

NOTICE:

- In the “*Official Gazette of the Republic of Montenegro*” No. 79/2004 dated **23 December 2004**, the **Law on Medical Devices** was published; Article 65 therein provides as follows:

**“Article 65**

On the effective date of this Law, the Law on Production and Marketing of Medicines (“*Official Gazette of FRY*”, Nos. 18/93, 23/02, 24/94, and 28/96), in the part pertaining to the medical devices, and the **provisions of Article 3 item 12, Article 31 paragraphs 1, 2, 4 and 5, in the part pertaining to the medical equipment, and Article 96 paragraph 2 item 1, in the part pertaining to the medical equipment, of the Veterinary Law** (“*Official Gazette of RM*” No. 11/04), shall cease to apply.”

These amendments shall become effective **eight days** after the day of publishing.

- In the “*Official Gazette of the Republic of Montenegro*” No. 80/2004 dated **29 December 2004**, the **Law on Medicines** was published; Article 112 therein provides as follows:

**“Article 112**

On the effective date of this Law, the Law on Production and Marketing of Medicines (“*Official Gazette of FRY*”, Nos. 18/93, 23/02, 24/94, and 28/96), in the part pertaining to the medicines, and the **provisions of Article 3 item 12, Article 31 paragraph 1, in the part pertaining to the transportation of veterinary medicines, paragraph 2, in the part pertaining to veterinary medicines, paragraph 4, in the part pertaining to veterinary medicines, paragraph 5, in the part pertaining to veterinary medicines, Article 32 paragraph 1, in the part pertaining to the veterinary medicines, Article 96 paragraph 1 item 6, in the part pertaining to the placement of veterinary medicines on market, and paragraph 2 item 1, in the part pertaining to veterinary medicines, Article 97 item 6, in the part pertaining to marketing on veterinary medicines, items 8 and 10, in the part pertaining to veterinary medicines, of the Veterinary Law** (“*Official Gazette of RM*” No. 11/04), shall cease to apply.”

*“Official Gazette of the Republic of Montenegro” No. 11/2004*

By virtue of Article 88 item 2 of the Constitution of the Republic of Montenegro, I herewith enact this

**EDICT**

**ON PROMULGATION OF THE VETERINARY LAW**

The Veterinary Law is being promulgated as adopted by the Parliament of the Republic of Montenegro, at the meeting of its first session in 2004, on the day of the 16<sup>th</sup> of February 2004.

No: 01-236/2

Podgorica, 17 February 2004

Signed by: Mr. Filip Vujanovic, President of the Republic of Montenegro

## VETERINARY LAW

### I. GENERAL PROVISIONS

#### Article 1

Veterinary Law shall regulate: infectious animal diseases; infectious animal diseases prevention, suppression, and eradication; veterinary preventive measures; mandatory animal health care level; animal welfare protection; funding of the animal health care programs; organizing legal persons for pursuing veterinary practice; ensuring provision of services of public interest; and other issues of relevance for veterinary practice.

#### Article 2

For the purposes of this Law, the specific terms shall mean as follows:

- 1) **Animals** are animals for production, animals for slaughter, pets, game, aquatic animals, hares, bees, silkworms, snails, other mollusks, laboratory animals, decorative and exotic animals;
- 2) **Animals for production** are all animals (including fish, reptiles and amphibians) which are bred for production of food, hide, wool, fur, or for other commercial purposes;
- 3) **Animals for slaughter** are animals whose body parts are used for human consumption, including aquaculture and fattening game;
- 4) **Pets** are dogs, domestic cats, exotic and decorative birds, small rodents, terrarium animals, aquarium animals, and other animals bred or kept to keep company, entertain, protect, or help, humans;
- 5) **Game** are wild animals which are freely roaming the nature, and wild mammals and wild birds which live free in the enclosed areas, designated by the regulations governing game and hunting, under the conditions similar to those in nature; their meat may be used for human consumption but they are not slaughtered like domestic animals but hunted in accordance with the regulations on hunting;
- 6) **Fattening game** are terrestrial mammals, reptiles, and wild birds, bred and slaughtered in the same way as domestic animals;
- 7) **Animals inhabiting free waters** are fish, crayfish, shellfish, and other animals which live in water and are designated by the regulations governing fishery, which are captured out of their natural habitat and whose meat and tissue is used for human consumption;
- 8) **Aquaculture** animals includes fish, crayfish, shellfish, and mollusks bred in farms, counting the captured individuals of these species intended for breeding;
- 9) **Aquaculture product** is a product obtained from aquaculture animals, regardless whether they are intended for breeding, such as ova and fertilized ova, or for human consumption;

- ~~10) **Fish, crayfish, shellfish and mollusks** include all fish, crayfish, shellfish and mollusks regardless of their stage of development;~~ Formatted: Bullets and Numbering
- ~~11)10) **Experiment animals** are the animals that are used or will be used in laboratory experiments;~~ Formatted: Bullets and Numbering
- ~~12)11) **Experiment** is any use of animal for laboratory examination purposes or other scientific purposes that may incur pain, suffering, mental distress or permanent injury, including any activity that may result in birth of an animal in any of such conditions, but not including intentional painful methods of killing and marking animals recognized as such in modern practice (so-called humane methods). The experiment begins at the time the animal is first prepared to be used and it ends when the observations for that experiment will no more be conducted. Elimination of pain, suffering, mental distress or permanent injury by effective utilization of anesthesia or analgesia or other methods does not include the use of animals outside the framework of this definition. This definition does not cover non-experimental, agricultural, or clinical veterinary practice;~~ Formatted: Bullets and Numbering
- ~~13)12) **Breeding animals** are animals of male or female gender intended for breeding;~~ Formatted: Bullets and Numbering
- ~~14)13) **Thoroughbred (breeding) animals breeding husbandry** refers ~~isto~~ breeding raising of thoroughbred males and females, ova and fertilized ova and semen donors; ~~facilities for thoroughbred animals breeding, artificial insemination centers;~~ parent poultry flocks, parent fish schools; ~~queen bee breeding facilities;~~~~ Formatted: Bullets and Numbering
- ~~15)14) **Marking of animals** is a procedure for marking individual animals for identification purposes, particularly by ear tags, tattoos, microchips, or in other durable manner, and collection of all data into integral IT system;~~ Formatted: Bullets and Numbering
- ~~16)15) **Owner or holder of animal** is any natural or legal person responsible for or put in charge of an animal, whether on temporary or permanent basis;~~ Formatted: Bullets and Numbering
- ~~17)16) **Products of animal origin** (hereinafter: products) are all products derived from animals, and eggs for hen-setting, semen, ova, fertilized ova;~~ Formatted: Bullets and Numbering
- ~~18)17) **Food of animal origin** (hereinafter: food) refers to all items used for human consumption regardless whether they are unprocessed, treated, or processed, if derived from animals;~~ Formatted: Bullets and Numbering
- ~~19)18) **Raw materials of animal origin** (hereinafter: raw materials) are integral body parts of animals, unprocessed, foodstuffs excluded;~~ Formatted: Bullets and Numbering
- ~~20)19) **Slaughter facility** is a registered facility, including facilities for transportation and collection of animals prior to slaughter, in which animals are slaughtered in compliance with the provisions of this Law;~~ Formatted: Bullets and Numbering
- ~~21)20) **Production of food** refers to obtaining, preparing, treating, processing, further processing, packaging, re-packaging, and packing of food, conducted in the facilities registered for production;~~ Formatted: Bullets and Numbering
- ~~22)21) **Marketed food** is such food for which veterinary inspector, based on veterinary examination at the place of origin, determines that there are no obstacles for market placement and permits loading and unloading from the registered facility;~~ Formatted: Bullets and Numbering

~~23)~~22) **Marketing of food** means keeping of food for the purposes of trade, including offering the food for sale or to transfer it any other manner, free of charge or otherwise, as well as for sale, distribution, and transfer in any other manner;

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~~24)~~23) **Marketing of animals, products, raw materials and waste of animal origin** refers to importation, transit, exportation, sales or any other type of transfer of goods to third parties;

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~~25)~~24) **Trader in animals** (hereinafter: trader) is a legal or natural person involved in purchase or sales of animals, not including animals referred to in paragraph 5 Article 13 of the Law, who meets the laid down requirements;

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~~26)~~25) **Transit** is any transfer of shipments of animals, food, raw materials, products, medical products and medical devices, feed and waste, across the border of Montenegro to/from other countries;

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~~27)~~26) **Medical products and medical devices for use in veterinary medicine** (hereinafter: veterinary medicines) are all substances or combinations of substances, prepared and intended for treatment of animals or prevention of animal diseases. Medicines shall also include substances or combinations of substances to be used on animals for diagnostic purposes, or to improve or alter physiological functions;

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~~28)~~27) **Residue** is remaining of pharmacologically active substances and their metabolites, and of other substances which may be transmitted to food of animal origin and may be detrimental for human health;

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~~29)~~28) **Waste of animal origin** (hereinafter: waste) are bodies or body parts of animals which are not intended or suitable for human consumption, and food and products which are not suitable for human consumption;

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~~30)~~29) **Waste waters** are waters produced in the facilities for breeding of animals, slaughter facilities and other facilities for treatment, processing, and collection of raw materials, food, and waste, for which a special technology for drainage and purification is required;

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~~31)~~30) **Feed** refers to all substances and products, additives included, whether processed, partially processed, or unprocessed, intended for feeding of animals orally;

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~~32)~~31) **Veterinary examination and control** is any physical control and/or administrative formality applied to animals, raw materials, products, food, animal feed and waste, waste and facilities, aimed at direct or indirect protection of human and animal health;

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~~33)~~32) **Place of origin** is a space or facility in which veterinary examination was conducted and as a result of which veterinary certificate was issued;

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~~34)~~33) **Infectious animal diseases** are diseases designated by the international zoosanitary codex of the International office for infectious diseases (OIE);

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~~35)~~34) **Zoonoses** are all diseases or infections which may be transmitted from animals to humans and *vice versa*;

36)35) **Epizooty or infectious disease epidemic** refer to numerous cases of infectious disease which have, in terms of incidence, time, place, and affected animal species, exceeded the expected incidence;

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37)36) **Infected area** is the area in which one or more than one sources of infection was detected, and in which further spreading of infection is possible;

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38)37) **Threatened area** is the area to which the infection from the infected area may be transmitted and in which further spreading of infection is possible;

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39)38) **Facility** is a space or premises intended for raising of animals; holding of animal competitions; sale of animals; animal hunting or training; disposal, treatment and destruction of animal carcasses and wastes of animal origin; production, storing and trade in products of animal origin, raw materials and foodstuffs of animal origin, and required for breeding of animals or a space or a plant in which food, products, raw materials, waste, and feed, are treated and processed;

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40)39) **Animals breeding facility of unconfirmed or dubious epizootic situation** is a facility in which prescribed examinations of animals have not been conducted, or a facility of an animal owner who is involved in disallowed and uncontrolled trade in animals and products;

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41)40) **Veterinary hygiene service** is a legal person providing services within the jurisdiction of its own municipality;

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42)41) **Safe disposal** is a prescribed procedure for safe disposal of carcasses, confiscates, certain byproducts of slaughter, cutting, treatment and processing of meat, fish, game, milk, eggs, honey, and products of animal origin, intended for production of animal feed or utilization in industry, when, due to veterinary reasons and in view of human health protection, they may not, or cannot, be used through further processing; it is carried out in the facilities approved for safe disposal, by interment in animal graveyards and mass graves, or by incineration;

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43)42) **Euthanasia** is killing of animals without incurring them any pain;

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44)43) **Veterinary workers** are veterinarians and supporting veterinary staff – technicians and paramedics;

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45)44) **Veterinarian** is a veterinary physician, namely, a veterinary medicine graduate holding a veterinary license;

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46)45) **Veterinary license** is a license for veterinary practice as laid down in this Law;

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47)46) **Veterinary legal persons** are legal organization forms providing animal health care services and registered as: veterinary dispensary, veterinary clinic, veterinary dispensary for pets, specialized veterinary laboratory, livestock-veterinary reproduction center, embryotransfer center, specialist veterinary laboratory, National Veterinary Institute, and Veterinary Chamber;

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48)47) **Authorized laboratory** is a laboratory which complies with the laid down requirements for performance of particular veterinary related activities and ; ~~it is~~ authorized by the Ministry to ~~provide-perform such activities;specific services;~~

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~~49~~48) **Emergency veterinary assistance** refers to providing required assistance in case of direct danger to life of animal;

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~~50~~49) **Veterinary service** refers to the activity of a veterinarian, within or outside veterinarian legal person, aimed at providing animal health care for the requirements of prevention or breeding, for veterinary examination or inspection, and for the interventions in reproduction and for other purposes, not including the activities conducted within the mandatory volume of animal health care;

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~~51~~50) **Veterinary public health care** includes activities within the scope of controlling animals, raw materials and products, as well as veterinary environmental protection, which are directly or indirectly meant to protect human health from zoonoses, other diseases and harmful residues, which are foodborne and may affect human health;

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51) **Written instruction** is an instruction issued by a legal veterinary person, or other legal person or entrepreneur authorized to provide services referred to in this Law.

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51(a) **Veterinary-sanitary measure** is a measure applied to protect life and health of animals and humans from the risks arising from entry, establishment or spread of extremely dangerous infectious diseases and dangerous infectious diseases of animals, or to protect human or animal life or health from risks arising from presence of harmful substances in products, foodstuffs and raw materials of animal origin and in animal feed;

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51(b) **Risk** is a likelihood of the occurrence of infectious disease or presence of harmful substances, which, directly or indirectly, may to a certain extent impair animal or human health or life;

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51(c) **Risk analysis** is a process encompassing scientific risk assessment, risk management and risk communication, for the purposes of ensuring the appropriate level of protection of animal or human health and life;

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51(d) **Risk assessment** is an evaluation of the likelihood of introduction, establishment or spread of an infectious disease within the Republic, and the evaluation of potential adverse effects on human or animal health arising from the presence of disease-causing organisms or harmful substances in products, foodstuffs and raw material of animal origin or in animal feed;

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51(e) **Risk management** is a process of identifying and implementing measures with the purpose of reducing the level of risk;

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51(f) **Appropriate level of protection** is a level of protection deemed appropriate for protection of human or animal life or health;

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51(g) **Area of low disease prevalence** is an area, whether all of a country, part of a country, or all or parts of several countries, for which low level of presence of a specific disease has been determined and which is subject to effective surveillance, control or eradication measures, in accordance with the recommendations of the OIE (Office International des Epizooties);

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51(h) Disease free area is an area, whether all of a country, part of a country, or all or parts of several countries, for which no presence of animal disease has been determined, in accordance with the OIE recommendations;

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51(i) Animal husbandry is raising of animals for production of foodstuffs and products and raw materials of animal origin;

51(j) Animal keeping is raising and care of animals other than animal husbandry;

51(k) Epizootiology area is the area encompassing the territory of one or more municipalities;

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51(l) Farmstead is a facility or space for animal husbandry or keeping;

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51(n) International organizations are: Office International des Epizooties (OIE); Food and Agriculture Organization of the United Nations (FAO), World Health Organization (WHO), World Trade Organization (WTO) and other international organizations in the animal and human health protection area of which the Republic of Montenegro is a member.

