the territory;
- 6) Ensuring proper and efficient measures to eliminate outbreaks of *animal disease* with the purpose to minimize loss of *animals* and, in the case of *zoonoses*, minimize the *risk* to humans;
- 7) Monitoring *feed* and water to ensure that *feed* and water consumed by *animals* is suitable and not capable of transmitting *animal disease*;
- 8) Ensuring the proper, appropriate, effective, and safe use of *veterinary preparations*;
- 9) Protecting the environment from negative effects associated with production and *circulation* of *animals*;

- 10) Protecting *animal* welfare by ensuring humane treatment of *animals* throughout their life span and particularly during development and application of *veterinary-sanitary measures* and *technical regulations*;
- 11) Conducting clinical examination of *animals* before slaughter and conducting *veterinary-sanitary testing* of *non-edible products of animal origin*, including bacteriological, radiological, parasitological and toxicological *laboratory examination*;
- 12) Implementing *state veterinary-sanitary control* and *supervision* during production and *circulation* of *veterinary preparations* and *feed* and implementing *state veterinary-sanitary supervision* during *circulation* of *feed additives, devices of veterinary medicine, and means of animal care*;
- 13) Implementing a national programme for monitoring of the hygienic suitability of *feed*;
- 14) Implementing a national programme for monitoring residues of *veterinary preparations* in *animals* and *animal* products intended for human consumption;
- 15) Facilitating continuing education and upgrading of the skills of *veterinary medicine specialists*;
- 16) Facilitating the practical introduction and wide implementation of achievements in *veterinary medicine*;
- 17) Implementing standard and/or extended border veterinary-sanitary control for *objects subject to state veterinary-sanitary control and supervision*;
- 18) Controlling the movement of *commodities* subject to *state veterinary-sanitary control and supervision* within Ukraine; and
- 19) Facilitating the implementation of an *animal* identification system.

SECTION II - STATE MANAGEMENT IN THE FIELD OF VETERINARY MEDICINE

Article 4: State Management Bodies in the Sphere Veterinary Medicine

State management in the sphere of veterinary medicine shall be carried out by the Cabinet of Ministers of Ukraine, central body of executive power on agrarian policy issues, the State Department of Veterinary Medicine, its *territorial bodies*, and *regional services*.

Article 5: Competence of the Cabinet of Ministers of Ukraine in the Sphere of Veterinary Medicine

The Cabinet of Ministers of Ukraine shall be responsible for:

- 1) Ensuring implementation of state policies in the sphere of veterinary medicine;
- 2) Drafting and implementing relevant general state programs;

- 3) Carrying out *veterinary-sanitary measures* directed at securing *veterinary-sanitary and epizootic welfare*, including protecting the territory of Ukraine against introduction of pathogens of *animal disease* from territories of other countries or from *quarantine zones*, ensuring safety of *products of animal origin*, introducing *animal quarantine*, and protecting the environment from potential negative effects associated with livestock rearing;
- 4) Ensuring financing and logistic support of the *state institutions of veterinary medicine*;
- 5) Implementing state policies as to licensing in the field of veterinary medicine;
- 6) Concluding international agreements, including agreements on equivalence of *veterinary-sanitary measures*; and
- 7) Executing other authorities in the administered sphere.

Article 6: Competence of the Central Body of Executive Power on Agrarian Policy Issues

The central body of executive power on the agrarian policy issues shall:

- 1) Guarantee implementation of state policies in the field of veterinary medicine and protect the territory of Ukraine from introduction of *animal diseases* from territories of other countries or from a *quarantine zone*;
- 2) Direct and coordinate activities of the state bodies of veterinary medicine to ensure *veterinary-sanitary and epizootic welfare* and adherence to the procedures regulating *state veterinary-sanitary control* and supervision.

Article 7: State Department of Veterinary Medicine and its Bodies

- (1) The State Department of Veterinary Medicine (hereinafter: *Department*) is the government body of state administration acting within the central body of executive power on agrarian policy issues that implements state policies in the sphere of veterinary medicine.
- (2) In order to carry out its tasks, the *Department* shall create relevant *territorial bodies* and *regional services*.
- (3) The *Department*, its *territorial bodies*, and the *regional services* shall constitute an integral system of state veterinary medicine bodies (hereinafter: *state veterinary bodies*).
- (4) The Head of the *Department*, his deputies and heads of the *Department* administrations are simultaneously, according to their positions, the Chief State Inspector of Veterinary Medicine of Ukraine (hereinafter: *Chief State Inspector of Veterinary Medicine*) and his deputies, respectively.
- (5) Heads of the *territorial bodies* of the Autonomous Republic of Crimea, oblasts, city of Kyiv and city of Sevastopol, cities, rayons and *regional services*, and their deputies are, simultaneously according to their positions, chief *state inspectors of veterinary medicine* and deputies to the chief *state inspectors of veterinary medicine* of the above regions, and *state veterinary doctors* of the *state veterinary bodies* are simultaneously, according to their positions, *state inspectors of veterinary medicine*.

- (6) The Departement shall develop, review and adopt *veterinary-sanitary measures*, including for example, prevention, medical treatment, diagnostics, and eradication of *notifiable diseases*;
- (7) The following shall be within the competence of the *state veterinary bodies*:
- 1) Applying *veterinary-sanitary measures* to protect Ukraine's territory from introduction of *animal diseases* from other countries and from *quarantine zones*;
 - 2) Implementing *state veterinary-sanitary control and supervision* for *animals, non-edible products of animal origin, micro-organism strains, reproductive material, pathological material, feed of animal origin, feed of plant origin, finished feed, veterinary preparations, devices of veterinary medicine*, and *facilities* where the above objects are kept, produced, processed, or *circulated* (hereinafter: *objects subject to state veterinary-sanitary control*);
 - 3) Coordinating and organising execution of *veterinary-sanitary measures*;
 - 4) Determining the *veterinary-sanitary status* of the country and particular zones within the country and the *veterinary-sanitary state of facilities (objects)* within Ukraine;
 - 5) Organizing, with the bodies of health care, the protection of people from *zoonoses* and timely exchange of information on such *animal diseases*;
 - 6) Issuing *veterinary documents*;
 - 7) Verifying the validity of *veterinary documents*;
 - 8) Conducting ante-mortem inspection of animals and organising *veterinary-sanitary testing* of *non-edible products of animal origin*;
 - 9) Issuing operating permits for *facilities (objects)* used for producing, processing, and *circulating non-edible products of animal origin, veterinary preparations, feed, and feed additives* and keeping the register of such *facilities (objects)*;
 - 10) Analysing causes of *animal diseases, maladies*, and murrain;
 - 11) Coordinating the activities carried out by *state veterinary doctors* and *specialists of veterinary medicine* employed by *state institutions of veterinary medicine*, regardless of their subordination;
 - 12) Providing insurance bodies with conclusions (reports) as to the infected *animals* forcedly slaughtered, perished or destroyed;
 - 13) Participating in the work of the commissions on allocation of land plots;
 - 14) Suspending the operating permit or imposing restrictions on the activities of *facilities (objects)* that are used for production, processing and *circulation* of *animals, non-edible products of animal origin, veterinary preparations, feed, and feed additives*, as well as related means of transportation, if *operators of facilities* violate *veterinary-sanitary measures*;
 - 15) Organizing laboratory-clinical (bacteriological, virus, chemic-toxicology, pathology-anatomy, histology, parasitology, radiology) and other analysis in order to diagnose *animal diseases* and evaluate the safety of *non-edible products of animal origin, reproductive material, feed, feed additives, veterinary preparations*, and water for *animals*;
 - 16) Organising disinfection and control of insects and rodents.

- 17) Conducting standard veterinary-sanitary border control, and, when warranted, extended veterinary-sanitary border control for *commodities, substances and feed of plant origin* that are presented for import; and
- 18)
- (8) The competence of the *Department* shall include:
 - 1) Registering of veterinary preparations, feed additives, premixes and finished feed
;
 - 2) Organising elaborating of, and adopting, *technical regulations* for *devices of veterinary medicine, means of animal care, veterinary preparations, finished feed, and other objects subject to state veterinary-sanitary control and supervision*, including *Good Manufacturing Practices* for *veterinary preparations, feed additives, premixes, and finished feed*;
 - 3) Keeping the State Register for Veterinary Preparations;
 - 4) Organising execution of *state veterinary-sanitary control and supervision* of production and *circulation* of *objects subject to state veterinary-sanitary control*, including ordering and conducting laboratory analysis of such objects;
 - 5) Organising evaluation of the usage of *veterinary preparations* and their effect on *animal* health;
 - 6) Distributing of funds allocated from the State Budget of Ukraine for financing programs in the sphere of veterinary medicine between the *state veterinary bodies* and *state institutions of veterinary medicine*;
 - 7) Notifying the World Animal Health Organisation upon activation of *animal quarantine* for a *List A disease*, its expected effective term, and the date of its deactivation;
 - 8) Introducing restrictions or prohibitions for import and transit of *commodities* and other objects that may carry *List A disease* or other *notifiable diseases* from certain countries or certain *zones* to Ukraine due to confirmed *outbreaks* of *List A diseases* or other *notifiable diseases*;
 - 9) Introducing restrictions or prohibitions for exports of *commodities* and other objects that may carry *List A diseases* or other *notifiable diseases* from the entire territory or certain *zones* within Ukraine due to confirmed *outbreaks* of *List A diseases* or other *notifiable diseases*;
 - 10) Participating in preparing and drafting of international agreements on veterinary medicine issues, entering into inter-departmental agreements with *Veterinary Administrations* of other countries, and participating in the work of the *relevant international organizations*;
 - 11) Drafting and approving regulations on the *territorial bodies, regional services, and state institutions of veterinary medicine*, including specifying the structure of the *veterinary services* and staff numbers necessary for efficient operation thereof;
 - 12) Drafting and approving *veterinary-sanitary measures* and other laws and sub-legal acts on veterinary medicine issues within its competence; and
 - 13) Establishing maximum permitted levels of *veterinary preparations, feed additives* and toxins and other *contaminants* in *feed* and *feed additives*.

- (9) *State veterinary-sanitary supervision* at the state border and for internal transport shall be conducted by the *Chief State Inspector of Veterinary Medicine of Ukraine, Chief State Inspectors of Veterinary Medicine* of the Autonomous Republic of Crimea, oblasts, cities of Kyiv and Sevastopol, cities, rayons, the *regional services*, their deputies, and *state inspectors of veterinary medicine*.
- (10) Sub-legal acts of the *Department* issued within its competence shall be mandatory for execution by the state bodies, legal persons (Ukrainian and foreign), citizens of Ukraine, foreigners, and persons without citizenship residing or otherwise staying in the territory of Ukraine.

Article 8: Veterinary Medicine Subdivisions of Ministries, Other Central Bodies of Executive Power, and Their Territorial Bodies

- (1) Veterinary medicine subdivisions of ministries, other central bodies of executive power and their *territorial bodies* shall organize and perform their work in accordance with this Law and shall functionally be subordinate 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) Veterinary medicine subdivisions of ministries, other central bodies of executive power and their *territorial bodies* shall operate in compliance with the provisions adopted by heads of these bodies upon approval of the *Department* and its *territorial bodies*.

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

- (1) Subdivisions of veterinary militia on quarantine veterinary measures enforcement of the Ministry of Interior of Ukraine and relevant subdivisions of its main offices and offices in the Autonomous Republic of Crimea, cities of Kyiv and Sevastopol, cities, rayons shall be established to provide practical assistance to the *state veterinary bodies* in organizing and enforcing measures relating to prevention, containment and, when appropriate, eradication of *notifiable diseases* and shall be staffed exclusively with *veterinary doctors*, who are according to the occupied positions, *state inspectors of veterinary medicine*.
- (2) The subdivisions of veterinary militia of the Ministry of Interior of Ukraine on Enforcement of the Quarantine Veterinary Measures on Control and Supervision over Fulfilment of the Requirements of Veterinary and Sanitary Measures shall be subordinated to the *Department*.
- (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 for subdivisions of veterinary militia on quarantine veterinary measures enforcement.

SECTION III - STATE VETERINARY-SANITARY CONTROL AND SUPERVISION

Article 10: Officials Providing State Veterinary-Sanitary Control

- (1) *State inspectors of veterinary medicine* shall carry out *state veterinary-sanitary control*.
- (2) The *Chief State Inspector of Veterinary Medicine* may empower *licensed veterinary doctors* with the authorities of *state inspectors of veterinary medicine* to conduct *state veterinary-sanitary control* (hereinafter: *authorised veterinarians*). The *Chief State Inspector of Veterinary Medicine* may also appoint doctors of veterinary medicine employed at state clinics of veterinary medicine as *authorised veterinarians* until such time when the state clinic employing such doctors are privatised.
- (3) *State veterinary-sanitary control* for objects affiliated to the Ministry of Defence of Ukraine, Ministry of Interior of Ukraine, Security Service of Ukraine, and the State Committee on Matters of Protection of the State Border of Ukraine shall be carried out by subdivisions of veterinary medicine of these bodies.

Article 11: Rights and Obligations of State Veterinarians Providing State Veterinary-Sanitary Control

- (1) State inspectors of veterinary medicine and *authorised veterinarians* conducting *state veterinary-sanitary control* shall have the right to:
 - 1) Check the adherence of persons to *veterinary-sanitary measures* for transportation of *objects subject to state veterinary-sanitary control and supervision*, and availability of relevant accompanying *veterinary documents*;
 - 2) Check the safety of *non-edible products of animal origin* and their conformity to requirements of legislation and *technical regulations*;
 - 3) Take samples of *commodities* and other *objects subject to state veterinary-sanitary control and supervision* for *veterinary-sanitary testing*
 - 4) Evaluate samples of *non-edible products of animal origin* and other *objects subject to state veterinary-sanitary control and supervision* for the purpose of checking their adherence to *veterinary-sanitary measures* and minimum quality specifications established in relevant *technical regulations*;
 - 5) Check the *veterinary-sanitary state* at production facilities and storage conditions for *reproductive material*;
 - 6) Check observation of *veterinary-sanitary measures* at the *facilities (objects)* used for maintaining *animals*, producing and circulating *non-edible products of animal origin, veterinary preparations, substances and feed*,
 - 7) Inspect and if necessary, give orders, instructions and commands regarding the disinfection of vehicles, according to *international standards, guidelines and recommendations*, and *veterinary-sanitary measures*, that have travelled through *quarantine zones* for *notifiable diseases*;
 - 8) Conduct standard veterinary-sanitary border control for transit consignments of *animals*;
 - 9) Conduct standard veterinary-sanitary border control, and when warranted extended veterinary-sanitary border control, for imported *commodities, substances and feed of plant origin*;

- 10)
- 11) Issue *international veterinary certificates* for export consignments of *commodities*.
- (2) State inspectors of veterinary medicine and authorised veterinarians providing state veterinary-sanitary control shall:
 - 1) Observe requirements of legal acts on issues of veterinary medicine and labour protection;
 - 2) Notify without delay the heads of relevant *state veterinary bodies* on revealed violations of *veterinary-sanitary measures* laid down by legislation.

Article 12: Officials Providing State Veterinary-Sanitary Supervision

- (1) *State veterinary-sanitary supervision* shall be carried out by the *Chief State Inspector of Veterinary Medicine* of Ukraine, chief *state inspectors of veterinary medicine* of the Autonomous Republic of Crimea, 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* shall coordinate execution of *state veterinary-sanitary supervision*.
- (3) Officials carrying out *state veterinary-sanitary supervision* shall be provided with uniforms at the account of the general and special fund of the State Budget of Ukraine.
- (4) Specimens of uniforms and mark of rank for officials providing *state veterinary-sanitary supervision* are approved by the Cabinet of Ministers of Ukraine.

