"Official Gazette of the Republic of Montenegro", No. 23/2005

By virtue of Article 28, paragraph 1, of the Veterinary Law ("Official Gazette of the Republic of Montenegro" No. 11/04),

The Ministry of Agriculture, Forestry, and Water Management enacts this

ORDINANCE

ON UNDERTAKING THE MEASURES TO PREVENT INTRODUCTION OF THE ANIMAL INFECTIOUS DISEASE BOVINE SPONGIFORM ENCEPHALOPATHY (BSE) IN THE REPUBLIC OF MONTENEGRO

Article 1

With the aim of preventing the introduction and appearance of the infectious animal disease Bovine Spongiform Encephalopathy (hereinafter: BSE) and Other Transmissible Spongiform Encephalopathies in animals (hereinafter TSEs) in the Republic of Montenegro, the following measures are being undertaken:

The following shipments are not allowed:

1) Live bovine animals;

2) Products, raw materials and wastes of bovine origin;

3) Embryos and fertilized ova for fertilization of bovine animals;

4) Animal feed containing ingredients of animal origin (meat meal, meat and bone meal, bone and meat meal, bone meal, blood meal, liver meal, and other animal feed additives originating from ruminants), and animal feed containing ingredients originating from ruminants;

5) Medicaments and vitamins for veterinary purposes, containing the ingredients originating from ruminants;

6) Raw materials and products used for consumption or in cosmetics containing the ingredients originating from ruminants, or other material by way of which BSE is transmittable;

7) Humanitarian aid and donations in the shipments referred to in items 1-6 of this Article.

Article 2

The ban on importation referred to in Article 1 of this Ordinance shall apply to shipments originating from the countries in which presence of BSE has been reported.
Imports may also be banned from other countries which, according to the rules of the International Organization for Animal Health (OIE) and World Health Organization, may be deemed to be at risk of BSE.

The risk assessment may be conducted based on the documentation issued by competent authorities and by direct inspection carried by the experts in this field.

**Article 3**

Transit shipments referred to in Article 1 of this Ordinance may be carried out based on a permit issued by the Veterinary Administration.

Forwarder shall be under obligation to have the shipments referred to in Article 1 of this Ordinance dispatched from the territory of the Republic of Montenegro within 24 hours from the time the shipment entered the country, in accordance with other requirements specified in the permit.

The competent inspector at the entry border crossing shall notify the competent inspector at the exit border crossing about the transit of shipments.

Should it be established that a shipment has not been dispatched, the competent veterinary inspector shall notify the competent authorities (Ministry of Interior and Customs Administration).

**Article 4**

The ban on importation referred to in Article 1 of this Ordinance shall not apply to the following shipments:

1) Milk and dairy products;
2) Seed for artificial insemination;
3) Bovine hides and parts of bovine hide;
4) Collagen and collagen products derived exclusively from bovine hide;
5) Bovine tallow for technical purposes, without protein (maximum allowed level of insoluble impurities up to 0.15) and products made from such fat;
6) Food for pets containing proteins originating from the ruminants, other than those included in the food chain;
7) Dicalcium phosphates (without traces of proteins and fats);
8) Bulls for the requirements of the center for artificial insemination for production of quality seed, which have to be returned within a period which may not exceed 30 months following the day of importation of bullocks weighing 220 -250 kg, which are imported to be fattened and exported when they reach the bodily weight of 450 -500 kg, or up to 800 kg for fattening animals with 24 months of age;
9) Pregnant high production dairy heifers intended exclusively for production of milk and without any possibilities of dislocation from the previously designated locations, both of heifers and their offspring, without previously obtaining written approval from the Veterinary Administration, before the establishment of the Program for BSE.
Control, Monitoring, and Diagnostic Examination, and completion of the process of identifying and registering the animals of such category;

10) Meat of the bovine animals weighing 450-550 kg, with 24 months of age, exclusively in quarters, from the animals which, after the inspection before slaughter and after slaughter, and testing for BSE, were assessed as healthy, and the meat which, after the inspection, was assessed as safe for human consumption without limitation, with mandatory negative findings of the testing for BSE.