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52) Written instruction is an instruction issued by a legal veterinary person, or other legal person or entrepreneur authorized to provide services referred to in this Law.

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## **1. Veterinary Practice**

### **Article 3**

Veterinary practice, in the context of the Law, shall include:

- 1) Protection and improvement of animal health;
- 2) Protection of animals against infectious and other diseases;
- 3) Detection and diagnostics of diseases and treatment of the diseased animals;
- 4) Implementation of the animal health care program;
- 5) Ensuring the measures for protection of humans against zoonoses, alimentary infections and intoxications; prevention of emergence, detection and eradication of these diseases; and prevention of transmittal of these diseases from animals to humans;
- 6) Ensuring safety of raw materials and food; ensuring food safety; and prevention of emergence of harmful substances in food by conducting control at the places in which animals are bred and raw materials and food are produced, processed and stored before placement in the market;
- 7) Ensuring safety of animal feed; and supervision of animal feed safety at the places in which animal feed is produced, processed and stored before distribution;
- 8) Ensuring safety of water for animal watering, and supervision of its safety;

- 9) Ensuring reproduction of animals, from the perspective of animal health care;
- 10) Ensuring measures for protection of environment from contamination by animal disease causes, and hygienic conditions and environmental safety in terms of animal health care;
- 11) Protection of animals from torture and pain, and care for animal welfare;
- 12) Production, distribution and control of medical products and medical devices for use in veterinary medicine;
- 13) Activities of disinfection, pest and rodent control, deodorization and decontamination;
- 14) Marking of animals in view of identification and control of movement;
- 15) Veterinary education, awareness raising and notification of the public.

#### **Article 4**

Administrative and related professional tasks pertaining to monitoring and prevention of incidence, detection, suppression, and eradication of specific infectious animal diseases; implementation of veterinary prevention measures for animals, products of animal origin, raw materials, wastes, food of animal origin, animal feed, seed for artificial insemination of ova, and fertilized ova in the trade within the country and the trade across the border of the Republic of Montenegro; implementation of the mandatory level of animal health care; ensuring provision of services of public interest; confirmation of compliance with veterinary-sanitary requirements for pursuing veterinary practice; and other tasks laid down by law; shall be performed by the administrative authority in charge of veterinary issues (hereinafter: the administrative authority).

## **2. Rights and Obligations of Animal Owners and Other Persons**

#### **Article 5**

Owners of animals shall have a right to animal health care.

All persons shall have an obligation to protect animal health and human health against diseases and infections transmittable between humans and animals, and against effects of the residues of harmful substances in food of animal origin.

A veterinarian shall have an obligation to provide emergency veterinary assistance.

Natural and legal persons shall have an obligation to enable veterinary examination and control, acquire the material needed for examinations, and implementation of other prescribed measures.

Should they establish that there is a risk to animal health, or ensuing risk to human health, natural and legal persons shall have an obligation to immediately notify a veterinary legal person or veterinary inspection, and to provide, within the specified term, necessary information about animal health care that was provided and measures that were implemented, and to facilitate verification of accuracy of provided data.

Owners and keepers of animals shall have an obligation to keep the records about the number of and health status of the animals.

Owners and keepers of animals, natural and legal persons, companies and entrepreneurs, shall have an obligation to register their farmsteads, facilities and animals, and to allow marking of animals for the purposes of animal identification and control of their movement; suppression and eradication of animal diseases; control of residues in animals, raw materials, foodstuffs, and animal feed; in accordance with the law.

Owners of animals shall have a right to freely choose the veterinarian, not including cases referred to in item 3 paragraph 1 Article 12, and cases referred to in Articles 21 and 21, and Article 64, items 2, 7, and 8, of the Law.

Owners of animals shall have a right to be informed about the chosen methods, prices of veterinary services, and possible effects.

Contents, form, and method of records keeping, as referred to in paragraph 6 of this Article shall be laid down by the Ministry in charge of veterinary issues (hereinafter: the Ministry).

### **3. International Obligations**

#### **Article 6**

International obligations pertaining to prevention of emergence, detection, suppression, and eradication, of infectious animal diseases in international trade in animals, products, raw materials, food, feed, and waste of animal origin, and items that may transmit infectious diseases, shall be met in compliance with the international conventions and other international agreements.

Veterinary Administration shall participate in the work and shall cooperate with international organizations.

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## **II. INFECTIOUS ANIMAL DISEASES**

### **A. TYPES OF INFECTIOUS ANIMAL DISEASES**

#### **Article 7**

Infectious animal diseases, on account of which general and specific preventive measures and other measures prescribed by this Law shall be implemented, according to the type of the agent of disease and measures required for prevention of their emergence, detection, suppression and eradication, are classified ~~into as diseases subject to the obligation of notification~~ List A Diseases, List B Diseases, and other diseases, according to the international codex of animal health care and epizootic situation.

Diseases subject to the obligation of notification shall be classified as exceptionally dangerous infectious diseases, dangerous infectious diseases.

~~List A includes~~ Exceptionally hazardous infectious diseases are diseases that may be suddenly and quickly spread across the state borders.

Exceptionally dangerous infectious disease List A diseases may imply serious social and economic effects for the country and/or endanger survival of certain animal species and compromise international trade with animals and products of animal origin.

~~List B includes~~ Dangerous infectious diseases which may cause considerable negative social and economic significance and/or negative consequences for the public health within the country, as well as negative consequences in the international trade in animals and products of animal origin.

Other diseases include less infectious diseases.

Zoonoses are diseases or infections which are transmitted in nature from animal to humans and vice versa.

Detailed classification of the diseases referred to in this Article, a manner of notification and reporting, and measures to be taken shall be laid down by the Ministry.

## **B. PREVENTION OF INFECTIOUS ANIMAL DISEASES EMERGENCE**

### **Article 8**

Protection of animals from infectious diseases and protection from zoonoses, in terms of this Law, shall be an obligation of animal owners, or animal keepers, which are, temporarily or permanently, in charge of animals; legal veterinary persons; veterinary inspection; public administration bodies and local self-government bodies; other legal persons; and all other persons suspecting that an animal is diseased of any infectious diseases specified in this Law.

### **Article 9**

Persons involved in a registered activity of breeding or production, coming into direct contact with animals, food, raw material, products or waste, shall have a basic knowledge of infectious animal diseases, prevention of their emergence, ways of their transmittal to humans, and regulations governing protection from infectious animal diseases, in accordance with the programs defined by the administrative authority.

### **1. Mandatory General Preventive Measures to be implemented by Animal Owners**

#### **Article 10**

Mandatory general preventive measures for protection of animals from infectious diseases to be implemented by owners of animals, and other legal and natural persons, shall include:

- 1) Providing hygienically safe drinking water, water for watering animals, and animal feed;
- 2) Ensuring and maintenance of prescribed hygienic conditions in the facilities for animal breeding and other places and structures in which animals are kept;
- 3) Ensuring hygiene in birth-giving assistance and milking of animals;

- 4) Ensuring minimum veterinary requirements in public spaces where animals are collected; in the means of transport for transportation of animals, products, raw materials, food, waste, and feed; in stock-yards and pastures; and in places for collection of animals, slaughter of animals, and collection, processing and storing of raw materials, food, waste, and feed;
- 5) Ensuring food safety and veterinary-sanitary conditions for food production and market placement;
- 6) Preventing entry of agents of infectious diseases into the facilities for breeding of animals;
- 7) Implementation of veterinary measures in the facilities for breeding of animals;
- 8) Handling animal carcasses and other waste, waste waters, excretions and urine in a prescribed manner;
- 9) Ensuring preventive disinfection, pest and rodent control in the facilities, in public spaces and in the means of transport;
- 10) Other general measures prescribed by this law.

## **2. Specific Preventive Measures to be implemented by Legal Persons**

### **Article 11**

With the objective of infectious animal diseases early detection and prevention of emergence, one or more than one specific preventive measure may be taken, subject to nature of the disease and likely risk, namely:

- 1) Streamlined training of animal owners and other persons in the area of veterinary medicine;
- 2) Registration and marking of animals;
- 3) Diagnostical and other examinations;
- 4) Determination of causes of death;
- 5) Winding-up of the estates, in case of suspected infectious animal disease;
- 6) Inoculation and serumization (immunoprophylaxis) and protection with drugs (chemoprophylaxis);
- 7) Disinfection, and pest and rodent control;
- 8) Safe disposal of animal carcasses, confiscates and waste;
- 9) Safe disposal or hygienization of waste waters and excretes from the facilities;

10) Destruction of infection reservoirs and prevention of transmittal of infectious disease agents via vectors;

11) Other specific preventive measures prescribed by this law.

For implementation of the measures referred to in paragraph 1 of this Article, the Ministry shall issue an Operative Program and other programs pertaining to animal health.

At the end of each year, the Ministry shall issue an Operative Program for the ensuing year by which it shall determine a type of the preventive inoculation, diagnostical and other examination to be conducted in the Republic of Montenegro (hereinafter: the Republic), with the objective of providing adequate epizootiological conditions and trade requirements.

Operative Program shall be published in the “Official Gazette of the Republic of Montenegro”.

The programs referred to in paragraph 2 of this Article shall specify timeframe for their implementation, methods of notification about the measures taken, entities which shall implement them, method of funding, and other terms for implementation of the specified measures.

### **3. Specific Preventive Measures against Zoonoses**

#### **Article 12**

Mandatory specific preventive measures for human health protection from zoonoses shall include:

- 1) Systematic prevention, detection and suppression of zoonoses in animals;
- 2) Implementation of preventive measures for protection of veterinarians, veterinary technicians, owners of animals, and other persons who may come in immediate or indirect contact with the infected animals, food, products, raw materials, or waste;
- 3) Ensuring food safety and preventing disallowed trade in infected animals and unsafe food, products, raw materials, and waste, which may constitute a risk for human health, through veterinary examinations and control of animals, food, products, raw materials and waste;
- 4) Prevention of the contamination of raw materials, products and food in the facilities for food production and other facilities;

The measures referred to in paragraph 1 of this Article shall be implemented based on the annual and long-term programs for protection of humans from zoonoses, which specify timeframe of implementation of measures, method of implementation of measures, and method of funding.

The programs referred to in paragraph 2 of this Article shall be issued by the Ministry, with approval of the Ministry in charge of health issues.

### **4. Registration, Control, and Reporting of the Facilities, Forwarders, Collection Centers, Traders, and Animals**

#### **Article 13**

Veterinary control shall cover: animals, raw materials, feed, products and food in production and trade as referred to in this Law, water for watering of animals, waste waters and waste, facilities, devices, accessories and equipment for their breeding, collection, production, treatment, additional treatment, processing, transportation, and storing, and forwarders and traders.

~~Facilities, forwarders, and traders referred to in paragraph 1 of this Article shall meet the prescribed veterinary sanitary requirements and shall be entered into appropriate registers.~~

Veterinary control shall also cover animals at fairs, markets, shops and other sales or collection places, at the exhibitions, sport competitions, bird-boxes, wild animal enclosures, and other public spaces in which animals are collected.

Natural and legal persons dealing in breeding, keeping, sales, transportation or marketing of animals; or production, storing and sales of products, food, waste, and animal feed; shall, within seven days, report the animals, facilities and equipment, as well as any change thereof, to the administrative authority.

Owner of a dog shall notify, within seven days, a legal person keeping register of dogs about acquisition of a dog, his death, confiscation, or escape, and any change with regard to the dog.

Acquisition of a puppy shall be reported before a puppy is four months old, at the latest.

Provisions of paragraph 4 of this Article shall not apply to keeping less than five adult individuals of the same species, nor shall not apply to breeding of house birds, aquarium fish, decorative poultry or small rodents.

~~Detailed requirements referred to in paragraph 2 of this Article shall be specified by the Ministry.~~

## C. SUPPRESSION AND ERADICATION OF INFECTIOUS ANIMAL DISEASES

### **1. Emergence of Infectious Animal Disease, or Suspected Emergence of Infectious Animal Disease**

#### **Article 14**

In case of emergence of infectious animal disease, or when detected signs of a disease give rise to a founded suspicion that an animal is diseased, or died, of an infectious disease, owner of such animal, or keeper who is temporarily or permanently in charge of the animal, shall:

- 1) Immediately notify the nearest legal person or veterinary inspector;
- 2) Isolate healthy animals from those suspected to be diseased;
- 3) Prevent entry of unauthorized person into the courtyard, or facility;
- 4) Restrain from taking or forcing the animal out of the courtyard, or facility;
- 5) Keep the dead animal until a veterinarian arrives;

- 6) Facilitate clinical examination, taking of the material for diagnostical examination, including killing, or sanitary slaughter of animals, and conduction of the epizootiological study.

It shall be considered that a suspicion of an infectious disease is present when, among the animals of the same courtyard, stock-yard, herd, flock, or apiary, there are two or more cases of a disease with the same or similar symptoms, or animals suddenly die without the apparent cause.

## **2. Determination of Infectious Animal Disease**

### **Article 15**

A veterinarian suspecting an infectious animal disease shall, without delay, issue to the owner or keeper of animal a professionally written instruction on the prescribed veterinary measures, in a prescribed manner undertake all measures necessary to confirm or exclude a given disease, or to determine the cause of death of animal and prevent spreading of the disease, and in a prescribed manner notify veterinary inspection about it.

A veterinarian supplying the material for examination of a suspicion of an infectious animal disease, and a veterinary legal person conducting the diagnostical examinations, shall ensure that sampling material is transported in a suitable manner so as to prevent any possibility of spreading the infectious disease or deterioration of the material.

A manner in which information about the suspicion and determination of infectious disease shall be supplied, a manner in which material shall be transported, measures to be undertaken by the veterinarian, and measures for determination of infectious animal diseases, shall be prescribed by the Ministry.

## **3. Notification about Infectious Animal Diseases**

### **Article 16**

Based on the report of an infectious animal disease, or a suspicion of an infectious animal disease, veterinary inspector shall conduct the epizootiological examination.

Veterinary inspector shall notify the relevant health institution about the suspicion or presence of zoonoses.