Article 13: Rights and Obligations of State Inspectors of Veterinary Medicine Providing State Veterinary-Sanitary Supervision

- (1) State inspectors of veterinary medicine implementing *state veterinary-sanitary supervision* shall have the right to:
 - 1) For the purpose of conducting *veterinary-sanitary control and supervision*, unhindered access to *facilities (objects)* where *commodities, veterinary preparations, feed, premixes*, and *feed additives* are produced, processed, or *circulated* during usual business hours ;
 - 2) In the event of an outbreak of notifiable disease, have unhindered access at any time to *facilities (objects)* engaged in producing or *circulating objects subject to commodities* that are located within a *quarantine zone* to verify the *veterinary-sanitary state* of such *facilities (objects)* and/or the *commodities* therein and/or implement measures required under *animal quarantine*;
 - 3) Obtain information needed to determine the *veterinary-sanitary state* of *non-edible products of animal origin* to identify causes of *animal diseases* with the aim of determining the *veterinary-sanitary status* of a zone;
 - 4) Verify execution of *state veterinary-sanitary control*;
 - 5) Issue binding orders on application of *veterinary-sanitary measures* (including slaughtering, forced slaughtering of *animals*, disinfecting or destroying *non-edible products of animal origin*, following procedures for processing, utilization (reconditioning), or destruction of objects if they are carrying *notifiable*

diseases or there is a suspicion that the objects are infected with or carrying a *notifiable disease*, or objects have toxins or radio-nuclides in amounts in excess of permitted levels);

- 6) Prohibit export, import, and other *circulation of commodities, substances, feed, feed additives, veterinary preparations, and devices of veterinary medicine* if they do not comply with relevant *veterinary-sanitary measures* and/or *technical regulations*;
 - 7) Issue orders on withdrawing from circulation *commodities, substances, feed, feed additives, veterinary preparations, and devices of veterinary medicine* that do not comply with relevant *veterinary-sanitary measures* or *technical regulation*;;
 - 8) Issue directives on the suspension, termination, renewal and annulment (cancellation) of approvals and certificates;
 - 9) Set up, if necessary, committees of veterinary medicine experts attracting *veterinary medicine specialists* of scientific-and-research institutions and higher educational institutions of the same profile in order to identify *animal diseases* and causes of death in *animals*;
 - 10) Inform the licensing bodies in the sphere of veterinary medicine on violations of licensing conditions by persons which have obtained the relevant license;
 - 11) Limit, prohibit or terminate, according to current legislation, business activities of legal or physical persons should they violate *veterinary-sanitary measures*, when such violations may cause immediate danger to human and/or *animal* life and health;
 - 12) Organise implementation of *anti-epizootic measures* by legal and physical persons involved in professional activity in *veterinary medicine*;
 - 13) Levy administrative fines pursuant to the procedure determined by legislation.
- (2) State inspectors of veterinary medicine implementing state veterinary-sanitary supervision shall:
- 1) Be bound within 24 hours of detection or suspicion of an occurrence of a *List A disease* or *outbreak* of other *notifiable diseases* or mass-scale poisoning of *animals* to notify the relevant bodies of executive power on the necessity of establishing a special regime and measures of *animal disease* control.
 - 2) Participate in activities of the State committees on putting into operation facilities (*objects*) within which *objects subject to state veterinary-sanitary control and supervision* are produced or *circulated*.

Article 14: State and Authorised Laboratories

- (1) Laboratory diagnostics of animal diseases and evaluation of the *veterinary-sanitary state* of *non-edible products of animal origin, feed, feed additives, veterinary preparations, and substances* shall be conducted in accordance with recommendations, guidelines and standards of the *relevant international organisations* by the Central State Scientific-Production Laboratory of Veterinary Medicine, (hereinafter: the Central Laboratory), the Republican Laboratory of the Autonomous Republic of Crimea, oblast, regional, inter-oblast, municipal, inter-district, and district state laboratories of veterinary medicine that are accredited by the national accreditation body or or a comparable accreditation body of a foreign country and authorised for the necessary diagnostic analysis according to the procedures established by the Department.
- (2) Laboratories of other institutions of veterinary medicine, scientific-research institutions, higher education establishments, and other legal entities that are accredited in accordance with national law may also carry out laboratory analysis pursuant to authorisation by the *Department*.

- (3) Authorized laboratories shall receive special permission from the *Department* to work with pathogens of *List A diseases*.
- (4) After conducting the appropriate laboratory analysis, authorised *accredited laboratories* shall issue a laboratory report with an evaluation of the laboratory tests results (an expert opinion).
- (5) The Central Laboratory shall be responsible for conducting the highest quality *testing* for detection and/or identification of *animal diseases* and analysis of *feed* for hygienic suitability, provide methodical support to the state laboratories of veterinary medicine and perform control over the activities of state and *authorized laboratories* of veterinary medicine.
- (6) The State Research and Scientific Control Institute of Veterinary Preparations and Feed Additives shall be responsible for conducting the highest quality *testing* for detection and/or identification of *veterinary preparations* and *feed additives*.
- (7) The Central Laboratory shall conduct *arbitration analysis* in response to an appeal regarding the results of laboratory testing of *commodities* or *feed*. The laboratory of the State Research and Scientific Control Institute of Veterinary Preparations and Feed Additives shall conduct *arbitration analysis* in response to an appeal regarding the results of laboratory testing of *veterinary preparations* and *feed additives* by an *authorised laboratory*. The results of the *arbitration analysis* shall be final. The procedure for conducting *arbitration analysis* shall be established by the central body of executive power on agrarian policy issues.
- (8) Laboratories in *markets* are structural units of relative *state institutions of veterinary medicine* that shall act on the basis of statutes approved by the *Department*. Owners or the authorized administration of *markets* shall be obliged to provide *market* laboratories with properly fitted premises.
- (9) State laboratories of veterinary medicine are legal entities acting on the basis of provisions approved by the *Department*.
- (10) All laboratories referred to in this Article shall be accredited according to international laboratory accreditation *standards* in accordance with relevant national legislation by the national accrediting body or the accrediting body of a foreign country.

Article 15: Guarantees of Rights of Officials Who Conduct State Veterinary-Sanitary Control and Supervision

- (1) State inspectors of veterinary medicine and authorised veterinarians who conduct state veterinary-sanitary control and state inspectors of veterinary medicine that conduct state veterinary-sanitary supervision are independent in their activity and are guided by this Law and other legal acts on veterinary medicine issues. State bodies, legal persons, citizens of Ukraine, foreign citizens, and persons without citizenship residing or staying in the territory of Ukraine shall be obliged to assist them when they carry out their official duties.
- (2) Offence of a person who conducts *state veterinary-sanitary control and supervision* as well as resistance, threats, violence and other actions that hinder fulfilment of such person's duties shall entail liability established by the law.
- (3) Damage caused to the property or health of *state officials* who conduct *state veterinary-sanitary control and supervision*, while fulfilling his (or her) official duties, shall be fully compensated from the state budget. The state in the case of such compensation shall acquire the right for the action of recourse to the persons guilty in causing the damage.
- (4) No officials' instructions can be grounds for any illegal action or inaction contrary to the duties of *state inspectors of veterinary medicine* and *authorised veterinarians*.

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

Article 16: Objectives of Veterinary-Sanitary Measures

The *Department* shall undertake appropriate and necessary *veterinary-sanitary measures* to fulfil the following objectives:

- 1) Protecting *animal* life and health from the *risks* resulting from the entry, establishment or spread of *animal diseases*, *animal disease*-carrying, or *animal disease*-causing organisms into Ukraine or minimizing those *risks*;
- 2) Protecting human life and health from the *risks* resulting from the entry, establishment or spread of *zoonoses*, *zoonoses*-carrying, or *zoonoses*-causing organisms or minimizing those *risks*;
- 3) Protecting *animal* life and health from the *risks* resulting from the existence of *contaminants* and *animal disease*-causing organisms in *non-edible products of animal origin* and *feed*.

Article 17: Appropriate Level of Animal and Related Human Health Protection

- (1) The Department 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 execution of *state programmes* for such *animal diseases*;
 - 2) The estimated economic costs to the livestock sector of Ukraine associated with introduction of an *animal disease* not present in Ukraine or further spread of *animal diseases* that are present in Ukraine;
 - 3) Determination of the level of *risk* accepted by neighbouring 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 18: Preparing, Reviewing, Revising and Adopting Veterinary-Sanitary Measures

- (1) *Veterinary-sanitary measures* shall be prepared, reviewed, revised and adopted by the *Department* based on the following:
 - 1) Subject to the provision of item 4 of this paragraph, all *veterinary-sanitary measures* shall be based on scientific principles and available scientific evidence, including relevant processes and production methods; relevant *inspection*, sampling, and *testing* methods; 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 *preventive animal quarantine* or other treatment.

- 2) All *veterinary-sanitary measures* shall be based on *international standards, guidelines, and recommendations* of the *relevant international organisations*.
 - 3) In case *international standards, guidelines, and recommendations* do not exist or are insufficient to fulfil the *appropriate level of animal and related human health protection*, *veterinary-sanitary measures* shall be prepared following a *risk analysis* using the methodology developed by the *relevant international organisations*.
 - 4) When scientific evidence needed for *risk analysis* is insufficient, or in *urgent circumstances*, *veterinary-sanitary measures* shall be prepared on the basis of available relevant information, obtained from the *relevant international organisations*, or the *veterinary-sanitary measures* employed by *interested trading partners*.
- (2) When preparing, reviewing, 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) When preparing, reviewing, revising, and adopting *veterinary-sanitary measures*, arbitrary or unjustifiable discrimination shall be prohibited between *interested trading partners* exporting to Ukraine when Ukraine and the *country of origin of commodities* or when one *country of origin* relative to another *country of origin* have identical or similar *veterinary-sanitary status*.
 - (4) When preparing, reviewing, revising, and adopting *veterinary-sanitary measures*, relevant measures in another country shall be considered equivalent to those of Ukraine, and consequently accepted, if the other country shows in an objective manner that its measures achieve the same or higher level of protection of *animal health and life* as is required by Ukraine.
 - (5) All *veterinary-sanitary measures* referred to in this Article, including measures adopted in *urgent circumstances*, shall be reviewed and updated as new scientific information becomes available or on the basis of significant (substantive) comments from *interested trading partners* or from *Ukrainian persons* in order to make sure that such measures achieve, but do not exceed, the *appropriate level of animal and related human health protection*.
 - (6) All *veterinary-sanitary measures* adopted due to *urgent circumstances* shall be reviewed and updated no later than within six months of the date of issue or last date of review 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 establish and approve a procedure for development and revision of *veterinary-sanitary measures* to implement the provisions of this Article.

Article 19: Conducting Risk Analysis

- (1) *Risk analysis* conducted in conjunction with the possible import of *commodities* shall be fully documented in written form. The document shall include the following minimum content:
 - 1) Purpose for the *risk analysis*;
 - 2) Identification of the *animal disease* and means of entry (hosts, mode of transmission) that allow the entry, establishment or spread of such;

- 3) Sources of information;
 - 4) Conclusions of the *animal disease risk assessment* including the probability of harm to *animals* and humans and the consequences thereof; and
 - 5) The *risk management* options that were identified and the reasons for rejecting alternative options.
- (2) When sufficient scientific and other technical data exist, a *quantitative risk assessment*, as defined by the *relevant international organisations*, shall be undertaken.
 - (3) When scientific and other technical data do not exist or are insufficient for the purpose of a *quantitative risk assessment*, a *qualitative risk assessment* shall be undertaken.
 - (4) The *risk analysis* document referred to in paragraph 1 of this Article shall be made available to any interested persons whether domestic or foreign in writing and/or electronic form.

Article 20: Risk Management Procedures

- (1) When importing *commodities*, the objective of *risk management* shall be to reduce the related *risk*, in line with the *appropriate level of animal and related human health protection* as defined for Ukraine.
- (2) When considering alternatives for reducing the *risk* of introduction of *animal disease* from importing *commodities*, the chosen *veterinary-sanitary measures* shall not be more trade-restrictive than necessary to achieve the *appropriate level of animal and related human health protection* taking into consideration the technical and economic feasibility of proposed alternative measures.
- (3) The economic feasibility of *veterinary-sanitary measures* shall include the potential damage in terms of loss of production or sales of *animals* or *products of animal origin* in the event of the entry, establishment or spread of *animal disease*; the costs of containment, control, or eradication of such disease; and the relative cost-effectiveness of alternative approaches to limiting *risks*.

Article 21: 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 organisations*;
 - 2) Fulfilment of reporting requirements to the *relevant international organisations* and application of *veterinary-sanitary measures* pursuant to international agreements concluded by Ukraine;
 - 3) The required qualifications for staff members of the *foreign Veterinary Administration*, including the level of their scientific background, necessary experience, and competence to make solid professional decisions;

- 4) Independence of staff members of the *foreign Veterinary Administration* from any commercial, financial, hierarchical, political or other pressures, which might affect their judgment or decisions;
- 5) The impartiality of staff members, impartiality of provision of services, and impartiality of decision making by the *foreign Veterinary Administration*;
- 6) The integrity of staff members of the *foreign Veterinary Administration* and the associated prevalence of fraud, corruption, or falsification;
- 7) The transparency of decision making by the *foreign Veterinary Administration*;
- 8) The presence of appropriate legislation and organisation that ensures control over the establishment and fulfilment of *veterinary-sanitary measures* and of *international veterinary certification* activities, including legislative acts, stipulating responsibilities and the structure of the *foreign Veterinary Administration*;
- 9) Establishment of procedures and *standards* relating to:
 1. Programming and management of activities, including international veterinary certification activities;
 2. Prevention and control of *animal disease* outbreaks;
 3. Epizootic surveillance and zoning of the country for *veterinary-sanitary status*;
 4. Inspection and sampling techniques;
 5. Diagnostic analysis for *animal diseases*;
 6. Preparation, production, and control of products of animal origin for use in the diagnosis of *animal diseases* and for production of *veterinary preparations*;
 7. Treatments intended to destroy pathogens in *products of animal origin*;
 8. Minimum qualification level (education and professional training) for laboratory specialists and those officials authorised to inspect *commodities* and issue *international veterinary certificates*;
 9. Use of *international standards, guidelines, and recommendations* when issuing *international veterinary certificates*;
 10. Use of *international standards, guidelines, and recommendations* on implementing control *animal disease outbreaks measures*; and
 11. Frequency of serological surveys for *animal disease*.
- 10) The frequency of invalid *international veterinary certificates*—certificates which attest to an import consignment's freedom from *animal disease* that have been invalidated by laboratory analysis of samples from such shipment—issued by officials of the *foreign Veterinary Administration* for consignments of *commodities* presented for import; and
- 11) Other factors recommended by the *relevant international organisations*.

- (2) All factors considered and relevant conclusions made when evaluating the effectiveness of a *foreign Veterinary Administration* shall be fully documented and promptly made available to the *foreign Veterinary Administration* upon request. In addition, should the foreign country request consultations or have comments on the evaluation, consultations shall commence promptly and the results of the consultations and clarifications shall be analysed to determine whether there is a basis for revising the evaluation of effectiveness of the *foreign Veterinary Administration*.

Article 22: Notifying Proposed Veterinary-Sanitary Measures

- (1) Except as provided in paragraphs 5 through 8 of this Article, whenever international *standards* do not exist or a proposed *veterinary-sanitary measure* does not conform to international *standards*, the *Department* shall take the following actions:
- 1) A notice shall be published promptly in mass media publications in such a manner as to enable interested parties to become acquainted with the content of proposed measures; and
 - 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 to be sent to *interested trading partners* through the centre for processing enquiries and notifications regarding *veterinary-sanitary measures* (hereinafter: *enquiry and notification centre*).
- (2) The notice referred to in item 2 of paragraph 1 of this Article shall be submitted no less than 60 days before adoption of the proposed *veterinary-sanitary measure*. The notice shall be prepared in the format required by the *relevant international organisations* or international agreements to which Ukraine is a party and 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, identify the parts which in substance deviate from *international standards, guidelines and recommendations*.
- (4) Upon written request of an *person* or *interested trading partners*, prior to finalizing the *veterinary-sanitary measure*, the *Department* shall discuss comments that were received, and, without discrimination, take those into account when preparing the final draft of the *veterinary-sanitary measure*.
- (5) When *urgent circumstances* arise and as a consequence an emergency *veterinary-sanitary measure* is adopted, a notice of the emergency *veterinary-sanitary measure* shall be published in mass media publications.
- (6) If the emergency *veterinary-sanitary measure* referred to in paragraph 5 of this Article is expected to significantly affect the exporting opportunities of other countries, the *Department* shall take the following actions:
- 1) A notice shall immediately be sent through the *enquiry and notification centre* to *interested trading partners*;
 - 2) The notice shall be prepared in the format required by the *relevant international organisations* or international agreements concluded by Ukraine;
 - 3) The notice 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 nature of the urgent problem(s).

