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 "Official Gazette of RM" No.

11/04), shall cease the 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 the 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

th 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

- 10) Fish, crayfish, shellfish and mollusks include all fish, crayfish, shellfish and mollusks regardless of their stage of development;
- <u>41)10)</u> *Experiment animals* are the animals that are used or will be used in laboratory experiments;
- <u>12)11</u> 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

- <u>Marketing of food</u> 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;
- <u>Marketing of animals, products, raw materials and waste of animal origin</u> refers to importation, transit, exportation, sales or any other type of transfer of goods to third parties;
- <u>25)24)</u> *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;
- <u>26)25)</u> *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;
- <u>27)26)</u> 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;
- 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;
- <u>Waste of animal origin</u> (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;
- 30)29) Waste waters are waters problemed root three Each Did 2. Apr constant and local multiposition at 3. ss

- <u>36)35)</u> 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;
- <u>37)36</u> *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;
- 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;
- 39)38) Facility is a space or premises intended for raising of animals; holding of animal

49)7si[

51(h) Disease free area

9)

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

<u>List A includes</u>E-exceptionally hazardous infectious diseases <u>are diseases</u> that may be suddenly and quickly spread across the state borders.

<u>Exceptionally dangerous infectious disease</u> <u>List A diseases</u> 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.

<u>List B includes Dangerous</u> 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)

- 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

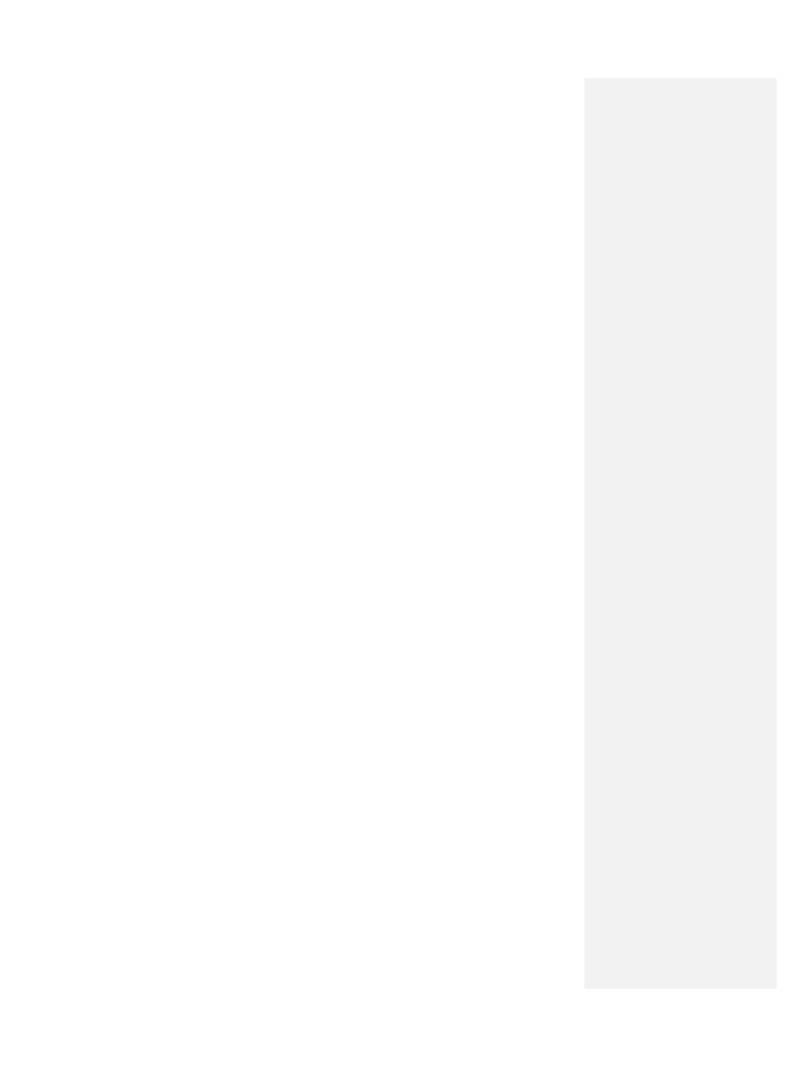
Article 12

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

1) Systematic prevention, detection and suppression of zoonoses in animals;

2)

Veterinary control shall cover: animals, raw materials, feed, products and food in production and



- 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;

Article 18

In case of emergence of an exceptionally dangerous infectious diseaseList 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:

- 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;
- 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

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.

