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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 ~~of~~ *hazard identification, animal disease risk assessment, risk management, and risk communication.*
- 2) **Arbitration analysis**

9) *Veterinary establishment*

- 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) animal disease by specific measures applied throughout the country or within 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, 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 the 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 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, anesthetics, 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) **Device**

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- 34) *Means of animal care* – means and substances for breeding and taking care of animals that have no medical or prophylactic effect;
- 35) *Zone*

- 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 material and premixes, which are not normally consumed *per se* by itself but are intentionally added to feed or water in order to favourably affect the characteristics of 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 in 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**

- 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 veterinary 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 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 (wing), 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 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~~ *and* 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~~ *measures* aimed at prevention, detection, and eradication of ~~notifiable~~ *notifiable* diseases;

77)

- 86) **Stamping-out** – carrying out under the authority of the relevant chief state inspector of veterinary medicine a set of measures including 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 contact, of a kind likely to cause the transmission of the causal pathogen. All susceptible, vaccinated or unvaccinated, are killed and their carcasses destroyed by burning or burial, or by any other method which eliminates the spread of infection through the carcasses and 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), parts, 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 production process or with terminology requirements as applied to a production process or production method. *Technical regulations for facilities (objects)*

97) *List A diseases* – transmissible ~~animal~~ *diseases* which have the potential for very serious and rapid

10) Protecting *animal* welfare by ensuring humane treatment of

- 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 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 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 *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 *veterinary medicine bodies* (hereinafter *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 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 Department 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 stored (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 *storing 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 *commission for the control of the Department of Veterinary Medicine and supervision*

- 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)

- (9) *State veterinary-sanitary supervision at the state border and for internal transport shall be conducted by the State Inspector of Veterinary Medicine of Ukraine, Chief State Inspectors of Veterinary Medicine of the Autonomous Republic of Crimea, oblasts of Kyiv and Sevastopol, cities, rayons, the national 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 and persons (Ukrainian and foreign), *z*



10)

11) Issue *international veterinary certificates* for export consignments of *commodities*.

(2) State inspectors of veterinary medicine and authorized 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 *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 of Kyiv and Sevastopol*, *cities, rayons, chief 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 *state 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 internal 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 (recording), or destruction of objects if they are carrying* *infectious*

- diseases* or there is a suspicion that the *objects* are infected with or carrying *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 *of 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 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 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 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 Republic *Capital* of the Autonomous Republic of Crimea, oblast, regional, inter-oblast, municipal-district, and district state laboratories of veterinary medicine that are accredited by the national accreditation body or or a comparable accreditation body of *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)

## **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 *eradication programmes* for such *animal diseases*;
  - 2) The estimated economic costs to the livestock sector in Ukraine associated with introduction of *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, *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





- 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*

- 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 organisational structures control over the establishment and fulfilment of *vetinary-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 *vetinary-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











### Article 31: Registration of Livestock Facilities

- (1) Persons involved in raising animals for personal household consumption, including cattle, pigs, sheep, goats, rabbits, and poultry, 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.

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

### 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 authorised laboratory for laboratory examination. Should *animal disease* be found, the temporary prohibition in paragraph 3 shall be lifted. If *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 *animal disease* shall be conducted according to the procedure prescribed by the *Department*.
- (6) The *Department* shall establish the procedure for systematic monitoring and 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, morphological properties, do not satisfy the basic conditions necessary for reproduction, or if they contain higher than permitted levels of bacterial *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 operation control, guidance, and co-ordination of the activities of local bodies of executive power, state services, and persons engaged in prevention and eradication of outbreaks of *diseases*.
- (3) The State Emergency Anti-Epizootic Committee of Ukraine shall be headed 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



Article 41: Confirmation of Outbreak of List A Disease  
(1)

- 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 fertilised ova, and embryos originating in 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 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 infected.

12)

- 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 *code book* have been met; or, if *no code 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 *onset* 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 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, 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 un



- 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 quarantine*.
- (12) In the first 24 hours after issuing a decision to introduce *local 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 broadcast 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 the *state inspector of veterinary medicine*.
- (4) Legal and physical persons whose activity 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*



- 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 veterinary body an application for such permit accompanied by the required information provided 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-legislation pursuant to this Law.
  - (2) All facilities for which the Department issues operating permits shall be subject to veterinary-sanitary supervision.
  - (3) Operators (owners) of the relevant facilities (objects) for which the Department issues operating permits shall pay for the 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)

- (2) The relevant *chief state inspector of veterinary medicine* or his deputy may issue a decision, based on the report of the *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 *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 provisions 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)* fulfills the requirements prescribed by the *Department* to register said *facility (object)* in the register.