- (7) Upon written request, the *Department* shall provide the text of the emergency *veterinary-sanitary measure* to *interested trading partners* or *persons*.
- (8) The *Department* shall review written comments about the emergency *veterinary-sanitary measure* received from *interested trading partners* and *persons*, and upon their written request, discuss such comments and take the comments and results of the discussion into account when considering revision of the emergency *veterinary-sanitary measure*.
- (9) The *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 officials in *Department* the responsibility for publishing and sending notifications to the *enquiry and notification centre*.

Article 23: Publishing and Enforcement of Veterinary-Sanitary Measures

All new and revised *veterinary-sanitary measures* shall be published promptly in the relevant official publication and the web site of the *Department* when adopted. Except for those emergency *veterinary-sanitary measures* adopted in response to *urgent circumstances*, and also in case of measures that reduce import restrictions, which are to come into force immediately, *veterinary-sanitary measures* shall come into force no sooner than six months after relevant publication.

Article 24: 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 fulfil the objectives referred to in Article 16 of this Law;
- 2) *Veterinary-sanitary measures* shall not be applied in a manner that would constitute a disguised restriction on international trade; and
- 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 on international trade.

Article 25: Equivalence Agreements for Veterinary-Sanitary Measures

The *Department* shall, upon request of *interested trading partners*, conduct consultations on the equivalency of general or specific *veterinary-sanitary measures* aimed at further (subsequent) conclusion by the relevant body of state power of such bilateral and multilateral equivalency agreements.

Article 26: Control, Inspection, and Approval Procedures

- (1) The *Department* shall ensure, with respect to any procedure to check and ensure the fulfilment of the requirements of *veterinary-sanitary measures*, that:
 - 1) Such procedures conform to the *standards*, recommendations, and guidelines of the *relevant international organisations*;

- 2) Such procedures are executed expeditiously and without unjustifiable delay;
 - 3) Sampling requirements for control, inspection, and approval procedures are limited to what is reasonable and necessary;
 - 4) The applicant requesting control, inspection and approval procedures must be immediately informed of any deficiencies in the application so as to avoid any delay and if there are deficiencies in the application, the procedures shall be undertaken as far as practicable upon the request of the applicant;
 - 5) The expected time for completing such procedures shall be communicated to the applicants upon their request;
 - 6) The results of the procedure shall be promptly transmitted in written form to the applicant and in a complete manner;
 - 7) Such procedures shall be applied equally to *objects subject to state veterinary-sanitary control and supervision* of foreign as well as Ukrainian origin;
 - 8) All adopted procedures, including procedures to ensure that a product that has been changed (treated, processed or otherwise changed) continues to meet requirements of *veterinary-sanitary measures*, as well as the information required to conduct control, inspection, and approval procedures must be limited to what is necessary for the fulfilment of the *veterinary-sanitary measures*;
 - 9) Confidentiality of provided information shall be protected in order to ensure the commercial interests of the applicants;
 - 10) The fees collected for control, inspection, and approval procedures for imported *commodities* shall be equitable in relation to those for domestic *commodities* and not exceed the approximate cost of the service rendered;
 - 11) The sampling procedure and requirements associated with use of particular facilities for carrying out control, inspection, and approval procedures shall minimize inconvenience and be equitable for all *objects subject to state veterinary-sanitary control and supervision*, regardless of whether they are imported or of domestic origin;
 - 12) A procedure for reviewing complaints concerning the operation of control, *inspection*, and approval procedures shall be established with the aim to take corrective action when a complaint is justified.
- (2) The relevant body of state power shall issue the necessary sub-legal acts for the execution of the provisions of this Article. Cabinet of Ministers of Ukraine shall establish the level of fees, if any, to be collected for control, *inspection*, and approval procedures, according to the provisions of Article 99 of this Law

Article 27: Documentation of Veterinary-Sanitary Measures

- (1) The *Chief State Inspector of Veterinary Medicine* of Ukraine shall appoint a group of officials in the *Department* that is responsible for receiving and coordinating responses to all questions associated with *veterinary-sanitary measures*, including control, inspection and approval procedures, from interested parties whether foreign or domestic, as well as for the provision of the copies of relevant documents, upon request of the above persons, regarding, at least:
- 1) Adopted or proposed veterinary-sanitary measures;
 - 2) Control, inspection, and approval procedures; and

- 3) *Animal disease risk assessment* procedures, factors taken into consideration, and means of determining the *appropriate level of animal and related human health protection*.
 - 4) The membership and participation of Ukraine in the relevant international organizations or international agreements regarding veterinary-sanitary measures and the texts of such agreements
- (2) The *Department* shall issue the necessary sub-legal acts for the execution of this Article, including establishing the level of any fees for provision of this information to interested parties.

SECTION V - PROTECTION OF ANIMAL HEALTH

Article 28: Notifiable Diseases

- (1) The list of *notifiable diseases* shall be determined by the *Department* and include:
- 1) All *List A diseases*;
 - 2) *Exotic animal diseases* where an unacceptable level of *risk* to the *animal* and/or human population would occur if such were introduced and subsequently established in Ukraine;
 - 3) Those *animal diseases* present in Ukraine that present an unacceptable level of *risk* to the *animal* and/or human population if an *outbreak* were to occur or such *disease* were to spread in the territory.
- (2) Upon the decision of the *Chief State Inspector of Veterinary Medicine*, an *animal disease* may be classified as notifiable in order to collect information regarding the prevalence of such disease.

Article 29: Rights and Obligations of Persons Relating to Provision of Veterinary-Sanitary and Epizootic Welfare

Legal entities and natural persons involved in activities connected with keeping and *circulation* of *animals* as well as in production, processing, and *circulation* of *non-edible products of animal origin*, reproductive material, *veterinary preparations*, substances, *feed, feed additives and premixes*, in order to ensure *veterinary-sanitary and epizootic welfare* shall have the right to:

- 1) Receive from *state veterinary bodies*, other *state institutions of veterinary medicine*, local bodies of executive power, and bodies of local self-government information on the epizootic situation within the territory in which they operate;
- 2) Appeal decisions and actions of officials of *state veterinary bodies*, *authorized veterinarians*, or other *persons* authorized to fulfil the responsibilities of the *Department* to the relevant chief state inspector of veterinary medicine or to a court.

Article 30: Obligations of Persons Keeping and Circulating Animals

Legal entities and natural persons involved in activities connected with keeping and *circulating animals* shall:

- 1) Ensure that *animals* they raise, keep and/or *circulate* do not have *notifiable diseases*;
- 2) Fulfil lawful requirements of *state inspectors of veterinary medicine* and *authorised veterinarians* relating to anti-epizootic and/or animal quarantine measures, including restrictions on movement of *animals* and/or persons that came into contact with diseased *animals* or with *animals* suspected to have a *notifiable disease*, and other veterinary measures;
- 3) Immediately inform a *state inspector of veterinary medicine*, an *authorised veterinarian*, or an official of the *state veterinary bodies* on the unexpected death of an *animal*, or suspicion or detection of a *notifiable disease*, or unnatural behaviour of *animals*;
- 4) Prior to moving *animals* from the *facility (object)* where they are kept, obtain a movement permit from a *state inspector of veterinary medicine*;
- 5) Protect *animal* health and welfare by:
 1. Fulfilling *veterinary-sanitary measures*, including zoo-hygiene requirements and conditions in facilities for keeping *animals*;
 2. Providing hygienically suitable *feed* and water;
 3. Implementing preventive veterinary measures for *animal* health;
 4. Promptly procuring the services of a doctor of veterinary medicine to diagnosis and treat ill *animals*;
 5. Using *veterinary preparations* according to the instructions of a doctor of veterinary medicine;
 6. Preventing cruel treatment of their *animals*; and
 7. Ensuring that appropriate means of transport are used when moving their *animals* by vehicle.
- 6) Meet the requirements for identification of *animals* belonging to them;
- 7) Deliver *animals* to a determined place or provide appropriate conditions at the holding where the *animals* are kept for conducting veterinary examination, diagnostics, prophylactic and medical treatment, including analysis and vaccination, and if necessary, secure *animals* during provision of care, conduct or permit the taking of samples of *animal* tissue, blood, and other material for diagnostic purposes;
- 8) Keep records for three years for each animal on the acquisition and use of *veterinary medicinal products (means)*, *veterinary immunological products (means)*, and *medicated feed*;
- 9) Assist state inspectors of veterinary medicine and authorised veterinarians when they are carrying out their official duties;
- 10) Upon request of a *state inspector of veterinary medicine* or an *authorised veterinarian*, provide samples of *non-edible products of animal origin* for conducting relevant analysis.

Article 31: Registration of Livestock Facilities

- (1) Persons involved in raising animals for personal household consumption, including cattle, pigs, sheep, goats, rabbits, and poultry but excluding common household pets, as well as animals held for recreational purposes, shall be registered with the relevant *territorial bodies*. Such registry shall include the name of the owner of animals, address, telephone number, and other contact information, the species of animals held by a certain person, and the number of animals within each species
- (2) *Operators of facilities* used for commercial growing (rearing) of animals shall be obliged to register them with the relevant *territorial bodies* of the *Department*. Such registry shall include the species of animals held on the relevant *facilities (objects)*, number of animals within each species, name of the *operator of facilities* and, when applicable, owner of the animals, their addresses, telephone numbers, and other contact information.

Article 32: Implementation of Preventive Animal Quarantine

Animals that are being introduced into a herd from other *facilities (objects)*, including imported *animals* and *animals* that were purchased in a domestic market shall be subject to compulsory *preventive animal quarantine* of a pre-determined period of time. During *preventive animal quarantine*, *animals* shall be kept separately in specially designated and isolated places (*quarantine stations*) under the supervision of a *state inspector of veterinary medicine* or *authorised veterinarian* and must pass veterinary-sanitary examination. *Animals* may be included in the herd only upon completion of *preventive animal quarantine* with a written permit from a *state inspector of veterinary medicine* or *authorised veterinarian*.

SECTION VI - REGULATION OF CIRCULATION OF ANIMALS AND REPRODUCTIVE MATERIAL

Article 33: State Veterinary-Sanitary Control and Supervision of Animal Movements

- (1) *State veterinary-sanitary control and supervision* relating to *animals* that are being moved off the facility (object) where they are kept shall be conducted by the state veterinary bodies.
- (2) *Circulation of animals* that have a *notifiable disease* or symptoms thereof or for which there is suspicion of a *notifiable disease* shall be prohibited, except in the cases of the conveyance of property rights to these *animals* as a result of legal succession. Any movements of *animals* with or suspected of having a *notifiable disease* shall be allowed only with permission of the *state inspector of veterinary medicine*.
- (2) *State inspectors of veterinary medicine* and *authorised veterinarians* shall control the observance of the requirements for *animal* identification, *circulation*, and movement, including any form or documentation that may be required to move or transport *animals*.
- (3) The system for registration of livestock *facilities (objects)*, the *animal* identification system, and the recording of *animal* movements shall be such as to enable clear identification of the *animals* and traceability of their *facility (object)* of origin, movement, and *circulation*.

- (4) During transport by vehicle, the loading, reloading, and unloading of *animal* shipments are allowed only in those places that have the facilities that meet *veterinary-sanitary measures*.

Article 34: State Veterinary-Sanitary Control and Supervision at Markets

- (1) It is prohibited to circulate *animals* that are not accompanied by the required *veterinary documents*
- (2) *State veterinary-sanitary control and supervision* shall be conducted at any *market* where there is organized trade of live *animals*.
- (3) *State veterinary-sanitary control* in markets shall be carried out by *authorised veterinarians* and *state veterinary-sanitary supervision* by *state inspectors of veterinary medicine*.
- (4) Trade of *animals* shall be carried out only in places that are established for this purpose.
- (5) In case a *state inspector of veterinary medicine* discovers that trade in animals is being conducted in places not established for that purpose, the *state inspector of veterinary medicine* shall issue a directive to prohibit *circulation* of such animals for three months and shall levy a fine.

Article 35: State Veterinary and Sanitary Control and Supervision while Hunting

- (1) Relevant *state veterinary bodies* shall authorize opening of a hunting season within a defined territory after conducting compulsory epizootic surveillance of hunting forests.
- (2) Users of hunting forests and fishing facilities shall inform the nearest *state inspector of veterinary medicine* on suspicious (unnatural) *animal* behaviour and suspicious deaths of animals. A *state inspector of veterinary medicine* shall investigate such reports and when applicable, by inspecting carcasses and, base on his professional judgement, take samples of animal tissue for testing to an authorized laboratory.

Article 36: Permits for Events Featuring Animals

- (1) Persons conducting exhibits of *animals*, *animal* competitions, and setting up performances of travelling *animals* (fairs, travelling zoos, etc.) shall be obliged to obtain a permit for such from the chief *state inspector of veterinary medicine* of the relevant territorial body.
- (2) The permit referred to in paragraph 1 of this Article (hereinafter: *permit for exhibition*) shall be issued upon fulfilment of the veterinary-sanitary requirements within five calendar days of receipt of an application.
- (3) The person that conducts the event featuring animals shall display the *permit for exhibition* in a prominent place where the event is conducted.
- (4) The *permit for exhibition* shall be valid for a specified period of time but shall not exceed 30 calendar days.
- (5) The form and content of the application for a *permit for exhibition*, including necessary supplementary information related to the *animals* and the conditions that must be met by facilities shall be prescribed by the *Department*.

Article 37: Monitoring of the Health of Breeding Animals

- (1) *Animal* breeding centres 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 centres shall maintain records of the systematic monitoring, including records on the outcome of artificial insemination, and shall be obliged to present such to a *state inspector of veterinary medicine* upon request.
- (3) A *state inspector of veterinary medicine* shall be obliged to issue a written directive on temporary prohibition of the production of semen, fertilised ova, and embryos if it is suspected that breeding *animals* have become infected with an *animal disease* that can be transmitted by *animal* semen, fertilised ova, or embryos.
- (4) Upon suspicion of infection of breeding *animals* with an *animal disease* that can be transmitted by *reproductive material*, the *operator of the facility* or the owner of the *animals* shall provide samples of material to an authorized laboratory for laboratory examination. Should no *animal disease* be found, the temporary prohibition in paragraph 3 shall be lifted. If an *animal disease* is confirmed, the diseased *animal* and any others found to be similarly infected shall be removed from production of *reproductive material* according to the relevant rule book.
- (5) Upon the request of the owner of the *animal* breeding centre or the owner of the *animal*, *arbitration analysis* to validate or repudiate the finding of an *animal disease* shall be conducted according to the procedure prescribed by the *Department*.
- (6) The *Department* shall establish the procedure for systematic monitoring and the records and means of maintaining the necessary records.

Article 38: Circulation of Reproductive Material

It is prohibited to circulate semen for artificial insemination, fertilised 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 - ANIMAL QUARANTINE

Article 39: Establishment of the State and Local Emergency Anti-Epizootic Committees

- (1) The Cabinet of Ministers of Ukraine shall establish through its decision the State Emergency Anti-Epizootic Committee of Ukraine and order establishment of supporting local emergency anti-epizootic committees that will function only in times of *outbreaks of notifiable disease*.
- (2) The State Emergency Anti-Epizootic Committee of Ukraine shall be responsible for operative control, guidance, and co-ordination of the activities of local bodies of executive power, state services, and persons that are engaged in prevention and eradication of outbreaks of *List A diseases*.
- (3) The State Emergency Anti-Epizootic Committee of Ukraine shall be chaired by the Vice Prime Minister of Ukraine and consist of the *Chief State Inspector of Veterinary Medicine*, who shall be the Deputy-Chairman of the Committee, the deputies of the *Chief State Inspector of Veterinary Medicine*, heads of central

bodies of executive power on issues of agrarian policy, interior, economy, health protection, transport, emergency situations, finance, communication and information, forestry, state border protection, customs service, and also the Ukrainian Academy of Agrarian Sciences, and other officials as determined by the Cabinet of Ministers of Ukraine.

- (4) Local emergency anti-epizootic committees shall be established within the Council of Ministers of the Autonomous Republic of Crimea, oblasts', Kyiv and Sevastopol municipal administration, and district state administrations. The local emergency anti-epizootic committees shall, during a suspected or confirmed *outbreak of a List A disease*, report on a regular basis to and follow the orders of the State Emergency Anti-Epizootic Committee of Ukraine.
- (5) *Veterinary medicine specialists* included on the State Emergency Anti-Epizootic Committee of Ukraine shall, as long as the above Committee is active, be authorised to perform the duties of *state inspectors of veterinary medicine*.
- (6) Members of the State Emergency Anti-Epizootic Committee of Ukraine shall be provided with the means necessary to contain the *outbreak of animal disease* and, when appropriate, eradicate the *animal disease*, including *devices of veterinary medicine*, *veterinary preparations*, communication means and priority use of communication channels, specialised veterinary medicine and other vehicles, tickets for all types of transportation means, and lodging while conducting their official duties. Expenses for means necessary to counteract the *outbreak of animal disease* shall be compensated from the funds allocated for conducting *anti-epizootic measures*.