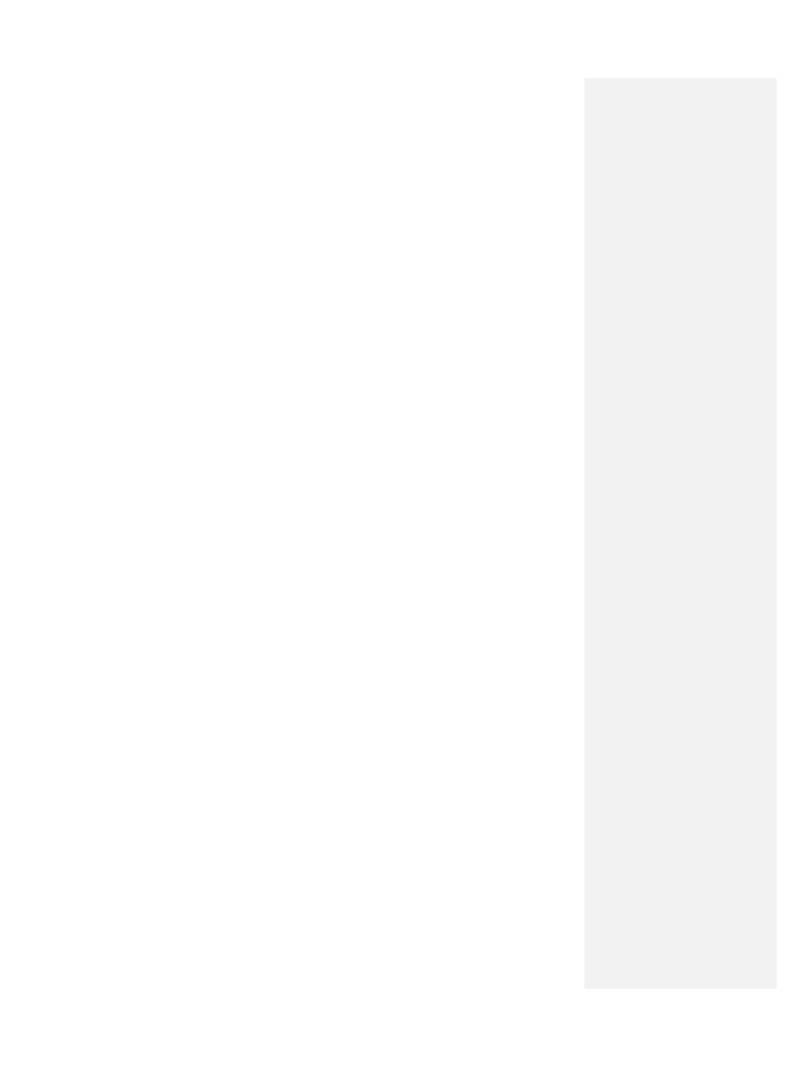
3. Veterinary Referral Form

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

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



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 anlysis.

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 hoofed and clovenhoofed animals, poultry, and hares which are imported to be immediately slaughtered, the

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.

<u>Veterinary-sanitary Measures in International Trade</u>

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Article 34 a

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Veterinary-sanitary measures in international trade shall be undertaken:

- 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:

- 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
- 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.

ExceptionalNotwithstanding to the provisions of paragraph 1 of this Article, the Veterinaryadministrative authority Administration may, in cases where relevant scientific evidence is insufficient for objective assessment of risk, or in urgentemergency 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.

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.

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 urgentemergency circumstances whenever new scientific evidence is becomes available.

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

Article 34 c

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:

- 1. publish a notice on the intention to introduce a measure, at an early stage of its development;
- 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
- <u>4. determine deadline to provide comments, and shall conduct consultations upon request of interested parties</u>

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.

1. quickly and without undue delay and in no less favorable manner for imported products than for like domestic products;

2.

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,

Foodstuffs of animal origin intended for public consumption containing the residues, or

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

Article 42 b

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

- control of animal feed and water for animal watering at the farmstead from which
 the animals originate or are shipped, and for the aquaculture animals –
 examination of water from which they are captured or in which they are reared;
 and
- other controls which are necessary for establishment of the origin or unacceptable residues.

When it is established in the analysis that half or more samples are positive, owner of animals shall have the right to choose between the examination of every potentially suspicious animal held on a farmstead, or slaughter of all animals.

Owner of animals shall not have the right to compensation of damage in the event referred to in paragraph 1 indent 1, and paragraph 2 of this Article.

Measures referred to in paragraphs 1 and 2 of this Article shall be implemented by the administrative authority.

Article 42 e

Importation of animals or foodstuffs of animal origin in the Republic may be implemented from the countries which implement systematic control measures according to the residue monitoring program which is at least equivalent to the program of the Republic.

Veterinarians, owners of animals and other legal and natural persons shall take measures to avert the consequences that may arise from use of harmful substances in raw materials, food and feed, and implement laid down preventive measures.