## **4. Measures**

### **Article 17**

When presence of an infectious disease is established, the Ministry shall impose, according to the nature of the infectious disease and the risk degree in the infected and threatened area, one or more than one of the following measures:

- 1) Isolation of healthy animals from diseased ones;

- 2) Enclosure of the diseased animals and closing up of the infected yards in which an infectious disease is established;
- 3) Prohibition or restriction of the movement of animals, vehicles and people;
- 4) Prohibition of taking out of the infected yards and facilities the animals, products, raw materials, and waste, and other items which may transmit agents of infectious diseases;
- 5) Sanitary slaughter, or killing of infected animals or animals suspected of infectious disease, provided the animal is first stunned in a humane and professional manner;
- 6) Disposal of carcasses of the killed or slaughtered animals and the infected material, and their safe destruction;
- 7) Prohibition of events at the fairs, markets, exhibitions, places in which animals are bought up, and other events pertaining to animals;
- 8) Prohibition of slaughter of infected animals or animals suspected of being infected;
- 9) Inventory and marking of animals;
- 10) Prohibition or restriction of animal breeding, and of acquisition, processing, storing and utilization of the semen for artificial insemination, ova, and fertilized ova;
- 11) Inoculation, diagnostical examinations, and treatment of animals;
- 12) Restriction of movement of the person coming in contact with infected animal, or animal suspected to be infected, and products, raw materials, and waste of infected animals;
- 13) Enclosure and blockade of the infected inhabited places and regions;
- 14) Castration of infected animals;
- 15) Disinfection, pest and rodent control in stables, stock-yards, courtyards, pastures, watering sites and other places in which infected animals or animals suspected of being infected are situated, and of items which came in contact with the infected animal or animal suspected of being infected;
- 16) Safe disposal and destruction of animal feed, bedding, excretions, and other matter from the facilities, which may not be rendered safe by cleaning or disinfection;
- 17) Enclosure of dogs and cats, and destruction of stray dogs and cats, in a humane manner;

In case of emergence of an exceptionally dangerous infectious disease~~List A disease~~, in the course of implementation of the measures referred to in paragraph 1 of this Article, the administrative authority shall be entitled to demand assistance of the administrative authority in charge of police or the authority in charge of defense.

About the measures implemented when restricting the movement of people or carrying out disinfection of people, a relevant health service shall be notified.

### **Article 18**

In case of emergence of an exceptionally dangerous infectious disease~~List A disease~~, the Ministry shall define borders of infected and threatened areas and form teams of veterinary workers to be sent into the infected or threatened area in case of an inadequate number of veterinary workers in such areas, or in case when it is required to involve a greater number of veterinary workers.

In case of a danger that an infectious disease enters the territory of the Republic of Montenegro, the Ministry may impose, in the threatened area:

- 1) Control, of animals, products, raw materials, and waste, at certain places (roads, bridges, etc.);
- 2) Prohibition, restriction, or conditional permission, for transportation of animals, products, raw materials, and waste, to a certain territory;
- 3) Disinfection of natural persons and means of transport.

### **Article 19**

A manner in which infected and threatened areas shall be defined, more comprehensive measures for infectious diseases determination, prevention of spreading, suppression, and eradication, terms and cessation of the measures from Article 17 of this Law, and manner of announcement and notification, reporting emergence and cessation of diseases, shall be laid down by the Ministry.

Infectious disease shall be deemed to have ceased when the last diseased animal recovers, dies, or is killed, or, after completion of disinfection, upon lapse of the longest incubation period for such infectious disease, unless otherwise provided by the professional veterinary standards.

In the state of emergency or war, during natural or other disasters causing disease in a larger number of animals, and in emergence of epizooties, the Ministry may order to natural or legal veterinary persons under this Law to promptly implement specific professional measures and tasks.

### **Article 20**

In the cases from paragraph 3, Article 19, of this Law (war, epizooty, natural disaster causing disease in a greater number of animals), the Ministry shall propose to the Government of the Republic of Montenegro to adopt measures as follows:

- 1) Mobilization of veterinarians and population to implement prescribed measures pertaining to animal health care;
- 2) Mobilization of equipment, medicines, and means of transport, in compliance with the specific regulations, and temporary utilization of land and buildings for implementation of the prescribed measures pertaining to animal health care;
- 3) Utilization of land and buildings for the purpose of safe disposal of carcasses of killed or dead animals, food, bedding, waste and other infected material by interment, incineration, or otherwise;

- 4) Specific duties for all veterinarian organizations, and, if necessary, for other legal persons and government authorities, with the objective of implementing specific measures pertaining to animal health care.

### **III. PREVENTIVE VETERINARY MEASURES**

#### **A. PREVENTIVE MEASURES IN THE COURSE OF DISTRIBUTION**

##### **1. Animal Health Certificate**

###### **Article 21**

Animals shall be marked in a prescribed manner.

Animals, while in distribution, shall be accompanied by animal health certificates issued by a suitable legal person.

Animal health certificate referred to in paragraph 2 of this Article shall confirm health condition of the animal, the fact that, in the place of origin of the animal, no presence of infectious animal diseases transmittable by the species of the animal was identified, and other prescribed requirements.

Health certificate shall be issued for a definite period of time.

Owner of animal shall pay a fee for issuance of the certificate referred to in paragraph 2 of this Article.

Detailed requirements for marking of animals, requirements for issuance of animal health certificate and its content and form, and level of the fee, shall be prescribed by the Ministry.

##### **2. Veterinary Certificate or Product Shipment Attestation**

###### **Article 22**

Products, when in distribution, shall be marked in a prescribed manner.

Products, when in distribution, shall be accompanied by the prescribed veterinary certificates and attestations.

A certificate or attestation referred to in paragraph 2 of this Article shall confirm that a product is safe and that, in the place of origin of such product no presence of infectious diseases transmittable by such products was detected, and other prescribed requirements.

Veterinary certificate or attestation referred to in paragraph 2 of this Article shall be issued for a definite period of time.

Owner of product shall pay a fee for issuance of the certificate or attestation referred to in paragraph 2 of this Article.

Detailed requirements for marking of the products, content and form of the certificate or attestation referred to in paragraph 2 of this Article, and level of the fee, shall be defined by the Ministry.

### **3. Veterinary Referral Form**

#### **Article 23**

Diseased and injured animals, and animals with impaired basic life functions, may be referred to a slaughter facility only under the prescribed conditions.

In cases referred to in paragraph 1 of this Article, owner of animal shall hold a veterinary referral form instead of animal health certificate.

Final veterinary examination of these animals shall be conducted in slaughter facilities.

Slaughter of animals referred to in paragraph 1 of this Article shall be carried out in the nearest registered slaughter facility complying with the prescribed requirements.

Before transportation of the animal to a slaughter facility referred to in paragraph 4 of this Article, all prescribed veterinary measures shall be implemented.

Owner of animal shall also hold a prescribed veterinary referral form for the animals which will be referred to the slaughter facility from a facility with unconfirmed or dubious epizootiological situation.

Owner of animal shall pay a fee for issuance of the referral form referred to in paragraph 2 of this Article.

Detailed requirements for issuance, contents, and a form of the referral form referred to in paragraph 2 of this Article, and a manner in which records shall be kept about the issued referral forms and the level of related fee shall be prescribed by the Ministry.

#### **Article 24**

Legal persons registered for the activities pertaining to hunting shall provide for temporary accommodation and veterinary examination of game, after catch and kill, in order to obtain health certificate, or attestation on safety of the shipment.

#### **Article 25**

Legal and natural persons dealing with buyout and processing of hide shall keep records of the origin of bought hide.

Hides originating from the animals slaughtered without prior veterinary examination, or from dead animals, shall be clearly marked with an ordinal number.

Legal and natural persons dealing in collection, purchase and distribution of hide shall supply, for each hide referred to in paragraph 2 of this Article, a sample to the authorized laboratory in order to be tested on splenic fever.

The sample shall be marked with the same number as the hide from which it originates.

The Ministry shall specify in what manner for keeping the records referred to in paragraph 1 of this Article.

#### **4. Veterinary Indication of Food Safety**

##### **Article 26**

Food, when in distribution, shall be indicated and certified in a prescribed manner.

Detailed requirements for indication and certification of food shall be defined by the Ministry.

#### **5) Veterinary Examinations and Control of Animals, Food, Raw Materials, Products, and Waste, in Distribution**

##### **Article 27**

Distribution of animals, food, products, raw materials and waste, shall be allowed only after completion of veterinary examination at the place of production, or place of origin, and if they can be identified and tracked, and if other prescribed requirements are met.

In transportation by railway, a ship, plane or road vehicles, the loading, re-loading and unloading of the shipments referred to in paragraph 1 of this Article shall be allowed only in places meeting the prescribed requirements.

Means of transport in which shipment referred to in paragraph 1 of this Article are transported shall be cleaned and disinfected in a prescribed manner.

Detailed requirements referred to in paragraphs 1, 2, and 3 of this Article shall be prescribed by the Ministry.

#### **6. Prohibition of Distribution**

##### **Article 28**

In case of emergence of an exceptionally dangerous infectious disease of animals~~List A infectious animal disease~~, or in presence of an immediate danger to health of humans or animals, the Ministry shall restrict or prohibit distribution of animals, food, raw materials, products, waste, animal feed, veterinary medicines and medical devices.

Notwithstanding the provision of paragraph 1 of this Article, before issuing the act referred to in paragraph 1 of this Article, the Ministry may, in case of a need to expeditiously undertake measures, issue required instructions so as to avoid immediate danger to human health or animal health.

## **7. Approval for Collection and Sales**

### **Article 29**

Relevant self-government bodies shall issue permits for the organization of exhibitions, zoo parks, evaluation and competition of animals, various events involving traveling animals (circus, traveling zoo parks, etc.), and for the organized sales of animals and raw materials outside business premises and with prior approval of the administrative authority.

## **8. Tasks in Transportation, and Accidents during Transportation**

### **Article 30**

Owners of animals and forwarders of animals, food, raw material, products and waste, shall comply with the requirements prescribed for transportation, and facilitate inspection examination.

Forwarder shall report any accident occurring in the course of animals, raw materials, products and waste, transportation to the police, and the police shall notify a legal veterinary person which shall provide emergency veterinary assistance to the injured animals.

Forwarder, or his representative, shall provide all that is necessary to implement all requisite measures for protection of animals, food, products, raw materials, and waste.

Animals which are not capable of undergoing further transportation should be immediately killed in a humane manner.

Veterinary Hygiene Service (hereinafter: VHS), or other legal person authorized to dispose of the waste, shall arrange for transportation of dead or killed animals, decayed food, raw materials, products, and waste, at the expense of the forwarder.

Forwarder shall provide a new means of transport for transportation of animals which are capable of undergoing further transportation, and unspoiled raw materials, products, and waste, from the place of accident.

By way of an exception, in the case of the absence of VHS or other legal person authorized to dispose of the waste, the forwarder shall arrange for transportation of dead or killed animals, decayed food, raw materials, products, and waste, and take care of their safe disposal according to the instruction of and supervised by a legal person or veterinary inspection.

Detailed requirements referred to in paragraph 1 of this Article shall be prescribed by the Ministry.

## **9. International Transport**

### **Article 31**

Transportation of animals, food, raw materials, products, veterinary medicines and medical equipment, feed and waste, in international transport, shall take place only at such border crossings which shall have veterinary control in place and which meet basic hygiene-technical working conditions.

Animals, food, raw materials, products, veterinary medicines and medical equipment, feed and waste, shall be subject to mandatory veterinary control at border crossings.

Shipments referred to in paragraph 2 of this Article shall be accompanied by the prescribed international veterinary certificate issued on the day the shipment was dispatched, which shall be endorsed as prescribed and written in the language that is in official use in the Republic and in the language of the country of origin, and, for the shipments in transit, also in other languages which are officially recognized in the international trade, unless otherwise provided by international contract.

Loading, reloading, unloading and storing of animals, food, raw materials, products, veterinary medicines and medical equipment, feed and waste, shall take place under veterinary control and in compliance with the prescribed requirements.

Importation, transit and storing of animals, food, raw materials, products, veterinary medicines and medical equipment, feed and waste, shall be approved, upon prior veterinary control and examination of each individual shipment at the border, according to the prescribed requirements for their importation, transit, and storing.

Notwithstanding provisions of paragraph 5 of this Article, importation, ~~and transit, and storing of the shipments of foodstuffs, raw materials, products, animal feed and wastes, and importation and transit of~~ pets shall be approved ~~without upon~~ prior veterinary examination and control ~~but, without laboratory analysis of individual shipments if the shipments provided the animals~~ are accompanied by a corresponding veterinary attestations and provided a number of successive previous shipments from a specific facility were safe for use and accompanied by proper international veterinary certificates.

Importation, transit, and storing, of other items which may carry infectious diseases (hunters' and fishermen' trophies, serums, microorganisms, etc.) shall be approved, upon previous veterinary control and examination of each individual shipment at the border, according to the prescribed requirements for their importation, transit, or storing.

For importation of foreign (allochthonous) living animal species, the import shall, in compliance with the regulations, obtain approval from the Ministry in charge of environmental issues.

For shipments referred to in paragraph 2 of this Article, which are exported, the attestation on health condition in importation (certificate) shall be issued in the form prescribed for the importing country, when loading at the place of origin of the shipment, and the veterinary inspector at the border shall verify this attestation when the shipment is leaving the country across the country border.

The certificate on health status of the shipment referred to in paragraph 9 of this Article shall be issued in a printed form, in compliance with a suitable model of the forms issued by international organizations, OIE, and EU Commission, or in compliance with the form prescribed by the importing country.

Detailed requirements referred to in paragraphs 1, 3, 4, 5 and 7 of this Article and the form of the certificate referred to in paragraph 9 of this Article shall be prescribed, and border crossing referred to in paragraph 1 this Article shall be designated, by the Ministry.

### **Article 32**

In importation of animals, food, raw materials, products, veterinary medicines and medical equipment, feed and waste of animal origin, all prescribed veterinary examinations and control shall be carried out in accordance with the risk analysis.

After importing the animals, the importer shall hold them in quarantine for examination purposes.

The place of quarantine, the types of examinations and the conditions for holding the animals in the quarantine, shall be laid down by the administrative authority.

For the animals that are imported for the purposes of participation at sports competition in the duration of max. 15 days, or at the exhibitions and fairs, as well as for the hooved and cloven-hooved animals, poultry, and hares which are imported to be immediately slaughtered, the administrative authority may determine that there is no need for them to be kept in quarantine, provided the epizootic situation in the exporting country is such that there is no danger of animal infectious diseases being introduced.

Importation and entry of living microorganisms which are pathogenic for animals shall be disallowed.