Article 40: Suspicion of Outbreak of Notifiable Disease

- (1) Owners (holders) of *animals*, *operators of facilities*, *licensed veterinary doctors*, *state veterinary doctors*, and *authorized veterinarians* shall be obliged to immediately inform a *state inspector of veterinary medicine* on the suspicion or detection of a *notifiable disease* or of an *animal disease* that was not registered in Ukraine before.
- (2) The *state inspector of veterinary medicine* who has responded to a report of suspicion of or detection of a *notifiable disease* shall notify the chief state inspector of veterinary medicine of the relevant territory immediately if the reported disease is believed to be a *List A disease*. The chief state inspector of veterinary medicine of the relevant territory shall immediately notify the *Chief State Inspector of Veterinary Medicine* of Ukraine, who in turn will notify the Chairman of the State Emergency Anti-Epizootic Committee of Ukraine.
- (3) The Chairman of the State Emergency Anti-Epizootic Committee shall immediately issue a decision on establishing local anti-epizootic committees..
- (4) In the event that the suspected *List A disease* is ruled out, the State Emergency Anti-Epizootic Committee of Ukraine may issue a decision on termination of its activities. If *outbreak of another notifiable disease* or of a highly infectious *animal disease* not previously known to occur in Ukraine is confirmed, the State Emergency Anti-Epizootic Committee of Ukraine shall determine whether it is necessary to remain continue its activities and/or which local emergency anti-epizootic committees shall remain active. If the State Emergency Anti-Epizootic Committee of Ukraine issues a decision to terminate its activities, it may empower a local emergency anti-epizootic committee to coordinate and manage the activities of all other local emergency committees with regard to containing and controlling the *animal disease outbreak*, and , eradicating such *animal disease*.

Article 41: Confirmation of Outbreak of List A Disease

- (1) When a *List A disease* is suspected, the *state inspector of veterinary medicine* attending the *animals* that are diseased or suspected to be diseased shall collect pathological material according to the procedures specified in the relevant *rule book* and subsequently dispatch such to an authorised laboratory equipped to conduct the necessary diagnostic analysis.
- (2) Upon the confirmation of a *List A disease*, the State Emergency Anti-Epizootic Committee of Ukraine shall, in consultation with the relevant local emergency anti-epizootic committees, determine the boundaries of *infected* and *buffer zones*, and if necessary, *surveillance zones*.
- (3) The State Emergency Anti-Epizootic Committee of Ukraine shall order one or more of the measures prescribed in the relevant contingency plan or rule book, or in the absence of such, order the implementation of one or more of those measures listed in Article 42 of this Law, according to the nature of the *List A disease* and the level of *risk* in the *infected*, *buffer*, and *surveillance zones*.
- (4) The Chairman of the State Emergency Anti-Epizootic Committee of Ukraine shall declare a state emergency due to the *outbreak* of a *List A disease* and announce in mass media publications the boundaries of the *infected* and *buffer zone(s)* and *surveillance zones*, if necessary, as well as the *veterinary-sanitary measures* to be implemented in each of the zones.
- (5) The Chairman of the State Emergency Anti-Epizootic Committee of Ukraine shall notify the Chief State Sanitary Doctor of Ukraine of the measures that shall be carried out with respect to restrictions on the movement of people and disinfection as appropriate.
- (6) As soon as practicable following the declaration by the Chairman of the State Emergency Anti-Epizootic Committee of Ukraine of a state of emergency due to an *outbreak* of a *List A disease*, the *Chief State Inspector of Veterinary Medicine* of Ukraine shall notify, in accordance with agreed procedures, *relevant international organisations*, and the *Veterinary Administrations* of neighbouring countries and *interested trading partners* that may be affected by the *outbreak* of *List A disease*. The notification shall include the details of the *outbreak* of *List A disease*, the probable source of infection, steps undertaken to control the *outbreak*, and planned *veterinary-sanitary measures*.

Article 42: Veterinary-Sanitary Measures Applied During Animal Quarantine

The State Emergency Anti-Epizootic Committee of Ukraine may, according to the nature of the *notifiable disease* for which an *outbreak* has been declared, and the level of *risk* in the *infected*, *buffer*, and, when applicable, *surveillance zones*, issue a decision to implement which ever of the following measures are appropriate to contain, control and, when appropriate, eradicate the *notifiable disease*:

- 1) Separation of healthy *animals* from sick ones;
- 2) Confinement of sick *animals* and closing of the *facilities (objects)* within which the *notifiable disease* is known to be present;
- 3) Prohibition or restriction on *animal* movements;
- 4) Prohibition of the removal of any *commodities, accompanying items*, and excreta from contaminated *facilities (objects)*;
- 5) Implementation, in a professional and humane way, a *stamping-out* policy;

- 6) Seizure and safe disposal of the carcasses of *animals* that have died or have been killed and of other *commodities* or excreta that cannot be decontaminated by conventional cleaning and disinfection;
- 7) Imposition of specific *veterinary measures* in *infected, buffer, and surveillance zones*;
- 8) Prohibition of the organisation of fairs, *markets*, exhibitions, gatherings or other collections of *animals*, and activities of sale yards;
- 9) Prohibition or restriction of the mating of *animals* as well as of the collection, treatment, storage, and use of semen for artificial insemination of *animals*, fertilised ova, and embryos originating in an *infected, buffer, or surveillance zone*;
- 10) Vaccination, clinical examination, and treatment of *animals*;
- 11) Limitations on 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*;
- 12) Closing and blocking approaches to contaminated zones and the erection of signs on such approaches to warn of the presence of the *List A disease* and of the controls that are in place;
- 13) Disinfection, insect and rodent control and deodorisation of stables, pens, yards, pastures, watering places, and other places where infected or suspected infected *animals* are kept, and of *accompanying items* that have been in contact with infected or suspected infected *animals*;
- 14) Strictly confining dogs and cats of known owners and exterminating stray dogs and cats in a humane way;
- 15) Surveillance of *animals*, including the collection of blood samples or pathological material for testing and access to farm records in *infected, buffer, and surveillance zones* and in other *facilities (objects)* under surveillance outside such *zones*; and
- 16) The use of the militia or, in accordance with established procedure, the military, as considered necessary and appropriate, to assist the *Commission* in the implementation and enforcement of measures for containment, control and eradication of the *List A disease*.

Article 43: Special Orders during Disease Emergency Situations

- (1) During a disease emergency situation, the Chairman of the State Emergency Anti-Epizootic Committee of Ukraine may issue a decision ordering all or some *licensed veterinary doctors, state doctors of veterinary medicine, authorised veterinarians*, and other relevant *veterinary medicine specialists* to carry out without delay special professional and other tasks in the context of relevant *veterinary-sanitary measures*.
- (2) The Cabinet of Ministers may in a state of emergency due to *outbreak* of a *List A disease* issue specific acts upon the proposal of the State Emergency Anti-Epizootic Committee of Ukraine for:
 - 1) Mobilisation of machinery equipment, *veterinary preparations, devices of veterinary medicine*, and vehicles, and the temporary usage of *facilities (objects)* in order to carry out necessary *veterinary-sanitary measures*, including in particular the safe disposal of *animal carcasses* and *accompanying items* seized for *animal disease* control purposes; or

- 2) Allocation of special tasks to relevant persons other than those referred to in paragraph 1 of this Article and to other relevant State bodies in order to carry out the necessary *veterinary-sanitary measures*.

Article 44: End of an Outbreak of List A Disease

- (1) An *outbreak* of a *List A disease* terminates when:
 - 1) The conditions specified in the relevant *rule book* have been met; or, if no *rule book* exists,
 - 2) The conditions specified in relevant *international standards, guidelines, and recommendations* have been met; or
 - 3) If no such *international standards, guidelines, or recommendations* exist, the period when, from the recovery or death of the last affected *animal* and the completion of disinfection, the longest incubation period for the *List A disease* has elapsed.
- (2) The Chairman of the State Emergency Anti-Epizootic Committee of Ukraine shall announce in at least two nationally circulated daily newspapers the end of the state of emergency due to an *outbreak* of *List A disease*.
- (3) The *Chief State Inspector of Veterinary Medicine* shall promptly inform the *relevant international organisations* and the *Veterinary Administrations* of neighbouring countries and affected trading partners of the end of the *outbreak*.

Article 45: Role of the Militia during Outbreak of Animal Disease

- (1) During an *outbreak* of *animal disease*, or upon basis of the statement of a *state inspector of veterinary medicine* or an *authorised veterinarian*, the militia shall provide help in restricting *circulation* of *animals*, in enforcing the prohibition of movement of *animals* and persons within an *infected zone*, and in the implementation of other quarantine measures specified by this Law.
- (2) In order to fulfil 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 anti-epizootic emergency committee.
- (3) In a state of emergency due to an *outbreak* of *List A disease*, the central body of executive power responsible for internal affairs must, upon a decision by the Cabinet of Ministers, provide assistance in the containment, control, and, when appropriate, eradication of the *List A disease*.

Article 46: Animal Quarantine for an Outbreak of Non-List A Disease

- (1) Upon suspicion of detection of a *notifiable disease* other than a *List A disease* that requires *animal quarantine* (hereinafter: *quarantine disease*), the chief state inspector of veterinary medicine of the relevant territory (hereinafter: *relevant chief state inspector of veterinary medicine*) shall issue an order on introducing *animal quarantine*:
 - 1) Immediately after confirmation of the *outbreak* of a *quarantine disease*;

- 2) In the case that, at the end of 24 hours after receiving information on the suspicion of the *outbreak* of a *quarantine disease*, the suspicion of *quarantine disease outbreak* has not been ruled out.
- (2) The order of the *relevant chief state inspector of veterinary medicine* on introduction of *animal quarantine* shall identify the boundaries of the *infected* and *buffer zones* and, if necessary, a *surveillance zone*, the *veterinary-sanitary measures* applicable in these *zones* during *animal quarantine* (hereinafter: *quarantine measures*) and the expected time of their effectiveness
- (3) The *chief state inspector of veterinary medicine* in the next highest administrative-territorial unit and the local body of executive power and/or the bodies of the local self-government of the relevant administrative-territorial unit and of the next higher level shall be immediately informed of the decision. Upon suspicion of the *outbreak* of *zoonoses*, the suspicion shall immediately be reported to the relevant chief state sanitary doctor.
- (4) The relevant *chief state inspector of veterinary medicine*, by his order on introduction of *animal quarantine*, may establish prohibition on movement of *animals*, vehicles, *persons*, and other objects that may be factors for transmission of the pathogenic agent into, out of, and within the *infected* and *buffer zones* and, if necessary, in the *surveillance zone*.
- (5) Implementation of the *quarantine measures* specified in the order of the *relevant chief state inspector of veterinary medicine* about introduction of *animal quarantine* 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 territorial unit shall be responsible for implementation of *animal quarantine*. State bodies and institutions shall be obliged to facilitate execution of *quarantine measures*.
- (7) The order of the *relevant chief state inspector of veterinary medicine* on introduction of *animal quarantine* shall be effective until the local emergency anti-epizootic committee issues a decision to introduce *animal quarantine*, but not longer than 72 hours.
- (8) During the first 48 hours of *animal quarantine*, the local emergency anti-epizootic commission of the next highest administrative-territorial level shall initiate activities. The State Emergency Anti-Epizootic Committee of Ukraine, at the Cabinet of Ministers of Ukraine, shall also initiate activities upon the recommendation of the *Chief State Inspector of Veterinary Medicine* of Ukraine if the nature of the *quarantine disease* is such that the *risk* of rapid or extensive spread of the disease is high or if the *quarantine zone* includes the territory or part of the territory of several oblasts or exceeds the boundaries of the Autonomous Republic of Crimea.
- (9) The *Chief State Inspector of Veterinary Medicine* of Ukraine shall inform the World Animal Health Organisation about establishment of *animal quarantine*, specifying the *quarantine disease* and the expected period for application of *animal quarantine*.
- (10) The relevant local emergency anti-epizootic committee shall issue a decision on establishment or termination of *animal quarantine* during the first 24 hours of activation of the committee.
- (11) The decision of the relevant local emergency anti-epizootic committee on establishment of the *animal quarantine* shall include:
 - 1) The name of the *quarantine disease(s)* for which *animal quarantine* is established;
 - 2) If known, the circumstances that caused the occurrence or *outbreak* of the *quarantine disease*;

- 3) Boundaries of the *quarantine zone*, including specification of the *infected*, *buffer*, and, when appropriate, *surveillance zones*;
 - 4) The special *veterinary-sanitary measures* applicable in the *infected*, *buffer*, and, when appropriate, *surveillance zones* that are directed at containing and eradicating the *quarantine disease*;
 - 5) The movement restrictions placed on *animals*, vehicles, and persons; and
 - 6) Any orders for mandatory commandeering of *veterinary medicine specialists* to perform quarantine measures and their duties during the *animal quarantine*.
- (12) In the first 24 hours after issuing a decision to introduce *animal quarantine*, the local emergency anti-epizootic committee shall take all measures necessary to inform persons within the territory of the *quarantine zone*, and the relevant local bodies of executive power and bodies of local self-government of adjacent administrative-territorial units. Notification on establishment of *animal quarantine* shall be published in a daily newspaper circulated in the territory of the relevant administrative-territorial unit. The local emergency anti-epizootic committee may employ television and other broadcasting media to provide prompt notification to persons on establishment of *animal quarantine*.
- (13) Persons guilty of violation of *quarantine measures* shall be liable in compliance with legislation.

Article 47: Measures Conducted under Animal Quarantine

- (1) During a declared *animal quarantine*, implementation of one or more of the measures prescribed in Article 42 of this law may be ordered.
- (2) Guard or *quarantine veterinary-militia posts* and signs that show obligatory *quarantine zone* detours shall be established at the entry to *infected* and *buffer zones* and upon the decision of the *local emergency anti-epizootic commission*, at the entry to *surveillance zones*.
- (3) The movement of *animals* and taking *other commodities* and *feed of plant origin* outside a *quarantine zone* is allowed only upon a decision of a *state inspector of veterinary medicine*.
- (4) Legal and physical persons whose activity is related to production, processing, and *circulation of commodities* and other products and materials that can be carriers of the *animal disease* for which *animal quarantine* was established, shall provide office buildings, necessary equipment, and communication means to be used by *veterinary medicine specialists* involved in execution of *quarantine measures*.

Article 48: Guarantees of the Rights of Natural Persons and Legal Entities during Animal Quarantine

- (1) Persons who have suffered property damage (make up losses) from declaration of *animal quarantine* or due to procedures and work to eliminate or prevent spread of *animal diseases* during *animal quarantine* shall be compensated for damages on the grounds of and under the procedure provided for by the legislation.
- (2) Persons attracted for performing works and rendering services under implementation of the *quarantine measures* have the right for remuneration for the works done and services rendered according to the procedure and in the amount established by the Cabinet of Ministers of Ukraine. Damage caused to life and health of a natural person engaged in performing works and rendering services in the process of implementing the *quarantine measures* and performing works (rendering services) thereby shall be subject to compensation in the full size at the State expense.

- (3) Persons whose property was used to prevent spread of or to eliminate the *animal disease* for which *animal quarantine* was established have the right to receive compensation for caused damages, via the procedure and in the amounts, set forth by the Cabinet of Ministers of Ukraine.
- (4) Amounts of compensations and remunerations shall be calculated on the basis of market prices for corresponding property (services) that were effective in the relevant locality on the day before establishment of the *animal quarantine*. All payments should be done not later than in one year from the day the *animal quarantine* is over.