The Ministry may, based on risk analysis, impose the prohibition on market placement, marketing, market withdrawal, of the food, raw materials, waste and feed, containing specific harmful substances, and prohibit the use of specific harmful substances.

The Ministry shall adopt a special program for systematic control—monitoring of animals, raw materials, food and feed, in respect of the content of harmful substances and control of disallowed substances.

4. Ensuring Animal Feed Safety

Article 43

Legal persons and entrepreneurs registered for production, storing and marketing of feed, shall ensure safety of feed in all stages of its production, storing and marketing.

It shall be disallowed to market unsafe feed.

Legal persons and entrepreneurs that are registered for animal feed production shall, before

To prevent emergence of foodborne infectious animal diseases, it shall be disallowed to use food

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

D. ENVIRONMENTAL PROTECTION

1. Rights and Obligations

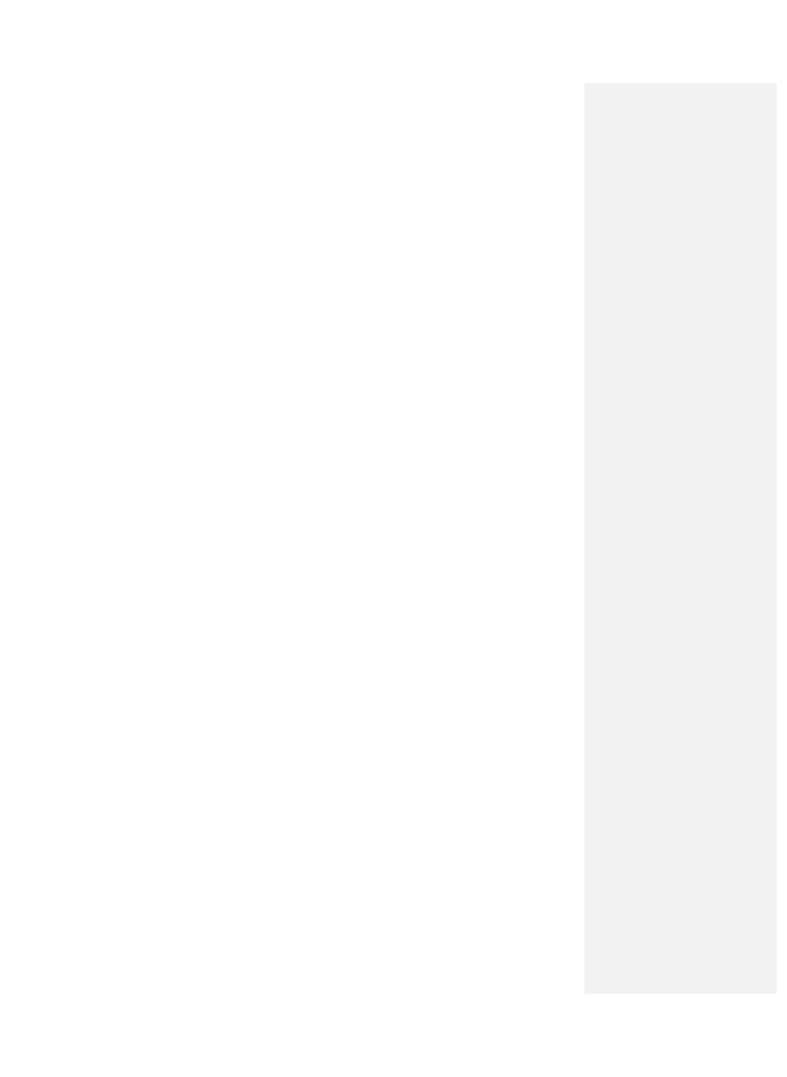
Article 51

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)



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.

- 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,

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;

- 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;
- Care of breeding animals health and breeding capacity, implementation of measures for prevention and treatment of sterility, and insemination and embryotransfer;
- 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;

4. Livestock-Veterinary Center for Reproduction and Artificial Insemination

Article 67

Activities of the Chamber shall include:

- 1) Adopting the Codex for veterinary profession and ensuing 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) e

- 1) Cessation of the compliance with the requirements for entry into the Register;
- 2) Permanent suspension of the license, and

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;
- 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,
- 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.

- 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 authorizationse 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

- 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 .8387 0 e001 1179c8oslaugh2(r)5.wiingut perw[P(o).2(r)ve2(r waryh)-6(;)]TJET56.

- 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

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 karener waiting period did not elapse before the moment of slaughter, until

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);

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

or products but the laid down kareneawaiting 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 karencewaiting periods and fails to keep the laid down records (Article 42b

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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