**Article 5**

Importation of shipments referred to in Article 4 items 3), 4), 5), 6), and 7) of this Ordinance may be allowed provided the raw materials and products in the shipment originate from the animals which were assessed, after the inspection before slaughter and after testing for BSE, as healthy and the meat and organs of which were assessed, after the inspection, as safe for human consumption, and if the raw materials and products in the shipment were subjected to a suitable technological procedure of production, specifically:

a) Bovine hide treated according to the following procedure:
   - Alkali treatment in a solution of calcium base at pH 12 to 13 during at least eight hours with sodium sulfide or diluted sodium hydroxide, followed by treatment in the acid pH 1 to 3 during at least six to ten hours;
   - Brined for at least seven days in sea salt to which 2% sodium carbonate was added;
   - Dried for 42 days at the temperature of 20 °C;

b) Parts of bovine hide treated according to the following procedure:
   - Alkali treatment in a solution of calcium base at pH 12 to 13, for at least eight hours with sodium sulfide or diluted sodium hydroxide;

v) Collagen and collagen products made from bovine hide and in the procedure that includes the following phases:
   - Alkali treatment in a solution of calcium base at pH 12-13, for at least 8 hours with sodium sulfide or diluted sodium hydroxide;
   - Neutralization;
   - Extraction with the acid at pH 0.8 for at least 6 hours at room temperature, or other appropriate treatment in the interval of up to pH of maximum 3.3 at least 48 hours at room temperature;
   - Drying at the temperature of at least 80 °C;

g) Tallow produced by hot process at the temperature of 130 °C to 140 °C at least 30 minutes under the pressure of 3 bars. Products from tallow must be hydrolyzed at the temperature of at least 250 °C;
   - Tallow fat and fat products must be filtrated in production;

d) Food for pets, if containing proteins originating from ruminants, must be treated and produced in the facilities other than those intended for wastes production, unless
containing bovine tissue originating from the countries listed under the Category 4, in the table constituting an integral part of this Ordinance.

Raw materials originating from bovine animals more than 24 months old, used for production of hide, parts of hide, collagen and tallow, must be from animals that were, after being tested on BSE, assessed as healthy and safe for human consumption.

**Article 6**

The treatment process referred to in Article 4 of this Ordinance shall be described and verified in the veterinary certificate accompanying the imported shipment.

**Article 7**

Importation of the shipments referred to in Article 4, items 8), 9) i 10) of this Ordinance may be allowed only if the requirements laid down in the Codex of the International Organization for Animal Health (OIE) are met, which is to be confirmed in the veterinary certificate issued by the exporting country, and the following measures shall be implemented:

- That bovine animals were calved, raised, and have stayed within the herds with no confirmed cases of BSE in last seven years, and that subsequently introduced bovine animals originate from a herd, or farming estate, with equal status, or that bovine animals were calved after the date on which the implementation began of the ban on feeding the ruminants with the proteins originating from mammals;

- Identification of animals that would enable tracing back to the mother of animal and the herd of origin, and that animals are not the offspring of a female animal which was suspected of BSE;

- That feeding of bovine animals with proteins of animal origin, including meat and bone meal, was banned in last eight years;

- That the exporting country have introduced a system that enables tracing the origin of fresh bovine meat as far back as the production facilities in which it was produced;

- That animals have not been slaughtered after stunning by means of gas injected into the cranial cavity or immediately killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity;

- Implementation of active program of testing on BSE;

- Introduction a referential laboratory for massive testing on BSE;

- Quarantine;

- Safe disposal of animal carcasses in accordance with regulations.

Importation of shipments referred to in Article 4 of this Ordinance may be allowed if the animals originate from the countries listed in the Exhibit 1 that was printed together with this Ordinance and constitutes an integral part thereof, specifically from Categories 1, 2, and 3.