Exceptionally, the administrative authority may allow the scientific and research organizations to import microorganisms, for scientific and research purposes only.

Types of examination and control, and place of examination, referred to in paragraph 1 of this Article, and detailed requirements with regard to the duration of quarantine, shall be laid down by the Ministry.

## **10. Facilities and Animals from Other Countries**

### **Article 33**

Importation of animals shall be allowed only if the prescribed requirements pertaining to animal health care and protection from torture, and transportation of animals, are met.

Importation of food, raw materials, products, feed and waste, shall be allowed only from such facilities which comply with the prescribed requirements, are registered in EU, and are under the control of relevant veterinary bodies.

~~Exceptionally, notwithstanding paragraph 2 of this Article, administrative authority shall allow; the Ministry may allow importation of foodstuffs, raw materials, products, animal feed and wastes from other, as referred to in paragraph 2 of this Article, of other facilities, after establishing that the regulations, standards, products and surveillance performed by the exporting country are at least equivalent to the regulations of the Republic, and when at least equivalent protection of consumers is guaranteed.~~

The administrative authority may conduct examination for the purposes of verifying the facilities referred to in paragraph 3 of this Article. Costs of examinations shall be borne by the importer.

Content and form of the application for approval, or inspection of facility, and level of costs referred to in paragraphs 3 and 4 of this Article, shall be laid down by the Ministry.

#### Article 34

In free customs zones and customs storage facilities, provisions of Articles 31, 32, and 33 of this Law shall fully apply.

#### Veterinary-sanitary Measures in International Trade

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#### Article 34 a

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Veterinary-sanitary measures in international trade shall be undertaken:

1. only to the extent necessary to protect life and health of humans and animals, and shall be based on scientific principles and available scientific evidence, international standards, guidelines and recommendations;
2. in such a manner not to arbitrarily or unjustifiably discriminate between countries where identical or similar conditions prevail, including discrimination between the own territory and other countries;
3. based on the assessment of the risks to human or animal life or health, taking into account risk assessment techniques developed by the international organizations; and
4. in such a manner that would not constitute a disguised restriction on international trade.

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#### Article 34 b

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In the assessment of risks to health and life of animals and humans, and for the purpose of determining veterinary-sanitary measures in international trade the following shall be taken into account in particular:

1. scientific evidence; relevant processes and production methods; relevant inspection, sampling and testing methods; prevalence of specific diseases; existence of disease free areas or areas of low disease prevalence; relevant ecological conditions; and quarantine or other treatment
2. economic factors encompassing the potential damage in terms of loss of production or sales in the event of the establishment or spread of a disease;
3. costs of control or eradication of disease; and
4. cost-effectiveness of alternative approaches to limiting risks.

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~~Exceptional~~Notwithstanding to the provisions of paragraph 1 of this Article, the ~~Veterinary~~administrative authority, Administration may, in cases where relevant scientific evidence is insufficient for objective assessment of risk, or in ~~urgent~~emergency circumstances, provisionally undertake veterinary-sanitary measures on the basis of available pertinent information, including that from the relevant international organizations, as well as information on veterinary-sanitary measures applied by other countries.

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Veterinary-sanitary measures shall be adapted to the veterinary-sanitary characteristics of the region from which animals, products, food and raw materials of animal origin originate, and to which they are destined. In assessing the veterinary-sanitary characteristics of a region, Veterinary Administration shall take into account, inter alia, animal health status in the Republic and exporting country, the level of prevalence of diseases, the existence of control and eradication programs, identification of disease free areas or areas of low disease prevalence, as well as the appropriate criteria or guidelines of relevant international organizations.

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Veterinary-sanitary measures may be undertaken to achieve the level of protection of life and health of animals and humans that is higher of than the level achieved by measures based on international standards, guidelines and recommendations, if it is scientifically justified, or if such level of protection is deemed appropriate.

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The administrative authority ~~Veterinary Administration~~ shall review veterinary-sanitary measures, including temporary veterinary-sanitary measures ~~from~~ referred to in paragraph 2 of this Article and measures undertaken in ~~urgent~~ emergency circumstances whenever new scientific evidence ~~is becomes~~ available.

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Regulation on introduction of a veterinary-sanitary measure shall be published in the "Official Gazette of the Republic of Montenegro".

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#### Article 34 c

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If international standards, guidelines or recommendations do not exist, or veterinary-sanitary measure does not comply with international standards, guidelines or recommendations, and if the measure may have a significant effect on foreign trade, the administrative authority ~~Veterinary Administration~~ shall:

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1. publish a notice on the intention to introduce a measure, at an early stage of its development;
2. notify interested WTO members, in accordance with the rules of international agreements of the products to be covered by such measure, and provide a rationale of the proposed measure;
3. provide copies of regulation introducing proposed measure, along with indication of parts which deviate from international standards, guidelines or recommendations, upon request of competent authorities of other countries, and in accordance with rules of international agreements, and
4. determine deadline to provide comments, and shall conduct consultations upon request of interested parties

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Notification referred to in paragraph 1, item 2 of this Article shall be submitted at least 75 days before the initiation of adoption process of the proposed veterinary-sanitary measure.

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#### Article 34d

If for the purpose of protection of life and health of animals and humans introduction of veterinary-sanitary measure can not be delayed, the Ministry shall introduce such measure through ~~urgent~~ emergency procedure.

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Provisions of Article 34c shall not be applied in the case of introduction of urgent emergency veterinary-sanitary measures.

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~~Veterinary Administration~~The administrative authority shall notify interested WTO members of the particular measure adopted in urgent emergency circumstances which does not comply with international standards, guidelines or recommendations, and may have a significant effect on foreign trade; of the products covered, and shall indicate in the notification rationale of the measure, nature of urgent emergency circumstances, and shall ask interested parties to provide comments on the veterinary-sanitary measure introduced in urgent emergency circumstances.

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The administrative authority ~~Veterinary Administration~~ shall review veterinary-sanitary measure introduced in urgent emergency circumstances within the period of 6 months from the day of its publishing publication in the "Official Gazette of the Republic of Montenegro", for the purpose of the determining the need for such urgent emergency veterinary-sanitary measure.

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#### Article 34 e

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The administrative authority ~~Veterinary Administration~~ shall provide information, submit documentation and notifications arising from international agreements, regarding the following:

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1. proposed and adopted veterinary-sanitary measures;
2. control, inspection and approval procedures, production and quarantine treatment;
3. risk assessment procedures and manner of determining appropriate level of animal health protection in the Republic;
4. membership and participation in the work of international and regional organizations and systems for animal health protection, existence and content of bilateral and multilateral agreements and arrangements.

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For supplied information and submitted documentation referred to in paragraph 1 of this Article, a fee may be charged at in the amount of actual costs of services rendered.

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The fee referred to in paragraph 2 of this Article shall represent the revenue of the budget of the Republic.

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The Ministry shall determine the amount of actual costs.

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#### Article 34 f

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Veterinary-sanitary measures of other country shall be accepted as equivalent to measures applied in the Republic; if the Veterinary Administration finds that other country's measures achieve the level of animal health protection required in the Republic or higher level.

Recognition of equivalence of foreign veterinary-sanitary shall be published in the "Official Gazette of the Republic of Montenegro".

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#### Article 34 gf

Procedure to ~~check confirm~~ verify fulfillment of requirements prescribed in veterinary-sanitary measures shall be undertaken:

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1. quickly and without undue delay and in no less favorable manner for imported products than for like domestic products;
2. based on facts and information necessary for completion of procedures by authorities;
3. so that the applicant is informed of the period required for completion of procedure, any potential deficiencies in the request, of the stage of the procedure and of the result of the procedure;
4. in such a manner that protection of confidential information is provided;
5. so that the requirements for quantity of samples are limited to what is necessary for conducting control and approval procedures;
6. so that if specification of a product is changed subsequent to conducted control, the procedure for the modified product is limited to what is necessary to determine whether the modified product still meets the regulations concerned.

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## B. PREVENTIVE MEASURES IN PRODUCTION AND DISTRIBUTION OF PRODUCTS, RAW MATERIALS, FOOD, AND FEED

### 1. Veterinary Control

#### Article 35

~~HProductionusbandry, keeping, and trading of animals, slaughter of animals whose meat is used for public consumption, production, market placement, marketing, storing, and distribution of the products, foodstuffs, and raw materials, food, waste of animal origin, and feed; production in which raw materials and food in untreated and unprocessed condition are used, and meat and meat products; slaughter of animals, preparation, treatment, processing, additional processing, packaging, repackaging, and packing of raw materials, foodstuffs, products of animal origin and animal feed, parent poultry flocks, parent fish schools, queen bee colonies, production, marketing and storing of agents for disinfection and insects and rodent control, collection, processing, and destruction of the waste of animal origin, may be carried out only by the companies, other legal persons and entrepreneurs, and other products, and storing and distribution of such products, raw materials, food and feed, which may carry an infectious disease, shall be allowed only in the facilities which, in respect of equipment, construction, veterinary-sanitary and other conditions, subject to the activities carried out in a specific facility, comply with the prescribed requirements for which the Ministry has issued an official document confirming that veterinary and sanitary requirements are met, or which are registered and for which the relevant authority has issued registration number and defined the method of control.~~

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For specific business activities in the facilities referred to in paragraph 1 of this Article, the Hazard and Critical Control Points Analysis (HCCAP) Program, and Good Manufacturing Practice (GMP) Program, shall be implemented by an expert assigned to such activities.

In the facilities referred to in paragraph 1 of this Article, veterinary control shall cover production, market placement, marketing, storing and distribution of products, raw materials, food and feed, as well as space, equipment, plants, internal control within the facility (HCCAP, GMP, etc), documentation and laid down records.

Veterinary control shall also cover means of transport used in the facilities registered for loading, or unloading of products, raw materials, food, waste, and feed.

Veterinary control in production and marketing of raw materials, food and feed, as well other products, shall also include animals, raw materials, products, food, feed, waste, waste waters, solid and liquid fertilizer, and use of the products and substances which come in contact with food and packing material

Veterinary control shall also include requirements for the safety of raw materials, food, feed, and other production in the production and marketing.

Detailed ~~requirements-veterinary-sanitary requirements for the facilities referred to in paragraph 1 of this Article for registration, production, market placement, and marketing of raw materials, food, feed, waste, waste waters, solid and liquid fertilizers, and control referred to in this Article~~ shall be as laid down by the Ministry.

#### **Article 36**

Slaughter of animals whose meat is used for public consumption shall be carried out in slaughter facilities meeting the prescribed requirements.

Animals referred to in paragraph 1 of this Article, or their meat, shall be subject to mandatory veterinary control.

In slaughter of individual hoofed animals or larger cloven-hoofed animals for the requirements of own household, the owner shall report the slaughter with the relevant legal person at least 24 hours before the slaughter.

Detailed requirements referred to in paragraph 1 of this Article shall be as laid down by the Ministry.

#### **Article 37**

Slaughter of animals and production of food and feed outside the registered facilities shall be allowed only in exceptional cases.

Detailed requirements referred to in paragraph 1 of this Article shall be as laid down by the Ministry.

#### **Article 38**

Safety of the food and feed shall be confirmed based on veterinary control of facilities, slaughter animals, raw materials, food and feed, as well as the documentation and records.

When, based on the controls referred to in paragraph 1 of this Article and other examinations, it is established that an animal may not be slaughtered, the slaughter shall be disallowed, the animal shall be marked in a laid down manner, and the laid down measures shall be imposed.

When, based on the controls and other investigations, it is established that raw materials, food or feed do not meet safety requirements, a decision shall be issued to disallow their further production and market placement, and to impose measures laid down for removal of causes for incompliance, laid down remedy of raw materials, food, or feed, and, if required, their destruction.

When slaughter of slaughter animals is disallowed, and when it is established that raw materials, food, and feed, do not comply with safety requirements, owner of the slaughter animal or owner of raw materials, food and feed, shall be entitled to demand that an examination is repeated, except when presence of the pathogenic microorganisms is being determined.

Repeated examination shall be carried out by a commission appointed by the administrative authority.

Request referred to in paragraph 4 of this Article shall be immediately submitted to the veterinary inspector who has conducted veterinary control and established incompliance with safety requirements.

Veterinary inspector referred to in paragraph 6 of this Article shall, within 24 hours, notify the Ministry about findings of the repeated examination and supply complete documentation about the repeated examination.

Findings of the repeated examination shall be final.

Costs of the repeated examination shall be borne by the administrative authority when the findings are in favor of the client. If not, the cost shall be borne by the client.

## **2. Erection, Classification, and Registration of Facilities**

### **Article 39**

Design documentation, required for erection and reconstruction of the facilities referred to in Article 35 paragraph 1 of this Law, shall comply with veterinary and sanitary requirements ~~related to specific types of such facilities.~~

~~The approval of the design documentation referred to in paragraph 1 of this Article, in respect of the compliance with sanitary-veterinary requirements, shall be issued by the administrative authority, upon the application of the investor appended to which shall be the currently in force administrative decision on the site shall issue veterinary and sanitary approval based on application submitted by the investor, or owner of the facility referred to in paragraph 1 of this Article, permit for building site, building permit and permit for construction of structures, as acquired from the relevant authority.~~

Detailed veterinary and sanitary requirements referred to in paragraph 1 of this Article shall be as laid down by the Ministry.

### **Article 40**

Facilities referred to in Article 35 paragraph 1 of this Law shall be classified as the facilities for food production and other facilities.

~~Compliance of the facilities referred to in paragraph 1 of this Article with the veterinary-sanitary requirements shall be decided by the administrative authority by way of an administrative decision. The facilities that comply with the laid-down requirements shall be entered in the Register of Facilities and assigned the veterinary control numbers may be registered with the Ministry.~~

Facilities referred to in paragraph 1 shall be removed from the Register if they do not comply with the veterinary-sanitary requirements.

Facilities referred to in paragraph 1 of this Article that do not meet the laid down requirements may be registered for pursuing only such activities for which the veterinary and sanitary requirements are duly met.

Detailed requirements for classification of facilities referred to in paragraph 1 of this Article, content of the Register, and procedure of entry in the Register referred to in paragraph 2 of this Article, shall be laid down by the Ministry.

#### Article 41

Application for registration of a facility referred to in Article 40 of this Law shall be submitted to the administrative authority, and appended to the application shall be the evidence that it is entered in the Central Register with the Commercial Court.

The administrative authority shall issue a decision by way of which a commission for evaluation of the facility shall be appointed and at least three members of such commission shall be veterinarians.

Decision on veterinary and sanitary compliance shall be issued by the administrative authority, based on the opinion supplied by the commission referred to in paragraph 2 of this Article.