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

Article 49: Obligations of Persons Producing and Circulating Non-Edible Products of Animal Origin

- (1) *Operators of facilities* where *non-edible products of animal origin, reproductive material, feed, premixes, feed additives, and veterinary preparations* are produced or *circulated* shall be required to fulfil *veterinary-sanitary measures* and hygiene and other specific requirements regarding structures, equipment, and machinery as prescribed in *technical regulations*, relevant rule books, and the provisions of this Law.
- (2) *Operators of facilities* used for the production or *circulation of non-edible products of animal origin, veterinary preparations, feed, and feed additives* shall:
 - 1) Ensure unhindered access of a *state inspector of veterinary medicine* to such *facilities (objects)* during normal business hours with the purpose of exercising *state veterinary-sanitary control or supervision*;
 - 2) Allow the taking of samples of *objects of state veterinary-sanitary control and supervision*, as well as other materials and substances within such *facilities (objects)*;
 - 3) Upon the request of the *state inspector of veterinary medicine*, provide all documents necessary for the purpose of exercising *state veterinary-sanitary control or supervision*;
 - 4) Keep records, according to lot (series batch) number when applicable, on the acquisition and use of *non-edible products of animal origin, veterinary preparations, feed, and feed additives*.
- (3) *Operators of facilities* conducting the activities of production or *circulation of non-edible products of animal origin, reproductive material, feed, and veterinary preparations* shall be obliged to ensure that that such products are free of, and not capable of, transmitting pathogenic agents of *animal disease*.

Article 50: Facilities Required to Obtain an Operating Permit from the Department

- (1) It is prohibited to conduct the activities of production or *circulation* at the following *facilities (objects)* without obtaining an operating permit from the relevant *state veterinary body*:

- 1) Rending facilities (objects);
 - 2) *Animal* breeding centres;
 - 3)
 - 4) *Facilities (objects)* for production and *circulation of veterinary preparations*.
 - 5) An operating permit that is valid for one year shall be issued upon submission to the relevant *state veterinary body* an application for such permit accompanied by the required information provided an on-site inspection verifies compliance of the above *facilities (objects)* with relevant *technical regulations, veterinary-sanitary measures*, and provisions of this Law.
- (1) The procedure of issuing and renewal of the *operating permit* and a list of documents to be presented with the application for obtaining an operating permit shall be specified by the *Department* and may include design and construction requirements, availability of qualified staff, and continuous operation of a quality control or safety or quality assurance system. The *Department* shall specify the relevant *technical regulations* and *veterinary-sanitary measures* for each type of *facility (object)* referred to in paragraph 1. The procedure for verification of compliance with such regulations and measures in sub-legal acts issued pursuant to this Law.
 - (2) All facilities for which the *Department* issues operating permits shall be subject to *state veterinary-sanitary supervision*.
 - (3) Operators (owners) of the relevant *facilities (objects)* for which the *Department* issues operating permits shall pay for *state veterinary-sanitary supervision* implemented by *state inspectors of veterinary medicine*.
 - (4) Any person producing, mixing, or preparing *feed* using meat-and-bone meal and other products from ruminants that can lead to development of bovine spongiform encephalopathy or other transmissible spongiform encephalopathies (TSEs) shall be required to have a separate *facility (object)* with a separate operating permit for production of *feed* containing such materials to avoid cross contamination of *feed* intended for ruminants with the products from ruminants identified above and minimize the *risk* of inadvertently including such products in *feed* for ruminants.

Article 51: Identifying Control Number for Facilities with Operating Permits

- (1) *Facilities (objects)* that obtain an operating permit from the *Department* shall be issued a control number identifying the facility.
- (2) The control number (hereinafter: *identifying control number*) shall be recorded in the relevant registry of *facilities (objects)* maintained by the *Department*.

Article 52: Suspension or Revocation of an Operating Permit

- (1) If during *state veterinary-sanitary supervision*, a *facility (object)* that has obtained an operating permit is found to be violating relevant *veterinary-sanitary measures* or relevant *technical regulations*, the *state inspector of veterinary medicine* shall issue written directives to be followed to correct the violation. If the severity of the violation is such that there is an immediate threat to *animal health*, the *state inspector of veterinary medicine* shall issue a directive for immediate repair of or prohibition of use of specific equipment and submit a report, along with any relevant documentation and materials, to the relevant chief state inspector of veterinary medicine or his deputy.

- (2) The relevant *chief state inspector of veterinary medicine* or his deputy may issue a decision, based on the report of the *state inspector of veterinary medicine* about violations of this law, to suspend the operating permit for the *facility*
- (3) The duration of suspension of an operating permit shall not be longer than three months. If the *facility (object)* does not correct the deficiencies within the term specified in the instructions of the *state inspector of veterinary medicine* on correcting the deficiencies or within the period of suspension of the operating permit, the *Department* shall revoke the operating permit and remove the *facility (object)* from the register.

Article 53: Registration of Facilities Using Non-Edible Animal Products

- (1) Owners of *facilities (objects)* other than those identified in Article 50 that use *non-edible products of animal origin* (i.e., for agricultural, industrial, pharmaceutical, or surgical purposes) that may carry or transmit *animal disease*, shall register said *facilities (objects)* with the *Department*.
- (2) The *Department* shall maintain a registry of facilities that use *non-edible animal products of animal origin*.
- (3) The *Chief State Inspector of Veterinary Medicine* shall prescribe the *facilities (objects)* that use *non-edible products of animal origin* for agricultural, industrial, pharmaceutical, or surgical purposes that are subject to the provision of paragraph 1 of this Article and the procedure for registering said facilities with the *Department*.

Article 54: Approved Exporting Facilities for Non-Edible Products of Animal Origin

- (1) Legal entities holding operating permits issued by the *Department* that want to export *non-edible products of animal origin* to countries of destination that have specific requirements for facilities producing, processing, or storing such products or other similar requirements may request verification of such specific requirements from the *Department*.
- (2) The *Department* shall make a decision on approval of the *facility (object)* (hereinafter: *approved exporting facility*) after verification by the *state veterinary bodies* that the *facility (object)* fulfils the requirements prescribed by the legislation of the country of destination.
- (3) Any products produced at an *approved exporting facility* destined for export shall be marked according to the requirements of the country of destination. If applicable, such marking shall also include the *identifying control number* referred to in Article 51 of this Law.
- (4) The *Department* shall maintain a register of *approved exporting facilities*. The register shall be published in electronic and written form.

Article 55: Removal of an Approved Exporting Facility from the Register of Approved Export Facilities

- (1) If during *state veterinary-sanitary control and supervision*, the *state inspector of veterinary medicine* determines that an *approved exporting facility* fails to fulfil the requirements of a country of destination, the *state inspector of veterinary medicine* shall collect evidence of the violation of the above mentioned requirements, as necessary. The relevant chief state veterinary inspector or his deputy shall review the evidence and make a decision on whether to remove such *facility (object)* from the register of *approved exporting facilities*.

- (2) The person who is the operator of the *approved exporting facility* may lodge an appeal for a decision on temporary or permanent removal of such *facility (object)* from the Register of *approved exporting facilities* with the central body of executive power on agrarian policy issues.
- (3) In case the decision on temporary or permanent removal of such *facility (object)* from the Register of *approved exporting facilities* has been adopted, the *Department* shall promptly notify the competent authority in the country of destination.
- (4) The competent authority of any country of destination for which the *Department* has conducted official verification of fulfilment of prescribed requirements, shall have unhindered access to *approved exporting facilities* with the purpose to inspect such facilities to verify fulfilment of prescribed requirements. 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 an *approved exporting facility* to verify fulfilment of prescribed requirements, the competent authority of a country of destination concludes that such *facility (object)* fails to fulfil the established requirements, the *Department* shall suspend or withdraw its approval of the *facility (object)* for exporting *non-edible products of animal origin* to the relevant country of destination in accordance with the instructions of the above competent authority of the country of destination. The decision on suspension or withdrawal of the approval of the *facility (object)* for exporting *non-edible products of animal origin* to the relevant country of destination shall be sent to the operator of the facility with the report by the competent authority of the country of destination identifying the violations of established requirements. Such decision when made in accordance with the instructions of the competent authority of the country of destination shall not be eligible for appeal.

Article 56: Processing and Circulation of Non-Edible Products of Animal Origin

- (1) It shall be prohibited to sell *feed of animal origin* in bulk, *non-edible products of animal origin*, and *devices of veterinary medicine* at *markets* and other places not established for such.
- (2) State inspectors of veterinary medicine shall carry out *state veterinary-sanitary supervision* of processing and *circulation of non-edible products of animal origin*.

Article 57: Circulation of Raw Hides and Skins

- (1) *Circulation* of raw cattle, sheep, and goat hides and skins is allowed only after examination for anthrax. The procedure for such examination, storage of hides and skins while undergoing examination, treatment for hides and skins found to be carrying anthrax, and marking indicating freedom from anthrax shall be specified by the *Department* in a sub-legal act issued pursuant to this Law.
- (2) Operators *circulating* raw hides and skins shall keep records on the origin of acquired raw hides and skins and keep such records for three years.
- (3) Unprocessed waste from hides and skins that have not been chemically treated must be safely destroyed in accordance with the procedure specified in the relevant rule book.
- (4) The *Chief State Inspector of Veterinary Medicine* shall prescribe the specific record keeping obligations.

Article 58: Record Keeping by Rendering Facilities

- (1) Operators of rendering facilities shall maintain records for three years enabling traceability of their purchases of raw materials of *animal* origin and sales of rendered products.
- (2) The records referred to in paragraph 1 of this Article shall be provided to a *state inspector of veterinary medicine* upon request.

SECTION IX - PRODUCTION AND CIRCULATION OF VETERINARY PREPARATIONS, SUBSTANCES, AND DEVICES OF VETERINARY MEDICINE**Article 59: State Pharmacology Committee for Veterinary Medicine**

- (1) The State Pharmacology Committee for Veterinary Medicine is an expert body on issues related to the safe and efficient application of *veterinary preparations* and *feed additives*, and their registration.
- (2) The State Pharmacology Committee for Veterinary Medicine functions under the auspices of the *Department*.
- (3) The State Pharmacology Committee for Veterinary Medicine acts on the basis of the Provision approved by the Cabinet of Ministers of Ukraine.

Article 60: State Veterinary-Sanitary Control and Supervision of Veterinary Preparations, Substances and Devices of Veterinary Medicine

- (1) The objective of *state veterinary-sanitary control of veterinary preparations, substances, and devices of veterinary medicine* shall be to take organisational and legal actions aimed at ensuring compliance of legal entities with the requirements of this Law and relevant *veterinary-sanitary measures* and *technical regulations*.
- (2) *State veterinary-sanitary control of veterinary preparations, substances, and devices of veterinary medicine* shall include registration of *veterinary preparations*; licensing of business entities engaged in producing and *circulating veterinary preparations*; continuing inspection of licensed business entities to verify compliance with licensing regulations; and verification of the purity (quality) of *veterinary preparations* and *substances* by sampling such during production, *circulation*, and/or use (application) and conducting tests thereon.
- (3) *State veterinary-sanitary control of veterinary preparations, substances, and devices of veterinary medicine* shall be carried out by by the *state institutions of veterinary medicine* authorized by the *Department*. Such control shall be conducted without prior notice, on a regular basis, according to inspection programmes drafted in advance, providing for the frequency of inspections and procedures to be followed when executing *state veterinary-sanitary control*, including the grounds for **increased probability of** non-compliance of *veterinary preparations, substances, and devices of veterinary medicine* with established requirements.

- (4) The *state institutions of veterinary medicine* authorized by the *Department* shall implement a national programme for monitoring residues of *veterinary preparations* in *animals* and, in accordance with relevant legislation of Ukraine, non-processed food products of animal origin to verify the proper use of preparations by *animal* owners (keepers). The results of the national monitoring programme shall be reported on at least a quarterly basis to the National Codex Alimentarius Commission of Ukraine.
- (5) When residues of *veterinary preparations* in non-processed food products of animal origin are in excess of established maximum residue limits, the authorised *state institutions of veterinary medicine* shall report their findings to the relevant chief state inspector of veterinary medicine so that he may take the necessary action in accordance with relevant legislation of Ukraine to prevent introduction into *circulation* of such products.
- (6) *State veterinary control of veterinary preparations* shall include studies of safe residual quantities of such preparations and side effects of *veterinary preparations*. The National Center for Monitoring and Evaluating Veterinary Preparations and Feed Additives shall be created at the relevant *state institution of veterinary medicine* for this purpose.

Article 61: State Registration of Veterinary Preparations

- (1) *Veterinary preparations* shall be subject to approval of registration prior to their *circulation* and use in Ukraine. The maximum length of time of validity of such registration shall be five years.
- (2) It is prohibited to register (re-register) *veterinary preparations* that may cause damage to *veterinary-sanitary and epizootic welfare*, or animal or human health.
- (3) In order to affect the state registration of a *veterinary preparation*, a person (hereinafter: *applicant*) shall submit to the *Department* an application, with accompanying relevant documents, the list of which is prescribed by the *Department* based on the recommendation of the State Pharmacology Committee for Veterinary Medicine, for obtaining a decision on approval of registration of relevant *veterinary preparations*. A decision on approval of registration of a *veterinary preparation* shall be issued within 90 days of receipt of a complete application package.
- (4) The *Department*, with participation of the State Scientific- Research Control Institute of Veterinary Preparations and Feed Additives or State Scientific-Control Institute of Biotechnologies and Microorganisms Strains, shall carry out evaluation of the submitted documents, organize the conducting of the necessary tests, and undertake other procedures to verify the information in the documents and prepare a recommendation for consideration by the State Pharmacology Committee for Veterinary Medicine, which shall make a decision on whether or not to approve *veterinary preparations*.
- (5) Approval of registration of a *veterinary preparation* shall be refused if, after verification of the particulars and documents submitted in accordance with paragraph 2 of this Article, it is found that:
 - 1) The applicant has not properly or sufficiently demonstrated the quality, safety or efficacy of the *veterinary preparation*;
 - 2) In the case of zootechnical *medicinal products (means)* and performance enhancers, when the safety and welfare of the *animals* and/or consumer safety have not been sufficiently taken into account during their use;
 - 3) The *withdrawal period* recommended by the applicant is not long enough or is insufficiently substantiated to ensure that animal products intended for human consumption from treated *animals* do not contain residues in excess of established maximum residue limits, which might constitute a health hazard for the consumer;

- 4) The *veterinary preparation* presented for approval of registration is prohibited under effective legislation.
- (6) A decision to deny approval of registration of a *veterinary preparation* shall be transmitted promptly to the applicant with a complete explanation for the denial. The applicant shall have ten days from receipt of such decision to lodge an appeal with the central body of executive power on agrarian policy issues regarding such decision.
- (7) A decision of approval of registration of the *veterinary preparation* shall be transmitted promptly to the applicant, along with a registration certificate. The registration certificate shall include the name of the *veterinary preparation*, information about the person that registered the *veterinary preparation*, the registration number of the preparation, the term of validity of the registration and technical requirements that must be fulfilled by the preparation.
- (8) Upon approval of a *veterinary preparation* for *circulation* and use in Ukraine, it shall be entered in the Registry of Veterinary Preparations maintained by the *Department*. The registry entry shall include the *veterinary preparation* name, information on the person who has registered thereof, the registration number of the preparation, the term of validity of the *registration certificate* and other data required pursuant to the effective legislation.
- (9) After approval of registration of *veterinary immunological products*, the applicant shall deposit microorganism strains (cultures) used in production of such immunological products with the National Center for Microorganism Strains. The National Center for Microorganism Strains, for which its regulations shall be approved by the Cabinet of Ministers of Ukraine, shall be responsible for storage and maintenance of microorganism strains.
- (10) The *person* to whom the registration certificate for a *veterinary preparation* has been issued shall establish a system to ensure that information about all suspected adverse reactions to the *veterinary preparation* referred to in the registration certificate is collected and evaluated, and provided to a *state inspector of veterinary medicine* or other authorised employee of the *veterinary services* upon his request. Such information shall be submitted to the *Department* or its designated person periodically in the form and manner prescribed by the *Department*.
- (11) A package of registration materials shall be submitted for re-registration 3 months before the lifetime of the registration certificate expires.
- (12) The *Department* may define authorized appropriately qualified persons to undertake all or some of the duties referred to in paragraph 3 of this Article, and also establish the procedure for authorizing or designating such persons and the requirements they must fulfil.
- (13) The amount and procedure of payments for registration of *veterinary preparations* shall be defined by the Cabinet of Ministries, taking into account the costs of services rendered for registration.

Article 62: Express Approval of Veterinary Preparations

- (1) *For some veterinary preparations* the possibility for their registration on the basis of an application for simple registration (hereinafter: *express approval*), shall be established.
- (2) *Veterinary preparations* for which *express approval* is possible are preparations that are essentially similar to preparations containing the same quantity of the same active substance in the same form, with appropriate documents indicating that it has the same bioavailability and bio equivalence and that it has essentially the same therapeutic effect as a preparation registered in Ukraine and in other countries specified by the *Department* that have equal criteria for registration of such *veterinary preparations*.