- (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~~ *(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~~ *(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 ~~ed~~ *of animal origin* in bulk, *non-edible products of animal origin*, and *devices of veterinary medicine* at *markets* and other places not

#### Article 58: Record Keeping by Rendering Facilities

- (1) Operators of rendering facilities shall maintain records for ~~three~~ *five* years enabling traceability of their purchases of raw ~~material~~ *animal* origin and sales of rendered products.
- (2) The records referred to in paragraph ~~this~~ *of* 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 a~~ *expert* body on issues related to the safe and efficient application ~~of~~ *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 ~~legislation~~ *legislation* with the requirements of this Law and relevant ~~veterinary-sanitary measures and technical regulations~~.
- (2) *State veterinary-sanitary control of*

- (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 presence 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 *exceed* 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 *Drugs* and Feed Additives shall be created at the relevant *institution of veterinary*

- 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 State Register 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, 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 so 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 *inspector of veterinary medicine* or other authorized 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 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 persons and the requirements they must fulfill.
- (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 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 bioequivalence 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 used for different medical treatment purposes, with a different dosage, or in a different manner compared to another 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 that 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*.

- 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 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 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 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 the 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 *chief 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 records referred to in paragraph 3 of this Article are not submitted to the *Department* as required, the relevant *chief 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 *chief inspector of veterinary medicine* shall issue an order to suspend the licence for retail sale of such *preparations*. If the licence of the veterinary pharmacy is suspended twice during two years, such licence shall be revoked by the *Department*. The veterinary pharmacy whose licence was revoked may apply to obtain a new licence not earlier than nine months after the date of revocation.
- (6) If during two years the licence of a *veterinary establishment* is suspended twice due to violation of the 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 licence of the *veterinary establishment*. The *veterinary establishment* whose licence is revoked may apply to obtain a new licence 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 ten days of the day of receipt of the notice of the suspension or revocation.
- (8) The *Department* shall prescribe the licensing conditions for 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 (quality) of such preparation and its compliance with all 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 labeled 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 the 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 (if approved as mandatory) by the Verhovna Rada;
  - 2) *Veterinary medicinal products (means)* for which their application needs taking special preventive measures 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 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 quantity 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 it is imported are submitted.*

- (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 *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, premixes, 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-legislation 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, premixes, and feed additives* shall indicate in the accompanying documents and affirmation in the supporting documentation whether 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, premixes, 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, premixes, and finished feed*, it shall be entered in the registry of *feed additives, premixes, and finished feed* maintained by the *Department*.
- (6) In case a decision is made to deny approval of registration, a decision and a complete explanation of the reasons for the denial shall be promptly transmitted to

- (8) *Finished feed, premixes, and feed additives* being *circulated* in Ukraine shall comply with the following labeling 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 office 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 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 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 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

- (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 decided 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 *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 *animals* intended for slaughter shall be allowed only if such waste food has been thermally processed.
- (3) Persons using waste food for feeding *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 pathogens *anim94 TD . 76 procl, 11.7104rovi.the*

(4)

- 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*

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*

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

- (1) All consignments of commodities and feed of plant origin from 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 customs authority of the country of origin is not damaged;
    2. The commodity is subject to a bilateral agreement regarding recognition of the equivalence of specific or general *veterinary-sanitary measures* between the country of origin and Ukraine; 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 *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 *extended 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 *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 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 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 a *quarantine station* at the designated border inspection post and the *state border*

- 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 *endemicifiable disease* subject to a *state control programme* or confirmation of infection with an *animal disease* that is capable of increasing the incidence of *endemicifiable disease* in Ukraine, the *consignment* shall be:
  1. Returned to the country of origin, provided such return does not endanger health; or
  2. With consent of the owner and observance of the necessary *quarantine-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 *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 *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 *List A disease* to which the *animals* are susceptible has been confirmed in one or *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 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 procedure 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 code

- (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 ~~assumes~~ 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 neighboring 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 im

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 Organization 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~~ special funds of the State Budget of Ukraine.

Article 98: Financing of Anti-Epizootic Measures

Measures on prevention, containment, when appropriate, eradication ~~of~~ *infectious diseases*, laboratory-diagnostic and regular radiological analysis ~~is of~~ *commodities*

### **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