~~Entry of a facility referred to in Article 40 of this Law into the register of facilities shall be made by the administrative authority, based on a decision by way of which registration number shall be assigned, method of control defined, conduction of specific activities in production and marketing approved, including restrictions, if so required.~~

Costs of the examination to be conducted by the commission referred to in paragraph 2 of this Article shall be borne by the applicant.

~~Detailed requirements for classification of the facilities referred to in paragraph 4 of this Article shall be as laid down by the Ministry.~~

### ~~3. Residues Systematic Residue Control Measures of Harmful and Disallowed Substances in~~ Animals, Raw Materials, Food, and Feed

#### Article 42

Companies, entrepreneurs and farmsteads involved in animal husbandry and trade, slaughter, production, marketing, processing, treatment, and reprocessing of the foodstuffs of animal origin, production and marketing of animal feed, shall implement all required measures and in particular the internal audit in order to ensure that animals, foodstuffs of animal origin, and animal feed, do not contain unacceptable residues.

Owners of animals, veterinary operators and producers of foodstuffs of animal origin shall respect the prescribed laid down measures and designated waiting periods ~~jakova laurence~~ in the use of drugs and other substances ~~transmittable~~ transmittable to the foodstuffs of animal origin, with the purpose of preventing the occurrence of unacceptable residues.

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Foodstuffs of animal origin intended for public consumption containing the residues, or containing the residues in the quantity exceeding the acceptable level, shall not be placed on the market.

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Maximum acceptable contents of residues in secretion and bodily liquids of live animals, organs and tissue of slaughtered animals, and meat, the sampling method, the laboratory methods and tissue for their determination, shall be laid down by the Ministry.

The measures of systematic control of residues (hereinafter: monitoring), the requirements and method for implementation of measures, control methods, the conditions and manner for samples taking and storing, and keeping record of the samples, and methods of laboratory analysis of samples for a particular residue or residue group, shall be laid down by the Ministry.

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The program of measures for systemic control of residues in animals, foodstuffs and animal feed (hereinafter: Program of Residue Monitoring), with the purpose of protecting human health, shall be laid down by the Ministry.

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Residue Monitoring Program shall in particular encompass: the funds required for financing of the program, the measures to be undertaken in the presence of unacceptable residues, organizational structure of the authorities and organizations for residue monitoring program, manner for residue monitoring program implementation, and other data of relevance for implementation of the residue monitoring program.

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Residue monitoring program shall be adopted before end of current year for the coming year.

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Funds for implementation of the Residue Monitoring Program shall be provided from the budget of the Republic.

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The administrative authority shall submit the annual report on the findings of monitoring to the Ministry before 31 March of current year for the preceding year.

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The Ministry may, on the basis of risk assessments, prohibit the marketing and withdraw from the market the foodstuffs, the wastes produced by slaughter, and animal feed containing particular harmful substances, and may prohibit the use of harmful matter.

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To protect human lives, the Ministry may prohibit that animals are treated with particular veterinary medicines, hormones, and other substances for which it is established that, by remaining in the foodstuffs of animal origin, may impair human life.

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#### Article 42 a

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The farmstead from which the animals are placed on the market, and companies and entrepreneurs involved in marketing of animals, shall be registered in accordance with the law.

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Farmsteads, companies, and entrepreneurs in the facilities for slaughter, treatment and processing of foodstuffs of animal origin may place on the market only:

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a) — animals which were not treated by unacceptable substances or products;

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b) — animals which were treated by acceptable substances or products, with which the laid-down kareneawaiting period has expired ;

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c) foodstuffs which originate from animals referred to in items a) and b) of this Article.

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#### Article 42 b

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For treatment of animals veterinarian shall use only such medicines which were approved for placement on the market and shall administer medicines in accordance with the manufacturer's instructions only for such purposes for which the medicines were approved and under the laid down conditions. Veterinarian who treats the animals shall kept the records of such treatment.

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Owner or keeper of animals shall administer laid down veterinary medicines only upon approval and under supervision of the veterinarian, and shall comply with the instructions provided by the manufacturer of medicines and the laid down ~~carene~~waiting periods.

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Owner or keeper of animals referred to in paragraph 2 of this Article shall keep the records that shall contain: the date and characteristics of the treatment implemented, the laid down treatment, namely the veterinary medicines that were used, the name and surname of the veterinarian, and shall keep the prescriptions for five years after they were issued.

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Data referred to in paragraph 3 of this Article shall be entered in the records by the veterinarian.

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#### Article 42 c

When it is suspected that unacceptable substances or products were used in treatment of animals, or acceptable substances or products were used for the purposes other than those for which they are acceptable, or used in circumstances other than those that were laid down, the following measures shall be implemented:

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- prohibition that the animals leave the farmstead and to dispose of animals from the farmstead, unless under supervision of the inspector;
- taking of samples from a number of selected animals and foodstuffs, by the method of random sample.

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Measures referred to in paragraph 1 of this Article shall be implemented by the administrative authority.

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Analysis of samples shall be conducted in an authorized laboratory.

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#### Article 42 d

When it is established on the basis of the analysis that unacceptable substances or products were used in treatment of animals, or that acceptable substances or products were used for the purposes other than those for which they are acceptable or in the circumstances other than those that were laid down, the following ~~measures~~measures shall be implemented:

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- animals whose findings are positive shall be slaughtered immediately, on site, in the presence of the inspector, or shipped to the slaughterhouse and safely destroyed at the expense of the owner;
- other animals at the farmstead shall be marked and placed under veterinary surveillance and samples shall be taken from all potentially suspicious animals and foodstuffs from such farmstead including the farmsteads in the chain of animal supply and shipment, at the expense of the owners of farmsteads;

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To prevent emergence of foodborne infectious animal diseases, it shall be disallowed to use food rejects (swill) and food waste deriving from the international transport, or food waste originating from the infected area or an area threatened by the hazardous infectious animal diseases.

Use of food waste (swill) for feeding animals in the households in which animals are bred and slaughtered for won requirements, shall be allowed only with previous thermal treatment.

Collection, transportation and treatment of the food waste referred to in previous paragraph shall be subjected to mandatory veterinary control.

Food waste (swill) shall be transported by such vehicles and containers in which there is no possibility of spillage, leakage, or contamination, and which are cleaned and disinfected after use in a laid down manner.

Detailed requirements for feed safety, and the requirements for use of food waste, type and method of food waste transportation, shall be as laid down by the Ministry.

#### **Article 44**

Feed in the distribution channels shall be accompanied by the veterinary certificate or other corresponding laid down document confirming feed safety.

Detailed requirements for issuance, and contents and form, of the veterinary certificate and other corresponding documents shall be as laid down by the Ministry.

#### **Article 45**

Veterinary control shall include feed and the facilities for production and storing the feed intended for market placement, and, if an infectious animal disease is suspected, or when feed is of dubious safety, also the facilities of the animal owner or keeper.

### **C. PREVENTIVE MEASURES IN ANIMAL REPRODUCTION**

#### **1. Requirements**

#### **Article 46**

Facilities for breeding animals shall be free of specific infectious animal diseases.

Owner of a facility for breeding animals shall provide systematic monitoring of the breeding animals health condition and reproductive capacity, and of acquisition, production, storing, and marketing of animal semen, ova and fertilized ova, in accordance with the laid down requirements, as a minimum requirement for preservation of the breeding capacity.

Infectious animal diseases from paragraph 1 of this Article, requirements for animal semen, ova and fertilized ova safety, as minimum requirements for preservation of the breeding capacity, shall be as laid down by the Ministry.

## **2. Acquisition, Storing and Market Placement**

### **Article 47**

Acquisition, storing and market placement of animal semen, ova and fertilized ova, shall be conducted only by legal persons which meet the laid down requirements and which are registered for pursuing such activity.

Legal persons referred to in paragraph 1 of this Article shall keep laid down records on acquisition, storing and market placement of animal semen, ova and fertilized ova.

Requirements for pursuing the activities referred to in paragraph 1 of this Article, and the contents and method of keeping the records referred to in paragraph 2 of this Article, shall be as laid down by the Ministry.

## **3. Insemination**

### **Article 48**

The activities of insemination shall be pursued by legal persons which meet the laid down requirements and are registered for pursuing such activity.

Detailed requirements referred to in paragraph 1 of this Article shall be as laid down by the Ministry.

## **4. Mating and Natural Breeding**

### **Article 49**

Legal persons referred to in Articles 47 and 48 of this Law shall systematically monitor health condition and reproductive capacity of breeding animals during mating and natural breeding, and notify the administrative authority about any suspicion of sexual or other infectious diseases, and of all congenital malformations associated with animal health.

## **5. Notification**

### **Article 50**

In each individual establishment of disease in a breeding animal which may be permanently detrimental to reproductive capacity, or in establishment of deteriorated health condition of animal semen, ova, or fertilized ova, owner of the facility for breeding animal raising shall provide for implementation of the laid down measures.

Legal persons pursuing the activity of insemination shall notify the administrative authority about the results of breeding capacity analysis in the area.

Detailed measures referred to in paragraph 1 of this Article shall be as laid down by the Ministry.

## **D. ENVIRONMENTAL PROTECTION**

### **1. Rights and Obligations**

#### **Article 51**

Legal and natural persons shall take measures to prevent contamination of living environment and consequences that may be detrimental to health and may arise from breeding, production, processing, marketing and use of animals, products, food, raw materials, feed and waste.

Preventive measures for environmental protection shall include:

- 1) Ensuring that waste, and liquid and solid fertilizers, are disposed of, processed, treated and used in an appropriate manner;
- 2) Ensuring that waste, and liquid and solid fertilizers, are stored in an appropriate manner;
- 3) Definition of a procedure for safe disposal of animal secretions and waste waters;
- 4) Reduction of infection risk to a lowest possible level by definition of appropriate hygienic conditions for the facilities for animal breeding and their surroundings (hygienic conditions, micro-climate, restrictions on ammonia content, waste and secretions disposal, cleaning and disinfection);
- 5) Confirmation of products, fertilizers, processed fertilizers, and compost, safety;
- 6) Prevention of subterranean waters contamination by agents of infectious and parasitic diseases.

### **2. Handling of Animal Carcasses and Waste**

#### **Article 52**

Animal carcasses and waste shall be processed, treated, or destroyed, in the facilities intended for processing, treatment, and destruction of animal carcasses and waste.

It shall be disallowed to dispose of animal carcasses in rivers or other waterways or drainage systems, or to leave them on the roads, in open space, in forests or anywhere else.

Animal carcasses shall be disposed of in a safe manner which is not hazardous to health of other animals, human health, or environment.

Owners of animal shall, in a laid down manner, report death of an animal to the Veterinary Hygienic Service (VHS) or other authorized legal person, and hand over carcass of the dead animal.

Veterinary Hygienic Service (VHS) or other authorized legal person shall, in a laid down manner, arrange for the receipt of reports on death of animal, and for transportation of animal carcasses from the place of death to the facility intended for post-mortem examination, hygienic maintenance, or disinfection of the place of death, vehicle, and equipment.

If it is suspected that the animal died from an infectious disease, and in systematic identification of the cause of death, it will be required to determine the cause of death for the dead animal.

Legal and natural persons pursuing the activities during which waste is produced, shall, in a laid down manner, ensure the transfer of waste to the nearest collection centre or a waste processing facility.

Detailed requirements for reporting death of animal, transportation, and animal waste handling, shall be laid down by the Ministry.

### **3. Interment of Animal Carcasses**

#### **Article 53**

In the cases when there is no VHS or other authorized legal person organized as referred to in Article 52 of this Law, animal carcasses may be buried or incinerated in a livestock graveyard or a livestock mass grave, providing laid down requirements are met.

In the cases referred to in paragraph 1 of this Article, owner of animal must provide for transportation of the carcass from the place where the animal died to the place of interment or incineration, according to the instruction of and under strict supervision of the veterinary inspector or legal person.

A manner of interment or incineration, and requirements with which livestock graveyards and livestock mass-graves shall comply, shall be as laid down by the Ministry in cooperation with the Ministry in charge of environmental issues.

## **IV. VETERINARY PROTECTION OF ANIMAL WELFARE**

#### **Article 54**

It shall be forbidden to abuse or torture animals in the course of breeding, keeping, using, using them for work, or specific forms of training.

Owner of keeper of animal shall treat the animal in a humane manner, and protect it from suffering and pain, and timely ask for veterinary help.

Animals shall be provided with appropriate and safe feed and water.

When transported or slaughtered, animals shall not be exposed to torture or pain.

Space and facilities in which animals are kept shall be suitable for the species and category of animals, and equipped in manner that would meet their biological needs.

Diseased or injured animal shall be, soonest possible, given suitable veterinary help and required care, unless disease or injury is of such a nature that the animal should be killed immediately and in a humane manner.

Scientific and research experiments on animals may be conducted only in veterinary, health and medical, pharmaceutical and other institutions, and animals shall not be exposed to torture and pain in the course of the experiment.

## **V. MANDATORY SCOPE OF ANIMAL HEALTH CARE**

### **Article 55**

The Republic shall provide mandatory scope of animal health protection from infectious diseases, as follows:

- 1) Systematic monitoring of animal infectious disease situation (diagnostical examinations; field, laboratory, and pathoanatomical examinations), and animal inoculation in compliance with the Operative Program referred to in Article 11 of this Law;
- 2) In case an infectious disease referred to in this Law is suspected, diagnostical examinations, field and laboratory, and pathoanatomical diagnostics, shall be conducted in order to confirm presence of disease and eliminate suspicion;
- 3) Prevention of emergence of infectious animal diseases during natural disasters and other disasters;
- 4) Prevention of the ~~exceptionally dangerous infectious diseases List A infectious animal diseases~~ spreading in case of their emergence in the neighboring countries, or in the Republic;
- 5) Laboratory and pathoanatomical examinations in order to identify infectious diseases, as laid down by the Ministry, where cause of death shall be determined immediately;
- 6) Studying epizootiological situation, development and introduction of new laboratory methods for diagnostics and control, and for implementation of new veterinary and medical inventions, new regulations, procedures, or professional operation methods;
- 7) Mandatory veterinary control referred to in this Law;
- 8) Preparing epidemiological studies and risk analysis pertaining to entry of infectious animal diseases in the territory of the Republic, examinations regarding optimal economic measures, and definition of financial plans for implementation of the measures laid down for the case of infectious animal diseases;
- 9) A form for veterinary certificate, referral, attestation and other forms referred to in this Law;
- 10) Adequate stock of vaccine, diagnostic agents, diagnosticums, disinfectant agents, and other means for prevention, detection and suppression of infectious animal diseases;

- 11) Organization and implementation of the courses to provide owners of animals and other persons with the basic knowledge of veterinary medicine;
- 12) Continuous veterinary activity on the field and laboratory diagnostics of animal infectious diseases, in which infectious disease and cause of death shall be immediately identified;
- 13) Further professional education for veterinarians and veterinary technicians;
- 14) Damages for the animals killed, slaughtered or died, as a result of the imposed measures, and for the items and raw materials damaged or destroyed as a result of imposed measures;
- 15) Identification and control of animal movement.