- (3) If the *veterinary preparation* for which an application for express approval has been submitted is to be used for different medical treatment purposes, with a different dosage, or in a different manner compared to an essentially similar preparation that is already marketed, the results of pharmacological-toxicological and/or clinical tests shall be enclosed in the application.
- (4) A decision on approval for express registration of *veterinary preparations* shall be issued within 20 days of receipt of a complete application package. The *Department* shall prescribe the procedures and a list of documentation which must be presented for obtaining a decision under *express approval* of registration.

Article 63: Suspension or Cancellation of Registration of Veterinary Preparations

- (1) The registration of a *veterinary preparation* shall be suspended if:
 - 1) The *veterinary preparation* does not comply with established purity specifications;
 - 2) The *veterinary preparation* does not comply with the requirements specified in its registration certificate;
 - 3) The approval of registration has been issued based on incomplete or untrue data;
 - 4) The holder of the *registration certificate* no longer complies with the prescribed requirements.
- (2) The registration of a *veterinary preparation* shall be cancelled if it is found to not be efficient under the prescribed conditions for its use or not safe for *animal* health or not safe for human health when **present in animal products intended for human consumption at levels in excess of established maximum residue limits**.
- (3) If a *veterinary preparation* is found to not be safe, in addition to the provision of paragraph 2 of this Article, the *Department* shall order prohibition on *circulation* of such preparation and its withdrawal from *circulation*.
- (4) The *Department* shall prescribe the procedure for suspension of registration and for reactivating the registration as well as the procedures for cancellation of registration of a *veterinary preparation*.
- (5) In the event of suspension or cancellation of the registration of a *veterinary preparation*, the holder of the registration certificate for the *veterinary preparation* in question may lodge an appeal against such decision with the central body of executive power on agrarian policy issues, which shall subsequently form an expert commission to evaluate the decision of suspension or cancellation of such registration and render a recommendation regarding such.

Article 64: Production of Veterinary Preparations

- (1) *Veterinary preparations* not registered in Ukraine shall be not permitted for full-scale serial production.
- (2) Persons producing *veterinary preparations* shall be obliged to obtain a license for such pursuant to effective legislation.
- (3) A license to produce *veterinary preparations* shall be issued upon fulfilment of the following requirements:

- 1) Compliance of the production *facility (object)* with relevant *technical regulations* regarding hygiene conditions and requirements associated with the manner and materials of construction;
 - 2) Implementation of *Good Manufacturing Practices* for production of *veterinary preparations*;
 - 3) Presence of a safety and quality control laboratory in the *facility (object)*; and
 - 4) Other requirements prescribed by the *Department*.
- (4) *Substances*, packaging materials, and other resources (inputs) to production of *veterinary preparations* shall be permitted for use by the *Department* based on testing of such by authorized *state institutions of veterinary medicine* to verify their safety .
- (5) The producer shall be obliged to carry out quality control for each lot (series batch) of *veterinary preparations* in accordance with established *Good Manufacturing Practices*.
- (6) Any *lot* (series batch) of *veterinary preparations* that has not passed quality control in the process of production, shall be subject to processing (changing the intended use) and/or destruction. Processing (changing the intended use) or destruction of such *preparations* shall be carried out by the owner or the authorised representative of the owner under the supervision of the authorised *state institutions of veterinary medicine* pursuant to the procedure established in the relevant sub-legal act issued pursuant to this Law.
- (7) General requirements for the conditions of production of *veterinary preparations* shall be established by the *Department* and controlled by authorized *state institutions of veterinary medicine*.

Article 65: Wholesale Circulation of Veterinary Preparations

- (1) All persons engaging in wholesale *circulation* of *veterinary preparations* (hereinafter: wholesale enterprises) shall obtain from the *Department* a license for conducting entrepreneurial activity in the wholesale *circulation* of *veterinary preparations*.
- (2) Wholesale enterprises engaged in wholesale circulation of *veterinary preparations* shall be entitled to sell such preparations only to persons registered as a wholesale enterprise or to a licensed *veterinary establishment*, and veterinary pharmacies..
- (3) Persons engaged in wholesale *circulation* of *veterinary preparations* shall maintain records on their purchase, import, export, and sales of such products.
- (4) The records referred to in paragraph 3 of this Article shall be submitted periodically to the *Department* or to the bodies authorised by the *Department* and, upon request shall be promptly provided to a *state inspector of veterinary medicine* for review.
- (5) The *Department* shall prescribe the procedure and requirements for licensing the wholesale *circulation* of *veterinary preparations*, the specific form and content of the records (reporting) on purchase and *circulation* of *veterinary preparations* and the periodicity and procedures for submitting such records to the *Department*.

Article 66: Licensing for Retail Circulation of Veterinary Preparations

- (1) Licensed *veterinary establishments* shall be eligible to conduct retail sale of *veterinary preparations* without additional authorisation on condition that such preparations are necessary within the course of treatment of a client's animal.
- (2) Veterinary pharmacies may conduct retail *circulation of veterinary preparations* only after obtaining an operating licence issued by the *Department* or the body it authorises.
- (3) Licensed *veterinary establishments* and licensed veterinary pharmacies shall maintain records on purchases and sales of *veterinary preparations*. The records shall be submitted monthly to the *Department* and, upon request, are subject to review by a *state inspector of veterinary medicine*.
- (4) If, as a result of *state veterinary-sanitary control and supervision* of the activities of *veterinary establishments*, violations of the requirements for retail sale or for keeping of *veterinary preparations*, or violations associated with maintaining the appropriate records are detected, or the records referred to in paragraph 3 of this Article are not submitted to the *Department* as required, the relevant chief *state inspector of veterinary medicine* shall issue an order to suspend the licence of the *veterinary establishment* or to prohibit the sale of *veterinary preparations* until the above deficiencies are corrected.
- (5) If the prescribed conditions for a licence for retail sale of *veterinary preparations* are violated by a licensed veterinary pharmacy the *state inspector of veterinary medicine* shall issue an order to suspend the license for retail sale of such *preparations*. If the license of the veterinary pharmacy is suspended twice during two years, such licence shall be revoked by the *Department*. The veterinary pharmacy whose license was revoked may apply to obtain a new license not earlier than nine months after the date of revocation.
- (6) If during two years the license of a *veterinary establishment* is suspended twice due to violation of the rules prescribed for retail sale or keeping of *veterinary preparations* or retail sales of such *preparations* are prohibited twice during two years, the *Department* shall revoke the license of the *veterinary establishment*. The *veterinary establishment* whose license is revoked may apply to obtain a new license not earlier than three months after its revocation.
- (7) An appeal may be lodged with the central body of executive power on agrarian policy issues regarding the decision to suspend or revoke a licence or eligibility to sell *veterinary preparations* within tens days of the day of receipt of the notice of the suspension or revocation.
- (8) The *Department* shall prescribe the licensing conditions for the implementation of the activity of retail *circulation of veterinary preparations*, the procedure for licensing for retail *circulation*, the specific form and content of the records referred to in paragraph 3 of this Article, procedures for submitting such records to the *Department*, procedures for exercising control over compliance with the established requirements, and procedures for suspending and revoking the licence or eligibility for retail sale of *veterinary preparations*.

Article 67: Circulation of Veterinary Preparations

- (1) The putting into *circulation* of a *veterinary preparation* by a producer and/or seller (supplier) shall be understood to be a guarantee of the safety of the preparation according to its intended use and fulfilment of the prescribed purity (quality) of such preparation and its compliance with other mandatory requirements established by relevant *technical regulations* and/or the terms of registration.
- (2) The *circulation* of *veterinary preparations* that are not registered in Ukraine shall be prohibited.

- (3) *Veterinary preparations* that are in circulation shall be accompanied by complete, legible, and understandable instructions for consumers and be labelled in Ukrainian. *Veterinary preparations* shall also have the registration number indelibly printed or otherwise marked on the packaging.
- (4) It shall be prohibited to sell *veterinary preparations* with an expired “use-by” date. The extension of the shelf life of *veterinary preparations* shall not be allowed.
- (5) *Veterinary preparations* and *substances* that are in *circulation* shall be subject to random control for compliance with the conditions of their registration and relevant *technical regulations*. *Veterinary preparations* and *substances* that do not comply with the requirements of this Law shall be subjected to the provisions of Article 73 of this Law.
- (6) Usage of *veterinary preparations*, which suppress the function of the endocrine gland, in particular having thyreostatic, estrogenic, androgenic, or gestagenic effect, as well as antibiotics and hormones, shall be possible for medical or other purposes taking into account that the residue of such preparations in animal raw materials, intended for human consumption shall not exceed established maximum residue limits.

Article 68: Veterinary Preparations that Require a Prescription for Dispensing and Using

- (1) It is prohibited to affect retail sale of the following *veterinary preparations* without a prescription from a *licensed veterinary doctor* or from a doctor of veterinary medicine working at a *state institution of veterinary medicine*:
 - 1) *Veterinary medicinal products (means)* for which their use and *circulation* shall be limited according to the UN Convention on Narcotic and Psychotropic Substances and other international agreements , ratified (approved as mandatory) by the Verhovna Rada;
 - 2) *Veterinary medicinal products (means)* for which their application needs taking special preventive means or which should be used only under control of a *licensed veterinary doctor* so as to avoid the unwanted *risk* for *animals*, persons administering the medicine to *animals*, consumers of *animal products* intended for human consumption from animals treated with the *veterinary medicinal product (means)*, or the environment;
 - 3) *Veterinary medicinal products (means)* intended for treatments or pathological processes, which require a prior precise diagnosis or the use of which may cause effects which interfere with subsequent diagnostic or therapeutic measures; and
 - 4) *Veterinary immunological products (means)* containing pathogenic organisms.
- (2) The *Department* shall establish the rules of prescribing the above *veterinary preparations*.

Article 69: Retail Sale of Veterinary Preparations

- (1) Retail sale of *veterinary preparations* shall be affected only by *licensed veterinary doctors*, *licensed veterinary establishments*, and *licensed veterinary pharmacies*.
- (2) *Licensed veterinary doctors* and *licensed veterinary establishments* shall prescribe and sell *veterinary preparations* only to their clients within a course of treatment of *animal disease* or *maladies* or prevention of such.
- (3) A *licensed veterinary doctor* issuing a prescription for a *veterinary preparation* shall be obliged to provide to *animal* owners or keepers the original copy of the prescription and a copy of the prescription that should be kept by the owners (keepers) together with records as provided by Article 72 of this Law.

- (4) *Licensed veterinary doctors*, licensed veterinary pharmacies and licensed *veterinary establishments* shall sell prescription *veterinary preparations* only on the basis of such prescription and keep the original copy of the prescription for each *veterinary preparation* sold for three years from the date of sale.
- (5) The prescription original provided by Item 3 of this Article shall include, in addition to the name of the *veterinary preparation* and instructions on its usage, the date of providing the prescription, the name, address, phone number, license number and signature of a *licensed veterinary doctor*, as well as the name and address of the owner of *animal* or *animals* the *veterinary preparation* is being prescribed for.

Article 70: Circulation of Means of Animal Care

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

Article 71: Import of Veterinary Preparations for Special Purposes

- (1) *Veterinary preparations* that are not registered for *circulation* and use in Ukraine may be imported for the purposes of:
 - 1) Registration in Ukraine;
 - 2) Displaying at exhibitions, fairs and conferences;
 - 3) Scientific research.
- (2) In the event that *veterinary preparations* are imported for the purposes specified in paragraph 1 of this Article, the quantities of such shall be limited to that necessary for the specific purpose and may not be *circulated* or used in Ukraine.
- (3) In case of calamity, natural disaster, or outbreaks of *animal disease* or natural or other disasters that may result in the infection of a large number of *animals* with *animal disease*, the Chief State Veterinary Inspector of Ukraine may, pursuant to the established procedure, issue a single use import permit for a specific *veterinary preparation* that is not registered for *circulation* and use in Ukraine provided that documents confirming the *circulation* and use of the aforesaid preparation in the country from which such will be imported are available.

Article 72: Record Keeping on Use of Veterinary Preparations and Medicated Feed by Animal Owners (Keepers)

- (1) Animal owners (keepers) shall be obliged to maintain records on purchase and use of *veterinary medicinal products (means)*, *veterinary immunological products (means)* and *medicated feed* according to each animal for the life span of the animal and, upon request, provide such records to a *state inspector of veterinary medicine* or *authorised veterinarian*. In case of animal transfer, the previous owner shall provide the new owner (keeper) such records.

- (2) Such records shall include the date of purchase, name of the *veterinary medicinal or immunological product (means)* or *medicated feed*, quantity of the product purchased, the name and address of the *veterinary establishment* or veterinary pharmacy that sold the product and information on the animals treated thereby.
- (3) The records specified in paragraph 2 of this Article may be inscribed in the form of a copy of the prescription for the *veterinary medicinal products (means)* or *veterinary immunological product (means)* and an invoice for the product or *medicated feed* from a veterinary pharmacy or *veterinary establishment* with a specification of the *animal* or *animals* treated by this product.

Article 73: Utilization (Change of Intended Use) and Destruction of Veterinary Preparations

- (1) *Veterinary preparations* that, in the course of implementation of *state veterinary control and supervision*, are found to violate the requirements of this Law, as well as those with an expired shelf life, shall be subject to withdrawal from *circulation* and utilization (change of intended use) and destruction.
- (2) Utilization (change of intended use) and destruction of *veterinary preparations* shall be carried out according to the rules approved by the *Department* and other requirements of the legislation.

Article 74: Regulating Devices of Veterinary Medicine

New *devices of veterinary medicine* for which a national *standard* or *technical regulation* does not exist and for which an ISO/IEC *standard* does not exist shall be submitted to the *Department* prior to its *circulation* for compulsory testing of its ability to achieve the relevant effect for which the device is designed and is to be used, and with regard to ensuring *animal* welfare.

SECTION X - REQUIREMENTS FOR PRODUCING ANIMAL FEED AND FEED ADDITIVES

Article 75: Approval of Registration of Finished Feed, Premixes, and Feed Additives

- (1) *Finished feed, premixes* and *feed additives* shall be allowed for *circulation* and use in Ukraine only after their state registration.
- (2) It shall be prohibited to register (re-register) *finished feed, premixes, and feed additives* that:
 - 1) Cause damage to the *veterinary-sanitary and epizootic welfare* of Ukraine;
 - 2) Have an adverse effect on *animal* health, human health, or the environment;
 - 3) Are presented in a manner which may mislead the consumer/user; and
 - 4) Harm the consumer by impairing the distinctive features of *animal* products or mislead the consumer with regard to the distinctive features of *animal* products.

- (3) In order to affect registration of *feed additives*, *premises*, and *finished feed*, an application for approval of registration shall be submitted to the *Department* along with samples of the product and the registration documents specified in a sub-legal act issued pursuant to this Law. The applicant is responsible for the accuracy of the information presented in the registration package. The applicant applying for approval of registration of *finished feed*, *premises*, and *feed additives* shall indicate in the accompanying documents any information in the supporting documentation that he wishes to remain confidential. The *Department* shall honour such request according to current legislation of Ukraine
- (4) The *Department* shall organise the performing of necessary examination, testing, and analyses of submitted information and subsequent submission of expert conclusions to the State Pharmacology Committee for Veterinary Medicine within 30 calendar days of receipt by the *Department* of a complete application.
- (5) The State Pharmacology Committee for Veterinary Medicine shall evaluate the expert conclusions and recommend approval or denial of the application for registration of *feed additives*, *premises*, and *finished feed* within 45 calendar days of receipt by the *Department* of a complete application. After issuing a decision on approval of registration of *feed additives*, *premises*, and *finished feed*, it shall be entered in the registry of *feed additives*, *premises*, and *finished feed* maintained by the *Department*.
- (6) In case a decision is made to deny approval of registration, such decision and a complete explanation of the reasons for the denial shall be promptly transmitted to the applicant. The applicant may, within ten days of receipt of such decision, lodge an appeal with the central body of executive power on agrarian policy issues. The central body of executive power on agrarian policy issues shall establish an expert commission to review the decision of denial of approval of registration of the *finished feed*, *premix*, or *feed additive* and recommend to the central body of executive power on agrarian policy issues whether or not to approve the *finished feed*, *premix*, or *feed additive* for registration within 45 days from the day the commission receives the materials of the appeal.
- (7) Registration of the *finished feed*, *premix*, or *feed additive* shall be certified by the issuing of a registration certificate whose period of validity cannot exceed 5 years. The registration certificate shall include:
 - 1) The name and address of the applicant;
 - 2) Specification of the purpose(s) for the *finished feed*, *premix*, or *feed additive*, and when applicable, purity criteria and method of analysis of purity;
 - 3) Any specific conditions or restrictions in relation to storage and use of the *finished feed*, *premix*, or *feed additive*, requirements for producers with regard to monitoring negative impact of the above products during *circulation* and use, and animal categories of animal species for which the above product is to be used;
 - 4) Any specific requirements in addition to those specified in paragraph 8 of this Article for the labelling of the *finished feed*, *premix*, or *feed additive* necessary as a result of conditions and restrictions imposed under item 3 of this paragraph;Maximum residue limits of feed additives or their active substances or of their metabolites in animal products intended for human consumption when establishment of such limits is envisaged by current legislation of Ukraine and no international standard, guideline, or recommendation of such maximum residue limit is established
- 5) The registration number;
- 6) Other information prescribed in a relevant sub-legal act issued pursuant to this Law.