**Article 8**
For importation of animals referred to in Article 4 item 9) of this Ordinance, it is necessary to provide the following:

- List of end users of heifers, location and data for each individual head (fact sheet from the farm of origin);

- Certified statement of the user of imported heifers that he will report each and every change in health status, and each and every movement, of these animals and their offspring with the veterinary department which was assigned by the Veterinary Administration to conduct continuous expert surveillance, and that these animals shall not leave the previously designated location before an approval in writing is obtained from the Veterinary Administration, in the period before the Program for BSE Control, Monitoring, and Diagnostic Examination and the National Laboratory for BSE are established and the process of identifying and registering the animals of this category is completed;

- Written confirmation of the Ministry or the authority in charge of veterinary issues in the exporting country that the BSE superanalysis was conducted on pregnant heifers in the exporting country, in the event an imported animal dies before the laboratory for BSE is established in the Republic of Montenegro. Upon the analyses are completed, dead animals shall be disposed of in a safe manner.

Verification of the data referred to in paragraph 1 of this Article shall be conducted by the competent veterinary inspection.

Imported animals and their offspring shall be the first to be marked after commencement of the animal identification and registration project in the Republic of Montenegro.

**Article 9**

Importation of animals and risk assessment shall be carried out in accordance with the categorization of the BSE risk countries, as shown in Exhibit 1.

Upon importation and conduction of diagnostic examinations, imported animals referred to in Article 4, items 8) and 9) of this Ordinance shall be entered in the Directory of Imported Bovine Animals that is kept by the Veterinary Administration. Any changes with regard to health status or movement of these animals and their offspring shall also be entered in this Directory in the period before the Program for BSE Control, Monitoring, and Diagnostic Examination and the National Laboratory for BSE are established and the process of identifying and registering the animals of this category is completed.

Imported animals referred to in Article 4 item 9) of this Ordinance shall be kept marked and under continuous expert surveillance.

In the event of a disease or death, the appropriate diagnostic procedure and the appropriate safe removal shall be carried out.

In the event of forced slaughter, or exclusion of animals from further raising for any reasons that call for their slaughter or safe destruction, all imported bovine animals, regardless of their age, shall be examined for BSE after being slaughtered.

Upon expiry of the time period referred to in Article 4 item 8) of this Ordinance, imported animals shall be returned to the country from which they were exported.
Article 10

In addition to the measures referred to in Article 1-4 of this Ordinance, the following measures shall be implemented:

1) Systematic monitoring of the epizootiological situation of BSE and other TSEs worldwide and the measures the competent authorities in other countries take with regard to BSE and other TSEs suppression;

2) More stringent veterinary control and control of the shipments of animals, products, raw materials and wastes of animal origin, animal feed, additives for animal feed, veterinary medicines, and other articles which may transmit BSE, by the competent authorities at border crossings;

3) Efficacious control of animals, products, raw materials, and wastes of animal origin, and animal feed, in production, processing, and circulation;

4) Marking and identifying the animals;

5) Safe disposal of animal carcasses and wastes of animal origin in the facilities for safe disposal, and, exceptionally, in other manner in accordance with regulations;

6) Ban on production and use of animal feed that contains the ingredients of animal origin for feeding the ruminants;

7) Monitoring of the BSE status according to the Program for BSE Control, Monitoring, and Diagnostic Examinations;

8) Training of veterinarians whose duty is to conduct clinical examinations and to control health status of ruminants, and to strictly implement the procedure for taking samples and delivering for laboratory examination the appropriate tissue samples of the animals which have shown neurological symptoms or have died with neurological symptoms;

9) Owners and keepers of animals, farmers, and persons involved in transportation or slaughter of ruminants shall be under obligation to report to the veterinary department any suspicion of neurological diseases in ruminants

Article 11

On the effective date of this Ordinance, the Ordinance on Implementation of Measures for Prevention of Introduction of Animal Infectious Disease Bovine Spongiform Encephalopathy (BSE) in the Federal Republic of Yugoslavia ("Official Gazette of FRY", No. 70/02) shall cease to apply.

Article 12

This Ordinance shall become effective on the day of its publishing in the "Official Gazette of RM".

No: 323/05-0501-1780
In Podgorica, on the 28th of March 2005
Ministry of Agriculture, Forestry, and Water Management

Signed by the Minister,
Mr. Milutin Simovic, M.Sc.

Exhibit 1

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