The Ministry may adopt a specific animal health care program, for each individual measure referred to in paragraph 1 of this Article, if required.

## **1. Compensations**

### **Article 56**

Compensation for the damage incurred to the owner of the animal that is killed or slaughtered, for the items and raw materials that are damaged, flawed or destroyed in implementation of the measures defined for suppression of the ~~exceptionally dangerous infectious diseases~~~~List A infectious animal diseases~~, or specifically defined infectious diseases and zoonoses, and for dead animals for which it was established that they have died of the ~~exceptionally dangerous infectious disease~~~~List A infectious animal diseases~~, and specifically defined infectious diseases and zoonoses, shall be due:

- 1) If the owner of animal has immediately notified a relevant veterinary legal person or veterinary inspector about the emergence of infectious disease or suspicion of such emergence;
- 2) When mandatory preventive inoculation was conducted within the laid down timeframe and diagnostical and other examinations of animals were conducted in compliance with the operative program;
- 3) If other laid down and defined preventive measures, and measures for suppression of disease, were also implemented.

Compensation for the damage referred to in paragraph 1 of this Article shall not be due to the owner of animal if he has delivered animals from an infected or threatened area without holding the animal health certificate, or if the disease emerged in the course of importation of the animal, or in the course of laid down examinations of animals in international distribution channels.

Specifically defined infectious diseases and zoonoses referred to in paragraph 1 of this Article shall be defined by the Ministry.

## **2. Compensation Payment Procedure**

### **Article 57**

Compensation of damages referred to in paragraph 1 Article 56 of this Law shall be defined based on market value of the animal, raw material or item, at the time of measure implementation. If the animal is killed or slaughtered, the items destroyed or flawed, and raw material still usable, in whole or in part, the value of the usable part shall be deducted from the compensation.

Procedure for compensation of the damage referred to in paragraph 1 of this Article shall be initiated by the owner of animal by submitting the application for compensation.

Application and supporting documentation shall be submitted to the Ministry within 30 days from receipt of the minutes on the damage incurred.

### **Article 58**

The Ministry shall issue a decision with regard to the right of the owner to a compensation of damage.

Level of the damage referred to in Article 57 of this Law shall be decided based on the findings of veterinary experts or a commission appointed by the Ministry.

If disputing the level at which the damage was evaluated, owner of the animal may, within 30 days from the receipt of the decision referred to in paragraph 1 of this Article, file a request to have the compensation for the damage determined at the competent court.

Procedure and the documentation required for payment of compensation, and the requirements pertaining to the experts and commission referred to in paragraph 2 of this Article shall be as laid down by the Ministry.

## **VI. ANIMAL HEALTH CARE FUNDING, PAYMENT AND COSTS**

### **1. Funding of Mandatory Scope of Animal Health Care**

#### **Article 59**

Funds for implementation of the mandatory scope of animal health care referred to in Article 55 of this Law shall be provided from the Budget of the Republic.

### **2. Compensations and Costs**

#### **Article 60**

The funds collected based on the compensations for: veterinary and sanitary examinations conducted by the veterinary inspection; issuance of the certificates confirming that veterinary and sanitary requirements are fulfilled, or operating permits for veterinary legal persons, and issuance of the permits for import, transfer, and export, ~~the funds collected based on the compensations for performed veterinary activities referred to in items 6 and 7 of Article 64 of~~

this Law, and the funds collected based on performed activities of disinfection at border crossings, shall be the income of the Budget of the Republic.

~~The funds collected based on the compensation for the veterinary activities conducted as referred to in Article 64 items 6 and 7 of the Law, and the funds collected based on the activities on disinfection conducted at the border crossings, shall be the income of the persons conducting such activities in the amount of 80%, and the income of the Chamber in the amount 20%.~~

Amount of ~~the~~ compensations for veterinary and sanitary examinations conducted by the veterinary inspection and ~~the~~ compensations for the performers of veterinary activities (services) referred to in items 6 and 7 of paragraph 2 of this Article, and activities of disinfection at border crossings, and the amount of compensation for the Veterinary Chamber for the performance of activities of public interest referred to in item 4 Article 74 of this Law, and the~~and the~~ method for their calculation and payment~~;~~ shall be laid down by the Government of the Republic of Montenegro.

Amounts of the compensations referred to in paragraph 2 of this Article shall not exceed the amount of actual costs of the procedure and shall not constitute a direct protection of local manufactures or indirect taxation of imports, or exports.

## **VII. LEGAL PERSONS IN VETERINARY PRACTICE**

### **Article 61**

Legal and natural persons meeting the requirements in terms of the staff, space (facilities), technical requirements, hygiene and the requirements in terms of equipment, may establish legal persons for pursuing the veterinary practice as laid down in this Law.

The requirements for pursuing the veterinary practice referred to in paragraph 1 of this Article shall be as laid down by the Ministry.

It shall be considered that a legal person meets the laid down requirements in terms of space if it concludes a rental contract with another legal or natural person.

Whether the requirements referred to in paragraph 2 of this Article are met shall be determined, and the license for pursuing the veterinary practice shall be issued, by the administrative authority, on the basis of the application to which the ~~project~~ design documentation and valid administrative decision on the site shall be appended.

Register of legal persons meeting the requirements, or holding the license referred to in paragraph 4 of this Article shall be kept by the administrative authority.

Contents of the register and procedure for entering in the register referred to in paragraph 5 of this Articles shall be specified by the Ministry.

### **Article 62**

Animal health care shall be provided in the entire epizootic territory of the Republic.

If animal health care is not organized in the individual parts of the Republic, the administrative authority shall take necessary measures to provide the animal health care in such areas.

## **A. Organizational Form of Legal Persons**

### **Article 63**

Legal persons referred to in Article 61 of this Law may be established in the form of:

- 1) Veterinary Dispensary;
- 2) Veterinary Clinic;
- 3) Veterinary Dispensary for Pets;
- 4) Livestock – Veterinary Center for Reproduction and Veterinary Insemination;
- 5) Center for Animal Embryotransfer;
- 6) Specialist Veterinary Laboratory
- 7) National Veterinary Institute
- 8) Veterinary Chamber

Specialist vVeterinary practice within the legal persons referred to in paragraph 1 of this Article may be conducted only by a veterinarian holding the license.

Specialist-technical veterinary activities, other than those associated with determination of diagnosis, method of treatment for animals, execution of surgical interventions, interpretation of laboratory or expert reports, and extension of expert opinions, may be performed by ancillary veterinary personnel, exclusively under the supervision of a veterinarian who holds the license.

### **1. Veterinary Dispensary**

#### **Article 64**

A veterinary dispensary shall perform its activities and provide its services both within the dispensary premises and in the field, including:

- 1) Monitoring animal health situation, proposing and undertaking measures for prevention, detection, suppression and eradication of infectious animal diseases and zoonoses;
- 2) Implementing the measures included in the operative program;
- 3) Implementation the measures for prevention, detection, treatment and suppression of animal diseases outside the operative program and injuries, and surgical interventions on animals;

- 4) Specialist, clinical, laboratory, x-ray, and other diagnostical examinations in accordance with the professional training;
- 5) Veterinary examinations of animals;
- 6) Issuance of animal health certificate and veterinary referral forms;
- 7) Veterinary examination at slaughter line, when loading and unloading the shipments, and at livestock markets;
- 8) Animal marking and keeping animal register in compliance with the regulations;
- 9) Care of breeding animals health and breeding capacity, implementation of measures for prevention and treatment of sterility, and insemination and embryo transfer;
- 10) Baseline field and laboratory diagnostics for examination of infectious and other animal diseases;
- 11) Counseling in the area of animal health, pathology and animal feeding and breeding from the veterinary perspective;
- 12) Organization and implementation of the courses on baseline knowledge about infectious animal diseases;
- 13) Procurement of veterinary medicines for provision of veterinary services;
- 14) Issuance of veterinary medicines, agents for disinfection and pest and rodent control, feed and dietetic preparations, to the owners of animals, including advice and instruction on their use with the objective of animal and human health protection;
- 15) Working closely with the commission for assessment, selection and licensing of thoroughbred animals intended for breeding, parent school of fish, and parent queen bees;
- 16) Provision of VHS;
- 17) Execution of disinfection, pest and rodent control;
- 18) Prevention of living environment contamination by infectious animal diseases causes and vectors;
- 19) Animal protection against pain;
- 20) Keeping laid down records and documentation;
- 21) Performs other activities for which it is registered.

Requirements for pursuing the activities referred to in items 12, 16, and 17, of this Article shall be as laid down by the Ministry.

## **2. Veterinary Clinic**

### **Article 65**

Veterinary clinic shall provide stationary and field treatment, protection and care for diseased and injured animals, including:

- 1) Examination, treatment and care of diseased and injured animals;
- 2) Laboratory, x-ray, and other specialist tests;
- 3) Surgical, birth-giving and other veterinary interventions;
- 4) Treatment of sterility and artificial insemination;
- 5) Dogs and cats inoculation against rabidness, and other immunoprophylaxis;
- 6) Issuance of animal health certificates;
- 7) Counseling of the owners of animals with the objective of animal health preservation;
- 8) Keeping of the laid down records and documentations;
- 9) Other activities for which it is registered.

### **3. Veterinary Dispensary for Pets**

#### **Article 66**

Veterinary dispensary for pets shall provide treatment and protection of pets, within the dispensary premises, including:

- 1) Examination and treatment of diseased and injured animals;
- 2) Laboratory and x-ray tests;
- 3) Surgical, birth-giving, and other veterinary interventions;
- 4) Treatment of sterility and artificial insemination of pets;
- 5) Inoculation of dogs and cats against rabidness;
- 6) Inoculation of pets outside the operative program;
- 7) Issuance of animal health certificates for pets;
- 8) Counseling of the owners of animals with the objective of animal health preservation;
- 9) Keeping the laid down records and documentation;
- 10) Other activities for which it is registered.

#### **4. Livestock-Veterinary Center for Reproduction and Artificial Insemination**

##### **Article 67**

Livestock-veterinary center for reproduction and artificial insemination (hereinafter: the Center) shall execute the activities as follows:

- 1) Provide veterinary conditions in acquisition, processing and marketing semen for artificial insemination, ova and fertilized ova;
- 2) Continuous internal control of breeding animals health and their breeding capacity, continuous internal surveillance over acquisition, processing, storing and marketing semen for artificial insemination, ova, and fertilized ova;
- 3) Health care for breeding animals in view of infectious and other animal diseases;
- 4) Acquisition and transplantation of fertilized ova;
- 5) Providing professional help in implementation of artificial insemination and infertility suppression.

#### **5. Center for Animal Embryotransfer**

##### **Article 68**

Center for animal embryotransfer shall conduct following activities:

- 1) Providing veterinary conditions in processing, storing and marketing ova and fertilized ova;
- 2) Acquisition and transplantation of fertilized ova;
- 3) Providing expert assistance in conduction of artificial insemination and infertility suppression.

##### **Article 69**

Marketing of ova, fertilized ova, or embryos, shall be conducted upon the veterinary and sanitary approval of the administrative authority.

#### **6. Specialist Veterinary Laboratory**

##### **Article 70**

Specialist Veterinary Laboratory at the epizootiological territory of the Republic shall conduct the following activities:

- 1) Systematic monitoring of epizootiological situation at the epizootiological territory;

- 2) Proposing measures for prevention, detection, suppression, and eradication of infectious, parasitic and animal breeding diseases;
- 3) Laboratory (bacteriological, serological, virological, parasitological, chemical, biochemical and radiological) diagnostics;
- 4) Laboratory examinations of health and quality assurance of food, products, and raw materials;
- 5) Laboratory examinations of feed, raw materials, feed supplements, and water, with the objective of determining its health and quality assurance;
- 6) Monitoring the preparation of, and taking part in, the courses on baseline knowledge in veterinary medicine for owners of animals and other persons;
- 7) Examinations of semen for artificial insemination of animals, ova and fertilized ova, from the perspective of animal health care;
- 8) Monitoring and implementation of the measures for animal fertility enhancement, and participating in investigation in the area of animal reproduction;
- 9) Monitoring and implementation of the measures for protection of animals and living environment against adverse effects arising from animal keeping;
- 10) Marketing of sera, vaccines, and diagnostic agents from the Operative Program;
- 11) Notification of the Ministry, without delay, about emergence and cessation of the established infectious diseases, and, in emergence of zoonoses, likewise notification of the Ministry in charge of health issues;
- 12) Other activities for which it is registered.

## **7. National Veterinary Institute**

### **Article 71**

National veterinary institute, in addition to the activities referred to in Article 70 of this Law, shall conduct the following activities:

- 1) Coordinates the operation of the specialist veterinary laboratory and authorized laboratories at the unique epizootiological territory of the Republic in the area of animal health care;
- 2) Controls and implements unique methods and procedures for laboratory and diagnostic examinations;
- 3) Verifies the findings of laboratory and diagnostic examinations of the specialist veterinary laboratory and authorized laboratories;
- 4) Prepares and proposes national programs for detection, suppression, and eradication of infectious animal diseases and zoonoses;

- 5) Prepares, proposes and follows expert solutions based on the insights gathered in the practice and science in the area of hygiene and food technology, and animal reproduction;
- 6) Laboratory examination of pharmacological agents in veterinary medicine;
- 7) Laboratory tests for residues and other biologically active substances, in meat, food, and raw materials;
- 8) Control in respect of presence of radioactive substances in animals, meat, products and feed;
- 9) Toxicological examinations of animals, products, and feed;
- 10) Clinical and pharmacological examinations of medicines and ancillary medicinal substances for use in veterinary medicine.

#### **Article 72**

The National Veterinary Institute (hereinafter: the Institute) and the Specialist Veterinary Laboratory (hereinafter: the Laboratory) shall be founded by the Government of the Republic of Montenegro.

The Act on foundation of the Institute, namely the Laboratory, shall specify in particular: seat of the Institute, namely the Laboratory; area of activity, management, internal organization structure and method of operation; amount of resources for the foundation and commencement of the of the Institute, namely the Laboratory; funding sources for operation of the Institute, namely the Laboratory; participation of the founder in management and decision-making; terms and method of management bodies selection; supervision over operation of the Institute, namely the Laboratory; persons to conduct the activities of a temporary business administration; the term for enacting the statute and appointing the director; and the terms and method for the provision of premises, equipment, means of work and professional staff.