- (8) *Finished feed, premixes, and feed additives* being *circulated* in Ukraine shall comply with the following labelling requirements in a conspicuous, clearly legible, and indelible manner in the Ukrainian language:
- 1) The specific name given upon registration;
 - 2) The name or business name and the address or registered place of business of the holder of the registration certificate;
 - 3) The net weight or, in the case of liquid additives and *premixes*, either the net volume or the net weight;
 - 4) Directions for use, and any safety recommendations regarding the use and, where applicable, the specific requirements mentioned in the registration certificate, including *animal* species and categories for which the *finished feed, premix, or feed additive* is intended;
 - 5) The registration number of the registration certificate issued by the *Department*; and; and
 - 6) The lot (series batch) number, date of manufacture, and date of expiration.
- (9) *Finished feed, premixes, and feed additives* that are not registered for circulation in Ukraine may be imported into Ukraine on the basis of a single use import permit, but not subsequently circulated, for the following purposes:
- 1) Registration in Ukraine
 - 2) Exhibiting at fairs, exhibitions, and conferences;
 - 3) Scientific and other purposes.
- (10) The *Department* shall establish the procedure for registration of *finished feed, premixes, and feed additives*. Registration shall be conducted, renewed, and changed only in compliance with the procedure established by the *Department*.
- (11) The amount and order of payments for registration of *finished feed, premixes, and feed additives* shall be defined by the Cabinet of Ministers, taking into account the cost of the services rendered.

Article 76: Registering Persons Circulating Feed of Animal Origin

- (1) Persons circulating feed of animal origin shall be registered with the Department.
- (2) Persons referred in paragraph 1 of this Article shall maintain records on purchases and sales of *feed of animal origin* for three years enabling traceability of such *feed* and provide such information to a *state inspector of veterinary medicine* upon request.
- (3) Persons *circulating feed* containing *animal* protein from ruminants shall maintain separate display and storage facilities and vehicles for transportation of such *feed*.
- (4) The *Department* shall issue the necessary sub-legal acts to implement the provisions of this Article.

Article 77: Production and Circulation of Finished Feed, Premixes and Feed Additives

- (1) Production of *finished feed*, *premixes* and *feed additives* that are not registered for *circulation* in Ukraine shall be prohibited.
- (2) During the production of *finished feed*, *premixes*, and *feed additives*, persons shall implement Good Manufacturing Practices established in relevant *technical regulations*.
- (3) Persons producing *finished feed*, *premixes* and *feed additives* shall keep records containing full details of the supplier and date of receipt of inputs to such production, including *feed of animal origin* and *feed of plant origin*, used in the production of the above products, as well as maintain records on the destination of all *finished feed*, *premixes* and *feed additives* sold for three years according to the form and instructions established by the *Department*.
- (4) The putting into *circulation* of *finished feed*, *premixes*, and *feed additives* by a producer and/or seller (supplier) shall be understood to be a declaration of its safety and its compliance with other mandatory requirements established by relevant *technical regulations* and the conditions of registration.
- (5) *Finished feed*, *premixes*, and *feed additives* 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 institutes of veterinary medicine* to carry out such control.
- (6) It is prohibited to *circulate finished feed*, *premixes* and *feed additives* that do not comply with the conditions of their registration and/or relevant *technical regulations*.
- (7) In addition to the requirement specified in paragraph 6 of this Article, it is prohibited to circulate *feed*, including *premixes* and *feed additives* that are not hygienically suitable. *Feed*, *premixes* and *feed additives* shall be deemed to be hygienically unsuitable if:
 - 1) They contain pathogenic micro-organisms in such quantities as to endanger *animal* health;
 - 2) They contain *contaminants*, in amounts in excess of maximum permitted levels; or
 - 3) The date of expiration has passed.
- (8) Upon issuance of a decision by a *state inspector of veterinary medicine*, *feed* referred to in item 3 of paragraph 7 of this Article may be used for a purpose specified by an authorised laboratory following laboratory testing.
- (9) Maximum permitted levels of *contaminants* and the permissible quantities of pathogenic microorganisms in *feed* shall be prescribed according to relevant legislation of Ukraine.
- (10) It is prohibited to feed ruminants with *feed* containing animal protein from ruminants.

Article 78: Monitoring and Surveillance Programme for Feed and Feed Additives

- (1) All *feed* and *feed additives* circulated in Ukraine shall be subject to a monitoring and surveillance programme that is designed and operated on the basis of *risk* assessment and implemented by the *veterinary services* to monitor the hygienic suitability of such and compliance with relevant *technical regulations*.

- (2) The results of laboratory analysis of samples of *feed, premixes* and *feed additives* may, within ten working days of notification of the results of *laboratory analysis*, be challenged by the owner of the above *feed, premixes* and *feed additives* from which the samples were taken by requesting *arbitration analysis*.
- (3) The owner of the *feed, premixes* or *feed additives* shall pay the cost of *arbitration analysis*.
- (4) The sampling frequency, facilities from which samples are taken, the method of sampling and *laboratory analysis*, measures to be taken when *feed, premixes* or *feed additives* are determined to be hygienically unsuitable or not comply with *technical regulations*, and recovery of any costs associated with implementation of the monitoring and surveillance programme shall be specified according to sub-legal acts issued by the *Department* pursuant to this Law.

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

- (1) In order to prevent outbreaks of *animal disease* caused by the feeding of infected material of *animal* origin, it is prohibited to feed to *animals* waste food (swill) transported by means, which took part in international transportation, from *infected* or *surveillance zones*.
- (2) The use of waste food from facilities selling or serving food other than that referred to in paragraph 1 of this Article for feeding to *animals* intended for slaughter shall be allowed only if such waste food has been thermally processed.
- (3) Persons using waste food for feeding to *animals* intended for slaughter shall keep records for three years on the origin of the waste food and provide such information to a *state inspector of veterinary medicine* upon request.
- (4) Waste food shall be transported in containers and by vehicles where there is no possibility of leakage or spillage and which are thoroughly cleaned and disinfected after use.
- (5) Detailed conditions for the use of waste food, including procedures for collecting such and its thermal processing, the type and method of transportation of waste food, the procedures for cleaning and disinfecting vehicles and containers, and keeping of records shall be prescribed by the *Department*.

SECTION XI - INTERNATIONAL TRADE

Article 80: Commodities and Other Products for which Imports are Prohibited

- (1) Ukraine's citizens, foreigners, and persons without citizenship shall be prohibited from bringing in *non-edible products of animal origin* for their own use into the territory of Ukraine.
- (2) It is prohibited to import live pathogenic microorganisms (e.g., bacteria, viruses, fungi, rickettsia, micro-plasmas, and other pathogenic microbes) and pathological material of *animal diseases* except for the purpose of conducting scientific research or for other approved purposes.
- (3) Imports of microorganisms and pathological material of *animal diseases* shall be permitted on the basis of an import permit issued by the *Department* in accordance with the provisions of **Article 82** of this Law.

- (4) It is prohibited to import into Ukraine *veterinary preparations, finished feed, premixes, and feed additives* that are not registered in accordance with the provisions of this Law, except as prescribed in Article 71 and paragraph 9 of Article 75 of this Law.

Article 81: Requirements for Consignments of Commodities Presented for Import or Transit

- (1) Import consignments of *commodities* shall:
- 1) Be free of *notifiable diseases* in compliance with the requirements established by the World Animal Health Organisation;
 - 2) Be accompanied by an original *international veterinary certificate* signed by a *state inspector of veterinary medicine* of the country of origin when so required by current *veterinary-sanitary measures*;
 - 3) Be accompanied by an import permit when so required by current *veterinary-sanitary measures*; and
 - 4) In the case of live *animal* imports, have originated from countries or *zones free from notifiable diseases* or, when recommended by the World Animal Health Organisation, *zones of low prevalence of notifiable diseases* within the country of origin, and not have transited through an area that is under restriction, as confirmed by a *relevant international organisation* or by the *Veterinary Administration* of the country of origin or transit, for control of a *notifiable disease* to which the live *animals* are susceptible.
- (2) Transit consignments of live *animals* shall meet the requirements specified in item 1 of paragraph 1 of this Article.
- (3) Transit consignments of commodities other than animals and feed of plant origin shall be cleared for transit through the territory in accordance with established general procedures for transit of other goods.

Article 82: Permit for Import of Commodities

- (1) When specified in relevant *veterinary-sanitary measures*, the import of *commodities* shall be subject to a permit issued by the *Department*.
- (2) The procedure for submission of the application for obtaining the permit for import, as well as the format and content of the application shall be established by the *Department*. Under no circumstances shall the decision on whether or not to issue an import permit take more than 30 calendar days.
- (3) An import permit shall be issued if the following conditions are met:
- 1) Import of the *commodities* is not prohibited due to the *veterinary status* in the *country of origin* or re-export;
 - 2) The *risk* associated with import or transit of the *commodities* is acceptable in relation to the *appropriate level of animal and related human health*.
- (4) Factors to be considered that determine the *risk* associated with importation of a *commodity* include:
- 1) The intended use of the *commodity*;

- 2) The geographic and other characteristics of Ukraine, the country of origin, and, when applicable, countries of transit that affect the ability of *notifiable diseases* to survive, establish, and spread;
 - 3) The existence of *state control programmes of animal diseases* in Ukraine, the country of origin, and transit countries;
 - 4) The existence of *zones free of notifiable disease* or of *low prevalence of notifiable disease* in the country of origin, from which *risks* of transmission of such *notifiable disease* may be nil or minimal;
 - 5) The effectiveness, as defined in Article 21 of this Law, of the *Veterinary Administration* in the country of origin;
 - 6) The effectiveness of measures that the *Department* may require be applied in the country of origin to reduce the *risk* associated with imports, including, pre-consignment *preventive animal quarantine*, specification of the *facility (object)* of origin, and sampling and laboratory analysis for confirmation of freedom from *notifiable diseases* in the country of origin; and
 - 7) When imports of *animals* are being considered, the expected effectiveness of post-entry *preventive animal quarantine* for monitoring *animal* health.
- (5) The import permit shall include the *veterinary-sanitary measures* that must be conducted by the exporter prior to shipment and by the importer after entry into Ukraine, as well as any declarations in addition to freedom from clinical signs of specified *notifiable diseases* that must be attested to in the *international veterinary certificate* issued by a *state inspector of veterinary medicine* of the country of origin. In the case of import of live microorganisms and pathological material of *animal diseases*, the import permit shall include specification of *veterinary-sanitary measures* to be applied by the importer to prevent the uncontrolled spread of the pathogenic agent.
 - (6) An import permit shall not be required for *non-edible products of animal origin* if they have been subjected to a technical procedure that ensures that no *notifiable diseases* can be transmitted by the product.
 - (7) Denial of an import permit shall be justified and be provided to the applicant promptly. An appeal may be lodged with the central body of executive power on agrarian policy issues within ten calendar days of receipt of notice regarding the denial. The term for consideration of the appeal shall not exceed ten calendar days.
 - (8) The *Department* shall notify by publishing on its web site the list of *commodities*, according to country of origin, from which *commodities* may not be imported due to the *veterinary-sanitary status* of the country.

Article 83: Import of Exotic Animals

For the import of exotic *animals* (those not normally resident in Ukraine), the importer shall, when required according to *relevant international agreements*, provide a document from the competent authority of the country of origin for the protection of natural resources that confirms that this authority permits the export of such *animals*.

Article 84: Designated Border Inspection Posts

- (1) Import, transit, and export of *commodities* are allowed only at designated *border inspection posts* which have *quarantine stations*, and are designated for entry or exit of *commodities* (hereinafter: *designated border inspection posts*).
- (2) The veterinary-sanitary, technical, and working conditions at the *designated border inspection posts* shall be prescribed by the *Department* and be suitable for the following purposes:
 - 1) Conducting clinical examination of *animals* and taking samples from such *animals* or of other *commodities* for diagnostic analysis;
 - 2) Isolating *animals* that are suffering from an animal disease or *malady* or are suspected to be suffering from an *animal* disease; and
 - 3) Carrying out disinfection of vehicles used for transportation of *commodities*.
- (3) Any consignment referred to in paragraph 1 of this Article that arrives at a border inspection post other than a *designated border inspection post* shall be redirected to the nearest *designated border inspection post*.

Article 85: Notification to State Inspectors of Veterinary Medicine of Imports of Live Animals

- (1) An importer or person assuming responsibility for a consignment of *animals* requiring post-entry *preventive animal quarantine* shall inform the relevant *regional service* not later than three working days before arrival of such consignment of *animals*.
- (2) The procedures and form of notification of the relevant *regional service* shall be prescribed by the *Departement*.

Article 86: Random Veterinary-Sanitary Border Control Programme

- (1) Import consignments of *commodities* shall be subject to mandatory extended veterinary-sanitary border control in accordance with the provisions of Article 89 of this Law when so selected according to a random veterinary-sanitary control programme.
- (2) Mandatory extended veterinary-sanitary border control shall be applied under the random veterinary-sanitary control programme during a calendar year for specifically determined percentages of consignments of *commodities* classified into three categories: live *animals*; *non-edible products of animal origin*; and other *commodities*.
- (3) The specifically determined percentages of consignments referred to in paragraph 2 of this Article shall be determined according to the historical incidence of detection of *notifiable* or other *animal diseases* in *consignments* of each category of *commodities* and other factors that affect the *risk* to *animal* health and life from import consignments of *commodities*.
- (4) The specifically determined percentages of *consignments* subject to extended veterinary-sanitary border control shall be specified by the *Departement* for each category prior to the beginning of each calendar year

Article 87: Standard Veterinary-Sanitary Border Control

- (1) All consignments of commodities and feed of plant origin for import and transit consignments of live animals shall be subjected to standard veterinary-sanitary border control in the form of *inspection*, conducted as follows:
 - 1) Verify that the consignment is accompanied by a valid import permit, when so required by current *veterinary-sanitary measures*;
 - 2) If an *international veterinary certificate* is required by current *veterinary-sanitary measures*, check that such certificate accompanying the consignment is complete and authentic, and that the *commodities* described in the *international veterinary certificate* are the *commodities* in the consignment; and
 - 3) Detect the presence of *notifiable diseases* in the animal.
- (2) The consignment shall be allowed to enter or transit Ukraine if:
 - 1) The consignment is accompanied by a valid import permit, when so required by current *veterinary-sanitary measures*; and
 - 2) If an *international veterinary certificate* is required by current *veterinary-sanitary measures*, the *international veterinary certificate* is complete, authentic, and pertains to the *commodities* in the *consignment*; and
 - 3) No symptoms or other indications of *notifiable diseases* has been detected in the *commodities*; and
 - 4) At least one of the following conditions is met:
 1. In the case of transit consignments, if the customs seal applied by the customs authority of the country of origin is not damaged; or
 2. The commodity is subject to a bilateral agreement regarding recognition of the equivalence of specific or general *veterinary-sanitary measures* between the country of origin and Ukraine; or
 3. A critical number of prior consignments of like *commodities* from the country of origin and/or particular *facility (object)* of origin were accompanied by valid *international veterinary certificates*; or
 4. The consignment presents a low level of *risk* to domestic *animals* based on the pre- and post-entry requirements for the *commodities*.
- (3) In the case that standard veterinary-sanitary border control leads to the conclusion that *the international veterinary certificate* is incomplete, does not apply to the *commodities* in the consignment, or the validity of the *international veterinary certificate* is doubted, the *state border inspector of veterinary medicine* shall implement the provisions of Article 88 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 border control programme or when the *risk* to *animal* or human health presented by a consignment is, based upon the professional judgement of the *state border inspector of veterinary medicine*, deemed to be high. When assessing the *risk* to *animal* and human health presented by the *commodity* in the consignment, the following shall be considered:
 - 1) The results of the standard veterinary-sanitary border control of the *commodities*;

- 2) The existence of a bilateral agreement regarding recognition of the equivalence of specific or general *veterinary-sanitary measures* between the country of origin and Ukraine;
 - 3) The required pre- and/or post-entry *veterinary-sanitary measures* for the *commodities* as specified in the import permit, if any; and
 - 4) The statistical record of the invalid *international veterinary certificates* attesting to freedom from *animal disease* of consignments of like *commodities* from the country of origin and/or particular *facility (object)* of origin.
- (5) Import consignments shall be deemed to not require extended veterinary-sanitary border control if a certain number of prior consignments with like *commodities* from the relevant country of origin and/or particular *facility (object)* of origin were accompanied by valid *international veterinary certificates* and the results of the standard veterinary-sanitary border control do not suggest a need for extended veterinary-sanitary border control.
- (6) Extended veterinary-sanitary border control shall 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 like other *commodities* from a country of origin and/or particular *facility (object)* of origin with valid *international veterinary certificates* that precludes extended veterinary sanitary border control.

Article 88: Procedures When the International Veterinary Certificate is not Acceptable

- (1) If the *state border inspector of veterinary medicine* finds that the *international veterinary certificate* accompanying a *consignment of commodities* is incomplete or fraudulent or otherwise falsified or concludes 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 designated representative shall be notified.
- (2) The *Chief State Inspector of Veterinary Medicine* of Ukraine or his designated representative shall immediately contact the *Veterinary Administration* of the *country of origin* for consultations and to jointly determine the measures to be taken with regard to the *consignment*.

Article 89: Extended Veterinary Border Control

- (1) If the *state border inspector of veterinary medicine* suspects that an import or transit consignment of *commodities* does not fulfil the necessary conditions for import or 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 or his designated representative, who in turn shall immediately notify the *Veterinary Administration* of the country of origin and of the country last transited through, if applicable, as well as the importer or owner of the consignment.
 - 2) The consignment shall be isolated at *quarantine station* at the *designated border inspection post* and the *state border inspector of veterinary medicine* shall collect samples of the *commodity* according to the procedures specified in the relevant rule book and dispatch such to an authorised laboratory equipped to conduct the necessary diagnostic analysis to confirm or rule out the suspicion of *animal disease*.

- 3) Upon ruling out of the suspicion of *animal disease*, the *state border inspector of veterinary medicine* shall issue a *veterinary affidavit* enabling movement of the consignment within Ukraine, after which the consignment shall be subject to further customs procedures according to effective legislation of Ukraine.
- 4) Upon confirmation of a *List A disease* in an *animal* or *animals* in the consignment, the *animals* shall be killed and the carcasses and any *accompanying items* destroyed in a manner guaranteeing they will not be capable of transmitting the disease. If the consignment contains *commodities* other than live *animals*, the other *commodities* shall be destroyed and in a manner guaranteeing they will not be capable of transmitting the disease.
- 5) Upon confirmation of an endemic *notifiable disease* subject to a *state control programme* or confirmation of infection with an *animal disease* that is capable of increasing the incidence of endemic *animal disease* in Ukraine, the *consignment* shall be:
 1. Returned to the country of origin, provided such return does not endanger *animal* health; or
 2. With consent of the owner and observance of the necessary *veterinary-sanitary measures*, sent for technical processing to eliminate the *animal disease* pathogen; or
 3. Destroyed in accordance with the provisions of item 4 of paragraph 1 of this Article.
- 6) The confirmation or ruling out of suspicion of *animal disease* and the actions subsequently taken by the *state border inspector of veterinary medicine* shall be promptly reported to the *Veterinary Administration* of the country of origin, and the importer and/or owner of the consignment.

Article 90: Import and Transit Restrictions due to Outbreak of List A Disease in the Country of Origin or Transit Country

- (1) An import or transit consignment of *animals* shall not be permitted entry regardless of whether an import or transit permit is held if:
 - 1) The presence of a *List A disease* to which the *animals* are susceptible has been confirmed in the *country of origin* in the *zone* where the *animals* originated; or
 - 2) The presence of a *List A disease* to which the *animals* are susceptible has been confirmed in one or more transit countries in the area or areas through which the *animals* have travelled.
- (2) In the above circumstances, the *Department* shall hold such consignment at the border and following consultations with the *Veterinary Administration* of the country of origin, promptly return the consignment or in the event of very high associated *risk*, destroy the animals in such a manner as to minimize the *risk* of introduction or spread of the *List A disease*.

Article 91: Quarantine Requirements for Imported Animals

- (1) Animals brought into the territory of Ukraine except those meant for slaughter shall be subjected to preventive animal quarantine to monitor and verify their health.
- (2) The length of *preventive animal quarantine* and the means of monitoring and verifying the health of the *animals* shall be specified in the relevant rule book approved by the *Department*. The place of *preventive animal quarantine* and the persons that will implement the procedures to carry it out shall be specified and controlled by the *veterinary services*.

Article 92: Procedures Applicable in Customs Warehouses, Customs Storage and Free Economic Zones

All commodities crossing the State border of Ukraine and placed in customs warehouses, customs storage or free economic zones shall be subject to the same veterinary border control applied to consignments intended for import.

Article 93: Documents Accompanying Consignments of Commodities Presented for Export

Export consignments of *commodities* must:

- 1) When so required by the country of destination, be accompanied by an original *international veterinary certificate* signed and issued by a *state border inspector of veterinary medicine* attesting to freedom from clinical signs of *animal disease* and any other declarations required by the country of destination; and
- 2) When so required by the country of destination, be accompanied by documentation or be marked indicating the *facility (object)* from which the *commodities* originate.

Article 94: Issuance of International Veterinary Certificates for Consignments of Commodities Presented for Export

- (1) Certificates for export consignments of *commodities* that must be accompanied by an original *international veterinary certificate* attesting to compliance of the consignment with the requirements of the country of destination shall be issued not earlier than 72 hours before loading the consignment on the export vehicle.
- (2) Compliance with the certification requirements of the country of destination shall be determined on the basis of:
 - 1) The *veterinary affidavit* issued prior to loading and transporting the consignment within Ukraine if the conditions for the *veterinary affidavit* are the same as those for the country of destination and, in the case of export *animals*, the date on said veterinary affidavit is no more than 72 hours prior to the final loading on the export vehicle; or
 - 2) In the event that a *veterinary affidavit* was not issued prior to loading and transporting the consignment within Ukraine or the conditions for the *veterinary affidavit* are not the same as those for the country of destination, verification of fulfilment of the requirements of the country of destination shall be carried out by the *state border inspector of veterinary medicine*; or
 - 3) In the event of expiration of the *veterinary affidavit*, recertification of the affidavit shall be conducted in accordance with the requirements of the country of destination.
- (3) If the consignment complies with the requirements of the country of destination, a *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 be permitted to leave Ukraine. Further, the owner or person assuming responsibility for the consignment shall promptly take the actions prescribed by the *state border inspector of veterinary medicine* in the relevant directive.
- (5) The *international veterinary certificate* shall be printed and serially numbered and conform to the appropriate model certificate of the *relevant international organisations* or conform to the format and contents prescribed by the country of destination.

Article 95: Measures to be taken due to Threat of Animal Disease

If there is a high *risk* of a *notifiable disease* being introduced into the territory of Ukraine from a neighbouring territory or being transmitted to or by a transit shipment or by consignments brought into the territory of Ukraine,, the *Chief State Inspector of Veterinary Medicine* may order that in the threatened area there will be:

- 1) Control of movement of *commodities* in threatened border areas, including roads, bridges, and ferries;
- 2) Prohibition, limitation or regime of mandatory prior conditional permission for the import, export or transit of commodities in relation to the *risk* associated with movement from and through such areas; and
- 3) Mandatory disinfecting of vehicles crossing the border in threatened areas.

SECTION XII - FINANCING AND LOGISTICAL SUPPORT

Article 96: Scientific Support of Veterinary Medicine

- (1) Scientific support of *veterinary medicine* is conducted by appropriate scientific institutions of the National Academy of Sciences of Ukraine, Ukrainian Academy of Agrarian Sciences, scientific institutions in the administrative sphere of central bodies of executive power, and veterinary medicine departments of higher education institutions.
- (2) Scientific support referred to in paragraph 1 of this Article, including necessary scientific research in the sphere of veterinary medicine as identified by the *Department* and practical application of scientific work in *animal* production and health, shall be funded from the State Budget of Ukraine and other resources, not prohibited by the legislation.
- (3) The Veterinary Medicine Departments of the Ukrainian Academy of Agrarian Sciences shall carry out coordination of work connected with scientific support of veterinary medicine jointly with the scientific-methodological council of the *Department*.
- (4) The *Department* is a customer of state scientific and research work in the sphere of veterinary medicine.

Article 97: Financing and Logistic Support of State Veterinary Bodies

- (1) Financing and logistic support of *state veterinary bodies* shall be carried out with funds from the state budget of Ukraine.
- (2) Contributions to the World Animal Health Organisation shall be made from the state budget of Ukraine.
- (3) *State veterinary-sanitary control and supervision* shall be executed on the account of allocations from general and special funds of the State Budget of Ukraine.

Article 98: Financing of Anti-Epizootic Measures

Measures on prevention, containment, when appropriate, eradication of *notifiable diseases*, laboratory-diagnostic and regular radiological analysis of *commodities*, and other *veterinary-sanitary measures* identified by the Cabinet of Ministers of Ukraine are financed from appropriate budgets.

Article 99: Fees for Services Rendered

All fees charged in connection with any administrative procedures, provision of information, laboratory analyses, expertise, control or other procedure required in accordance with this Law shall be limited in amount to the approximate cost of services rendered.

Article 100: Payments for Services Provided by State Veterinary Medicine Institutions and Organizations (Bodies)

- (1) Payment for measures on prevention and eradication of *animal diseases* (except those mentioned in Article 98 of this Law), treatment of *animals* suffering from *animal diseases* and *maladies*, *laboratory examination*, *veterinary-sanitary testing* of *non-edible products of animal origin* as well as payment for services provided for export/import transactions, and transportation of *objects subject to state veterinary-sanitary control and supervision* throughout the territory of Ukraine shall be from the funds of the owners (holders, operators) of *objects subject to state veterinary-sanitary control and supervision* according to the fees established by the Cabinet of Ministers of Ukraine, which shall be fixed at the level of the costs of the service rendered.
- (2) Payment for services of *veterinary medicine specialists* in *veterinary establishments* engaged in private practice on fulfilment of obligatory or required *anti-epizootic measures* in accordance with the list approved by the Cabinet of Ministers of Ukraine shall be made from appropriate budgets and at the expense of other financing sources not prohibited by legislation.

SECTION XIII - VETERINARY PRACTICE, TRAINING AND STATUS OF VETERINARY MEDICINE SPECIALISTS

Article 101: Veterinarians and Veterinary Establishments

Legal entities or natural persons (Ukrainian citizens, foreigners, and persons without citizenship residing in Ukraine) may practice *veterinary medicine* provided they have obtained a license for such issued pursuant to the legislation of Ukraine.

Article 102: Professional Training, Post-Graduate Education and Attestation of Veterinary Medicine Specialists

- (1) Professional training of *veterinary medicine specialists* shall be provided only on a full-time basis.
- (2) Post-graduate education of *veterinary medicine specialists* shall be provided according to the procedure stipulated by legislation.
- (3) Periodicity of professional upgrading of *veterinary medicine specialists* – at least once per five years.
- (4) *Veterinary medicine specialists* shall be subject to attestation according to the procedure established by legislation. According to the results of the attestation, it shall be determined whether an employee meets the requirements of his office, the level of his/her qualification, with the qualification rank and the respective labor payment being specified.
- (5) The *Department* shall approve the regulations on post-graduate education and periodic professional upgrading of specialists, as well as the procedure for attesting *veterinary medicine specialists*.

Article 103: Social and Legal Protection of Veterinary Medicine Specialists

- (1) In case of disability, injury, professional illness or death, provided the above mentioned is resulting from conducting of the duties of office, lump-sums are repaid to *veterinary medicine specialists* or their successors according to the procedure, conditions and in the amount specified by the Cabinet of Ministers of Ukraine.
- (2) *Veterinary medicine specialists* of state institutions shall be provided with specialized transportation vehicles to carry out their official duties. Monetary compensation pursuant to the determined amounts shall be paid for the own motor vehicle use for execution of the above duties.
- (3) *Veterinary medicine specialists* shall be paid double official salaries (of *veterinary medicine specialists* of *state institutions of veterinary medicine*) for hours worked in *zones* where outbreaks of *notifiable diseases* take place.
- (4) The issues of social and legal protection, material support for *veterinary medicine specialists* being on military service or employed as servicemen with the bodies of Interior, state border protection, security service, shall be regulated according to the relative legal normative acts.

SECTION XIV - LIABILITIES OF PERSONS FOR VIOLATIONS IN THE FIELD OF VETERINARY MEDICINE

Article 104: Liabilities for Violations in the Field of Veterinary Medicine

- (1) For violation in the field of veterinary medicine, legal entities and natural persons—subjects of entrepreneurial activity, whose activities are connected with producing and *circulating objects subject to state veterinary-sanitaryveterinary control and supervision*, as well as those providing laboratory diagnostic services and practicing veterinary medicine, shall be subject to penalty according to the effective legislation.
- (2) Payment of penalties does not release natural persons and legal entities from elimination of admitted violations and from reimbursement for damages caused by them according to the procedure stipulated by legislation.

Article 105: Bodies Authorized to Consider Cases on Violations in the Field of Veterinary Medicine

- (1) Cases on violations aforesaid in 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 disclosure.
- (2) The Chief state inspectors of veterinary medicine, and their deputies are empowered with the right to impose penalties on behalf of the *Department*, its *territorial bodies*, and *regional services*.

Article 106: Decisions in Cases on Violations in the Field of Veterinary Medicine

- (1) Decisions on imposing penalties for violations in the field of veterinary medicine shall be issued in relative resolutions.
- (2) Natural persons and legal entities shall pay a penalty within one month of the date the relative resolution has been received. In case this term is violated the penalty is exacted according to the court procedure.

Article 107: Appellation of Decisions in Cases on Violations in the Field of Veterinary Medicine

Decision in cases on violations in the field of veterinary medicine may be appealed in accordance with court procedure.

SECTION XV - INTERNATIONAL COOPERATION

Article 108: International Cooperation in the Field of Veterinary Medicine

International cooperation in the field of veterinary medicine is conducted in the following ways:

- 1) Participation in the activities of the World Animal Health Organisation and other international organizations, ratification of international agreements, and harmonisation of *veterinary-sanitary measures*;
- 2) Harmonizing legislation on veterinary medicine in accordance with international best practice; unification of prophylactic and *anti-epizootic measures*, and diagnostic methods respectively for *animal diseases*; and application of immune-biological, biological, vegetable, 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

If any international agreement concluded by Ukraine which was approved by the Verkhovna Rada of Ukraine as mandatory establishes rules other than this Law then the rules of the international agreement shall be applied.

SECTION XVI - FINAL PROVISIONS

- (1) This Law shall come into force on the date of its publishing.
- (2) Laws and other legal-normative acts adopted before the date of this Law coming into effect and also legal-normative acts that did not come into effect before the date of this Law coming into effect, shall become effective in parts that do not contradict with this Law.
- (3) The Cabinet of Ministers of Ukraine shall:
 - 1) Prepare and submit to the Verkhovna Rada of Ukraine proposals on amending legislative acts pursuant to this Law;
 - 2) Bring their legal normative acts in compliance with this Law;
 - 3) Ensure drafting of legal normative acts needed to implement this Law and their further adoption by ministries and other central bodies of executive power;
 - 4) Ensure revision and annulment of sub-legal acts inconsistent with the present Law by ministries and other central bodies of executive power of Ukraine.