Laboratories for pursuing the activities referred to in Article 70 of this Law may be founded by other legal and natural persons.

### **8. Veterinary Chamber**

#### **Article 73**

With the objective of protecting and enhancing the level of expertise, preserving professional ethics, raising the level of animal health protection, and protecting professional interest, the persons holding university degrees in veterinary medicine and practicing veterinary medicine in the territory of the Republic shall group together into the Veterinary Chamber (hereinafter: the Chamber) as their professional organization, and their rights and obligations shall be as laid down in the Law and the Statute of the Chamber.

The Chamber shall be a legal person.

#### **Article 74**

Activities of the Chamber shall include:

- 1) Adopting the Codex for veterinary profession and ensuring its implementation;
- 2) In compliance with the Codex referred to in item 1 of this Article, ensuring reputation of the profession, the discipline in providing animal health care, and undertaking appropriate measures in case of non-compliance with ethical norms;
- 3) Keeping register of members;
- 4) Issuing, extending, and withdrawing licenses and keeping register of issued licenses (hereinafter: the Register);
- 5) Verifying quality of professional staff;
- 6) Providing the opinion in the procedure of adopting law, plan documents and other regulations governing the area of veterinary medicine;
- 7) Participating in drafting the normative rules for determination of prices for veterinary services, professional education and further professional training of veterinarians;
- 8) Participating in the procedure of the activities of public interest concession;
- 9) Providing the opinion on the programs for educational courses laid down in this Law;
- 10) Other activities as laid down in the Statute of the Chamber.

The funds for the activities referred to in item 4 of this Article, provided they are of public interest, shall be provided from the Budget of the Republic.

The norms to apply in issuance of the licenses referred to in item 4 of this Article shall be laid down by the Ministry.

#### **Article 75**

Entry into the register shall be made upon a request of the person holding university degree in veterinary medicine (hereinafter: the veterinarian).

Request for entry shall be decided by the body designated in the Statute of the Chamber.

The party submitting the request shall enclose evidence of compliance with the requirements for entry into the Register, specifically the evidence that he holds university degree in veterinary medicine, that he has successfully passed the professional examination and that he has been granted the license.

Should the Chamber fail to, within 30 days, decide regarding the request for entry into the Register, and all evidence is submitted as required, the party submitting the request shall be considered entered into the Register.

#### **Article 76**

Removal from the Register shall be made in the event of:

- 1) Cessation of the compliance with the requirements for entry into the Register;
- 2) Permanent suspension of the license, and
- 3) In other events as laid down in the Statute of the Chamber.

#### **Article 77**

The veterinarian complying with the requirements shall be issued license.

License is a document by way of which a veterinarian is granted the right to pursue the professional activity, based on the compliance with the requirements related, in particular, to the results achieved in professional training and the professional competence for pursuing the activities of animal health care.

#### **Article 78**

License shall be issued for the period of five years, after which follows the verification of compliance with the requirements for extension, or revocation of the license.

#### **Article 79**

Veterinarian may be suspended the license, on a temporary or permanent basis.

Temporary suspension of license, for maximum three years, may be imposed in the following events:

- 1) If it is found that the veterinarian may, in his operation, seriously affect health or life of animals, or humans;
- 2) If the veterinary worker is, in the procedure of license extension, referred to further professional education, and, before expiry of the license, he failed to present evidence of professional accomplishment in professional education as the requirement for pursuing the activity of animal health care;
- 3) In case of incompliance with the veterinary profession codex; and
- 4) In other cases as laid down in the statute of the chamber.

#### **Article 80**

Method and procedure for making decision about issuance, extension and suspension of the license, the evidence, and the body of the Chamber to decide about the issuance, extension and suspension of the license, shall be closely regulated by the Statute of the Chamber.

Provisions of the Statute of the Chamber that regulate the issues referred to in paragraph 1 of this Article shall be approved by the administrative authority.

#### **Article 81**

The Chamber shall adopt the Statute.

The Statute of the Chamber shall closely regulate the following:

- 1) Scope of operation of the Chamber;
- 2) Bodies of the Chamber and their scope of operation;
- 3) Method of determining the level of membership fee and funding the operation of the Chamber;
- 4) Other issues within the competence of the Chamber.

#### **Article 82**

Operation of the Chamber shall be funded from the following sources:

- 1) Membership fee;
- 2) Budget of the republic for foundation and start-up operation of the chamber, and for conduction of the activities of public interest referred to in item 4 article 74 of this law;
- 3) Based on the compensations referred to in paragraph 2 article 60 of this law;
- 4) Grants, and
- 5) Other sources.

Upon request of the Chamber, legal persons, administrative authorities and local self-government authorities, shall provide data about the veterinarians and their operation, as required for operation of the Chamber.

### **B. Continuous Veterinary Practice**

#### **Article 83**

When it is necessary to provide emergency veterinary services in the cases of emergency and other similar cases, or in order to provide for the continuous provision of animal health protection and care, competent legal persons shall have the obligation to provide that their employees work after working hours (in on-duty or if-duty shifts) or overtime.

#### **Article 84**

Administrative authority shall be in charge of professional surveillance over animal health care that is provided by the registered veterinary legal persons.

#### **Article 85**

In the procedure of professional surveillance referred to in Article 84 of this Law, which is conducted at least once in two years, the following shall be determined:

- 1) Compliance with the requirements laid for pursuing the veterinary practice;
- 2) Staff professional capability and equipping level;
- 3) Method and efficiency of service provision;
- 4) Operation in compliance with accomplishments of modern veterinary science and practice, and other elements of relevance for quality operation.

For pursuing the professional surveillance referred to in paragraph 1 of this Article, the administrative authority may appoint a special commission.

### **C. Removal of Legal Persons from Register**

#### **Article 86**

Legal person shall be removed from Register referred to in Article 61, paragraph 5, of this Law, if:

- 1) Submitting the request to be removed from the Register,
- 2) Not complying with the laid down requirements or failing to remove flaws within the specified term,
- 3) Pursuing the veterinary practice in contravention with the regulations and Veterinary Profession Codex.

Upon proposal of the Commission referred to in Article 85 of this Law, the administrative authority shall issue a decision on revocation of the operation license and removal of the veterinary legal person from the Register.

## **VIII. ENSURING PROVISION OF SERVICES OF PUBLIC INTEREST**

#### **Article 87**

Services of public interest referred to in this Law, such as services referred to in Article 64, paragraph 1, items 2, 7 and 8, and Article 62, paragraph 2, of this Law, and services of preventive inoculation for specific kinds of pets against rabidness in the registered veterinary dispensaries, veterinary dispensaries for pets, and veterinary dispensaries in the facility (hereinafter: public services) shall be provided through authorized legal persons in compliance with this Law.

Public services referred to in paragraph 1 of this Article shall be conceded to legal persons by way a public tender to be announced by the administrative authority and by way of a decision issued by the administrative authority.

#### **Article 88**

The public services referred to in Article 87 of this Law that shall be conceded to legal persons through a public tender shall include the services referred to in Article 64, paragraph 1, items 2 and 8 of this Law.

Public tender referred to in paragraph 1 of this Article shall include:

- 1) Definition of public services;
- 2) The area in which public services shall be provided;
- 3) Commencement and duration of public services provision;
- 4) Requirement to be met by the party providing public services;
- 5) Compulsory content of the application for provision of public services;
- 6) Selection criteria;
- 7) Deadline for issuance of the decision to the party providing public services;
- 8) Other professional and technical requirements, if any;
- 9) Contact person for information about the content of public tender;
- 10) Date, place, and time of opening the tenders;
- 11) Method of candidates' notification about selection of the party to provide public services.

Procedure of tenders opening and assessment shall be conducted by the Commission to be appointed by the administrative authority.

Candidates or their authorized representatives may attend tenders opening.

Incomplete tenders may be supplemented within eight days from the day of warning, or else they shall be rejected and the candidates duly notified.

Tenders arriving after the given deadline shall not be considered.

#### **Article 89**

Based on the decision on selection, the Ministry shall conclude a contract with the party to provide public services, to specify:

- 1) Public services which are the subject matter of the contract;
- 2) The area in which public services shall be provided;
- 3) Veterinarians to provide specific public services from the contract;
- 4) Terms and method of providing public services from the contract;

- 5) Rights, obligations and responsibilities of the party providing public services and the veterinarians;
- 6) Working hours or method of ensuring nonstop animal health care;
- 7) Commencement and validity term of the contract;
- 8) Funding sources for public services to be provided based on the contract;
- 9) Suspension of the operation for the party providing public services or the veterinarian;
- 10) Deadline for submission of requests for termination of the contract.

Parties providing public services and veterinarians referred to in this Article shall be accountable to the administrative authority.

#### **Article 90**

Public services referred to in Article 87 of this Law that may be conceded to legal persons directly, by way of a decision issued by the administrative authority, include:

- 1) Services of preventive inoculation against rabidness, for specific kinds of pets, in the authorized veterinary dispensaries, veterinary dispensaries for pets and veterinary clinics in the facility;
- 2) Services referred to in article 62, paragraph 2, of this law;
- 3) Services referred to in article 64, paragraph 1, item 7, of this law.

Decision referred to in paragraph 1 of this Article shall be final in the administrative procedure.

#### **Article 91**

Network of legal person in the Republic, pursuing the public services within the area of veterinary medicine includes: the Institute, the Laboratory, and legal persons pursuing the services of public interest based on the authorization transferred to them in accordance with this Law.

When establishing the network referred to in paragraph 1 of this Article, the following shall be taken into account: strategy for development of agriculture in the Republic; health status of animals and epizootic situation; geographical characteristics of the terrain; number of animals, population, intensity of livestock breeding and agricultural production, and similar.

Network referred to in paragraph 1 of this Article shall be determined by the Government of the Republic of Montenegro.

### **IX. FURTHER PROFESSIONAL EDUCATION**

#### **Article 92**

Veterinarians and veterinary technicians shall have the right and obligation with regard to further professional education.

Veterinarians employed with the Ministry, namely with the administrative authority, shall acquire further professional education and undergo laid down knowledge tests, within the programs to be adopted by the administrative authority.

Other veterinarians shall acquire further professional education and undergo the laid down knowledge tests, within the programs to be adopted by the Chamber in cooperation with the administrative authority.

### **X. REGISTERS, RECORDS, DATABASES, AND IT SYSTEM**

#### **Article 93**

All persons pursuing the veterinary practice shall keep the records, registers and databases laid down in this Law, which shall be interconnected into an integrated IT system.

The Ministry shall ensure interconnection of the IT system referred to in paragraph 1 of this Article, with international IT systems in the field of veterinary medicine.

Detailed requirements for keeping registers, records, and databases referred to in paragraph 1 of this Article shall be laid down by the Ministry.

### **XI. SPECIFIC AUTHORIZATIONS OF THE MINISTRY**

#### **Article 94**

With the objective of preventing entry and spreading of the specific exceptionally dangerous infectious disease List A infectious animal diseases from other countries and their suppression in the territory of the Republic, the Ministry may restrict or prohibit the persons to cross the state border in both directions, when the specific disease emerged or spread in the near-border region of the Republic, or in the corresponding border region of a neighboring country.

### **XII. INSPECTION SURVEILLANCE**

#### **Article 95**

Activities of inspection surveillance related to veterinary medicine shall be implemented by the administrative authority through the Republic veterinary inspectors, in accordance with the Law.

#### **1. Powers of the Inspectors**

#### **Article 96**

In addition to the powers vested in inspectors based on the Law on Inspection Surveillance, the Republic inspector shall have the power to:

- 1) Examine animals and impose measures for prevention of emergence, detection, suppression, and eradication, of infectious animal diseases;
- 2) Supervise over the implementation of the operative program and contractual obligations as envisioned by the authorizations, the Residue Monitoring Program, and other programs for health care of animals referred to in paragraph 2 of Article 11 of this Law;
- 2a) Supervise further than the Residue Monitoring Program with the purpose of the identification of unacceptable substances or products that are administered to animals in fattening, or the use of unacceptable substances or products for purposes other than those for which they are acceptable or in the circumstances other than those that were laid down;
- 3) Supervise and examine animals, products, raw materials, and food, animal semen, ova, and fertilized ova, feed, water for watering of animals,
- 4) Monitor and control efficacy and safety of veterinary medicines;
- 5) Take samples of food and raw materials, additives and waste, feed, water and devices for protection of animals, animal semen, ova and fertilized ova, with the objective of examining their safety;
- 6) Supervise marketing and use of veterinary medicines and agents for disinfection and pest and rodent control, from this law;
- 7) Control the records to be kept by the importers;
- 8) Control veterinary certificates insurance;
- 9) Review business books, evidence of the examination findings and other documents of natural and legal persons related to implementation of veterinary regulations and regulations governing market placement of veterinary drugs;

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In addition to the powers referred to in paragraph 1 of this Article, the Republic veterinary inspector conducting supervision over the border crossing shall also have the power to:

- 1) after previous veterinary examination of the shipment and supporting documentation, approve the importation, transit, or storing of animals, food, raw materials, products, veterinary medicines, and medical equipment, feed and waste, by way of a decision which shall be passed for each individual shipment and confirming, based on the laid down requirements, that there are no veterinary obstacles for their importation, transit, or storing;
- 2) inspect and control shipments intended for export, if they are reloaded at border crossing, or stored in the registered storing facilities under the laid down conditions, and issuance of animal health certificate and shipment safety attestation;
- 3) take samples of food, products, raw materials and waste of animal origin, and feed, and refer them to be examined in the authorized laboratories, or conduct required examinations in the laboratory at border crossing;

- 4) review business books and documents of the persons involved in international transport;
- 5) review and control veterinary and sanitary situation at border crossings, storing facilities, customs storing facilities, and customs-free zones;
- 6) keep records of import, export, and transit, shipments when crossing the state border;
- 7) supervise disinfection of the means of transportation, storing facilities, and equipment, at border crossings, customs storing facilities, and customs-free zones;
- 8) monitor emergence and movement of infectious animal diseases in neighboring countries and notifies the administrative authority about it.

## **2. Duties and Powers of the Inspector**

### **Article 97**

In addition to the duties and powers laid down in the Law on Inspection Surveillance, when finding that the law or other regulations have been infringed, the Republic veterinary inspector shall have a duty and power to:

- 1) Prohibit marketing the animals which are not marked in the specified manner;
- 2) Prohibit production, marketing and use of feed and water for watering of animals, if containing pathogenic microorganisms, or substances that may be detrimental to animal or human health;
- 3) Prohibit marketing of hides from the animals slaughtered without prior veterinary examination, or originating from dead animals for which the cause of death is not identified, or from the animals for which it was not established that they originate from the unaffected area, or when they are not stored separately from the examined hides;
- 4) Prohibit loading and reloading of animals, products, raw materials, food, feed, and waste, if not complying with the laid down requirements;
- 5) Prohibit marketing and use of raw materials and food if they are not safe;
- 6) Prohibit marketing and use of veterinary medicines, baits and toxins used in veterinary medicine, if not examined;
- 7) Prohibit veterinary certificate issuance in emergence of infectious disease or in suspicion of the infectious disease, or when animal originates from a facility with unverified or dubious epizootiological situation;
- 8) Order confiscation and destruction of unsafe raw materials, food, feed, and veterinary medicines;

- 9) Define the method for rectification of conditionally usable raw materials, food, feed, and their processing for other intended use;
- 10) Order removal of flaws in the production and marketing of animals, food, raw materials, feed, and marketing of veterinary medicines;
- 11) Determine boundaries of infected and threatened area, and notification about the emergence of infectious animal diseases and operation of the veterinary legal persons with regard to emergence of an infectious animal disease;
- 12) Order the measures for protection of animals against torture.

### 3. Administrative Measures and Actions

#### Article 98

In addition to administrative measures and actions laid down in the Law on Inspection Surveillance, the Republic veterinary inspector shall have a duty and power to:

- 1) Prohibit the use of means for transportation of animals, products, raw materials, food, feed, water for animal watering, and wastes, if not complying with the prescribed requirements;
- 2) Prohibit the use of facilities for animals raising, stations and ports intended for loading, reloading, and unloading of animals, if not complying with the prescribed requirements;
- 3) Prohibit slaughter of animals, collection and treatment of raw materials and production of food, if not complying with the prescribed requirements;
- 4) Prohibit the use of business facilities, installations, and equipment for production and marketing, for industrial, handicraft and other intended use, if not complying with the regulations;
- 5) Order destruction of food in the market, if not properly marked or accompanied by the laid down veterinary certificates;
- 6) Seal the work instruments, work premises, equipment, and items, under its control;

6a) Order separate slaughter of animals when suspecting or having proof that the animals brought for slaughter were treated in an unacceptable manner or were administered unacceptable substances or products;

6b) Temporarily seize ~~the~~ ~~remove iznutric~~ trunks and offals and conduct the required sampling procedure in order to identify unacceptable residues when suspecting or having proof that the animals brought for slaughter were treated in an unacceptable manner or were administered unacceptable substances or products;

6c) Destroy or safely remove ~~remove iznutric~~ trunks, offals, and other edible tissue of examined animals at the expense of the owner when the findings of the analysis are positive;

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6d) Postpone the slaughter of animals for the necessary time when suspecting or having proof that the animals were treated by approved substances or products but that the laid down ~~waiting~~ waiting period did not elapse before the moment of slaughter, until the residue level of substances or products is lower than or equal to the maximum acceptable or the number of days laid down in the manufacturer's instructions for the approved substance or product has lapsed.

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- 7) Order the required measures for protection of feed and water for watering the animals;
- 8) Ordering removal of flaws with regard to acquisition, storing and marketing of animal semen, ova, and fertilized ova;
- 9) Prohibit marketing of unsafe animal semen, ova, and fertilized ova;
- 10) Destruct unsafe animal semen, ova, and fertilized ova;
- 11) Order removal of flaws with regard to collection, transportation and processing of waste;
- 12) Order removal of animal carcasses, slaughter facility waste and other waste of animal origin.

In addition to administrative measures and actions referred to in paragraph 1 of this Article, the Republic veterinary inspector conducting inspection surveillance at the border crossing shall be under obligation to take other administrative measures and actions, as follows:

- 1) Prohibit importation, exportation, and transit of shipments, if:
  - the shipment or means of transportation do not comply with the laid down requirements;
  - the shipment originates from infected area;
  - the shipment is infected;
  - there is no laid down animal health certificate or safety attestation for the shipment, or other required documents to accompany the shipment;
  - ~~finding that~~ the shipment of animals, animal feed, products and foodstuffs for human consumption contain residues of acceptable substances or products in the quantity exceeding the maximum acceptable quantity is affecting animal or human health;
  - the shipment is not in compliance with the laid down requirements with regard to protection of animals from torture;
- 2) Temporary prohibit importation, exportation, or transit, of shipments, if it is necessary to remove flaws in shipments or accompanying documentation, or if contamination of shipment is suspected;

- 3) Confiscate from the persons crossing the state border of the republic, the animals, food and raw materials, and ordering their safe destruction, in compliance with this law;
- 4) Prohibit the use of the facilities at border crossings, if not complying with the laid down requirements;
- 5) Prohibit the use of feed and bedding, if not complying with the laid down requirements;
- 6) Prohibit the use of the means of transportation of shipments, if not complying with the laid down requirements.

#### **XIV. PENAL PROVISIONS**

##### **Article 99**

The authority, legal entity, or entrepreneur in the Republic shall be punished by a fine of not less than two hundred fifty times nor more than three hundred times the amount of the minimum salary for an offense, if he fails to immediately notify a veterinary legal entity or veterinary inspection if he finds that the danger for animal health is present or, consequently, danger for human health, and if within a specified time period he fails to provide the necessary data on the animal health protection carried out, and the measures implemented, as well as if he fails to enable the verification of the veracity of the data provided (Article 5).

The authority, legal entity, or entrepreneur in the Republic shall be punished by a fine of not less than two hundred times nor more than three hundred times the amount of the minimum salary for an offense, if:

- 1) failing, or failing within the specified time period, to implement one or more measures for the prevention of outbreaks of infectious animal diseases and special preventive measures against zoonoses (Art. 11 and 12);
- 2) failing, or failing within the specified time period, to implement one or more measures for suppression and eradication of infectious animal diseases in the event of an outbreak or a suspicion of the outbreak of an infectious animal disease (Article 14);
- 3) failing to without delay issue professional instructions pertaining to the required veterinary measures, failing to undertake such measures for confirmation, exclusion, or determination of cause of animal death, and other prescribed measures pertaining to transport and notification aimed at preventing the spreading of an infectious disease or the spoiling of the testing material (Article 15);
- 5) failing inform the competent health organization of the suspicion of or incidence of zoonosis (Article 15 paragraph 2);
- 6) failing to provide the prescribed requirements for trade in animals, food, products, raw materials, and offal, their loading, reloading and unloading in railway, water, air and other means of road transport (Article 27);

- 7) engaging in trade in animals, food, raw materials, products, offal, animal feed, veterinary drugs, and medical equipment during such times when the trade is prohibited or restricted in the event of emergence of an exceptionally dangerous infectious disease ~~List A animal disease~~ or for other veterinary reasons (Article 28);
- 8) failing to act in accordance with Article 31 of this Law;
- 9) failings to perform the prescribed veterinary examinations and tests, as well as other acts in violation of Article 32 of this Law;
- 10) failing to act in accordance with Article 33 of this Law;
- 11) failing to act in accordance with Article 35 of this Law;
- 12) failing to slaughter the animals, whose meat is used for public consumption, in slaughter facilities, and failing to conduct mandatory veterinary inspection of such animals, or their meat, and to report the slaughter of hooved and cloven-hooved animals to the competent veterinarian (Article 36)
- 13) failing to avoid consequences arising from the use of harmful substances in raw materials, food, and feed; and failing to forbid the use of specific harmful substances (Article 42);
- 14) failing to act in accordance with Article 43 of this Law;
- 15) failing to provide systematic monitoring of the health status and reproductive capacity of breeding animals, and other conditions in accordance with Article 46, paragraph 2, of this Law;
- 16) acquisition, storing and marketing of animal seed, ova and fertilized ova is carried out by legal persons not meeting the prescribed requirements for pursuing such activities, or if they fail to keep the required records of such activities (Article 47);
- 17) insemination is carried out by legal persons failing to meet the requirements defined by law for pursuing such activities (Article 48);
- 18) failing to take preventive measures aimed at protection of the environment and health-detrimental effects in accordance with this Law, by-laws enacted based on this Law, and environmental regulations; and failing to take preventive and other measures in accordance with Article 51 of this Law;
- 19) failing to bury or incinerate carcasses in accordance with Article 53 of this Law;
- 20) veterinary activities are carried out by legal persons failing to meet the prescribed requirements pertaining to the staff, facilities, hygiene, technical conditions and equipment (Article 61);
- 21) failing to act in accordance with Article 74 of this Law;
- 22) failing to provide non-stop presence on-duty or if-duty availability (Article 83);

- 23) failing to keep the specified records, registers and databases (Article 93, paragraph 1);

For an offense referred to in paragraphs 1 and 2 of this Article, a natural person, as well as a responsible person in the legal person, shall be punished by a fine of twenty times the amount of minimum salary in the Republic.

For an offense referred to in paragraphs 1 and 2 of this Article, the veterinary inspector may determine a fine on the spot where an offence was committed, and that in the amount of three times the amount of the minimum salary in the Republic.

### Article 100

By a fine of not less than fifty times nor more than two hundred times the amount of the minimum salary in the Republic, a legal entity or entrepreneur shall be punished for an offense, if:

- 1) failing to enable the veterinary examinations and controls, obtaining the material necessary for testing, or to implement other required measures (Article 5, paragraph 4);
- 2) failing to provide ~~urgent~~emergency veterinary help (Article 5, paragraph 3);
- 3) failing to keep the prescribed records (Article 5, paragraph 6);
- 4) failing to report animals, facility and equipment within the specified time limit, as well as any change thereof, to the administrative authority, or the purchase of a dog, death, escape and any other change related to the dog or puppy (Article 13, paragraphs 4, 5, and 6);
- 5) failing to carry out the marking of animals in the prescribed manner (Article 21, paragraph 1);
- 6) failing to obtain the required approval (Article 29);
- 7) animal feed is not accompanied by prescribed veterinary certificate or other corresponding document that confirms feed safety (Article 44 , paragraph 1);
- 8) failing to label or certify the food placed on the market (Article 26);
- 9) failing to keep records about the origin, failing to mark, and failing to supply samples of the hide purchased for the purpose of testing on splenic fever (Article 25);
- 10) owner of forwarder fails to comply with the requirements for transportation, and failing to enable inspection surveillance, and to take other measures and actions laid down in Article 30 of this Law;
- 11) failing to act in accordance with Article 38 of this Law;

11a) farmstead from which the animals are placed on the market, and the companies and entrepreneurs involved in marketing of such animals are not registered in accordance with the law, or they place on the market the animals which were treated by unacceptable substances or products or the animals treated by acceptable substances

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or products but the laid down ~~karene~~waiting period did not lapse, and foodstuffs derived from such animals (Article 42a paragraphs 1 and 2);

11b) veterinarian using the medicines other than those approved for placement on the market or not administering them in accordance with the instructions provided by the manufacturer of the medicine, and for the purposes other than those for which the medicines are acceptable and under laid down conditions, failing to keep records of the treatment, or the owner or keeper of animals fails to administer laid down veterinary medicines upon approval and under supervision of a veterinarian and fails to comply with the instructions provided by the manufacturer of medicines and the laid down ~~karene~~waiting periods and fails to keep the laid down records (Article 42b paragraphs 1, 2 and 3);

12) failing to act in accordance with Article 49 of this Law;

13) failing to treat animal carcasses and waste in accordance with Article 52 of this Law.

13a) specialist technical veterinary activities, other than those associated with determination of diagnosis, method for treatment of animals, execution of surgical interventions, interpretation of laboratory and specialist reports and extension of expert opinions is performed by ancillary veterinary personnel without the supervision of the veterinarian who holds the license (Article 19 paragraph 2).

For an offense referred to in paragraph 1 of this Article, a natural person, as well as a responsible person employed with the legal person, shall be punished by a fine of not less than five times nor more than fifteen times the amount of minimum salary in the Republic.

For an offense referred to in paragraph 1 of this Article, veterinary inspector may determine a fine on the spot where an offence was committed for the natural person, and that in the amount of three times the amount of the minimum salary in the Republic.

#### Article 101

In case of an offense referred to in Article 99, paragraph 2, items 8 and 11 of this Law, in addition to the fine, the preventive measure of confiscating the article used in committing the offense shall be pronounced.

In case of an offense referred to in Article 99, paragraph 2 item 11 of this Law, in addition to the fine, the preventive measure of forbidding further pursuing of related business activities shall be pronounced.

### XIV. TRANSITIONAL AND FINAL PROVISIONS

#### Article 102

Existing legal persons pursuing the veterinary practice, and relevant departments within such legal persons, shall, within six months from the effective date of this Law, ensure compliance of their activities with this Law.

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### **Article 103**

All state owned facilities intended for carrying out veterinary activities, as well as means and equipment used for that purpose, shall be used exclusively for carrying out veterinary activities.

### **Article 104**

The Public Veterinary Institution of Montenegro shall cease operation upon expiry of six months after the effective date of this Law since until then it will be transformed in accordance with the special program adopted by the Government of the Republic of Montenegro.

### **Article 105**

Until the time of issuing veterinary licenses in accordance with this Law, the veterinary medicine doctors or the persons holding university degree in veterinary medicine and having successfully passed the professional competence examination, may pursue veterinary activities in accordance with the existing authorizations.

Issuance of veterinary licenses referred to in paragraph 1 of this Article shall be carried out within 12 months from the effective date of this Law.

### **Article 106**

Bylaws and regulations for enforcing this Law shall be adopted within a year from the effective date of this Law.

Before the adoption of regulations referred to in paragraph 1 of this Article, the existing regulations shall apply, unless they are in contravention of this Law.

### **Article 107**

Provision of Article 35, paragraph 2, of this Law shall apply to industrial and export facilities upon expiry of 12 months, and, in case of other facilities, it shall apply from 1 January 2010, upon expiry of 36 months from the effective date of this Law.

### **Article 108**

The Government of the Republic of Montenegro shall create the administrative authority referred to in Article 4 of this Law within 30 days from the effective date of this Law.

### **Article 109**

Lists of the diseases referred to in Article 7 of this Law shall be published in the "Official Gazette of the Republic of Montenegro".

### **Article 110**

On the effective date of this Law, the Law on Animal Health Protection ("Official Gazette of the Republic of Montenegro" Nos. 39/92 and 59/92) shall cease to apply.

### **Article 111**

Upon expiry of the time period referred to in Article 104 of this Law, the Decision on Establishing Public Veterinary Organization (“Official Gazette of the Republic of Montenegro” No. 59/92) shall cease to apply.

#### **Article 112**

This Law comes into effect on the eighth day from the day of its publishing the “Official Gazette of the Republic of Montenegro”.

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