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Self-declaration by Romania of historical freedom from brucellosis in bovids

Declaration sent to the OIE on 10 June 2020 by Dr Robert Viorel CHIOVEANU, OIE Delegate for Romania, Chief Veterinary Officer.

1. Historical data on the epidemiological situation of bovine brucellosis in Romania

Bovine brucellosis is a disease caused by *Brucella abortus*, clinically characterized by reproductive disorders, abortion, born of non-viable conception products, orchitis and epididymites, with frequent sterility, especially in males.

In Romania, the first reports on abortions due to infections in cows were registered in 1906, then in 1953 and in 1954. The first normative regulation on supervision, prevention and control of bovine brucellosis in Romania was drawn up in 1955, when the State Council Ordinance no. 167 is developed and implemented on the organization of animal health defence. Brucellosis was classified as a notifiable disease. By this ordinance, bovine brucellosis was classified as officially notifiable and subjected to specific sanitary veterinary measures, including quarantine.

The control of the disease was achieved by slaughtering and disposal of all affected animals and of those suspected of disease or contamination associated with protective measures of antiepidemiologic protection and prohibition of the consumption of products from the mentioned animals.

In 1974, Law no. 60 and the Order no. 114 of October 2, 1975 (564 pages) of the Ministry of Agriculture and Food Industry, approving the "Sanitary veterinary norms and measures" was drawn up. Part II of the Order provided general measures for preventing and controlling animal diseases transmissible to animals, including those applied for bovine brucellosis, and Part III provided special measures for the prevention and control of infectious transmissible and parasitary diseases, while bovine brucellosis disease was included among the diseases subjected to official reporting and quarantine measures.

After 1990, specific measures for prevention and disease control were contained in the structure of "The strategic program of sanitary veterinary actions for the surveillance, prevention and control of animal disease, pest control on lawns," drawn up by the General Sanitary Veterinary Directorate within

the Ministry of Agriculture and Food published in the Veterinary Journal no. 1/1991 with no. 37109/1991.

In 1993 the first normative act was drawn up to prevent and control bovine brucellosis according to Community legislation.

In 1993, Romania became an associated country of the European Community, and had the responsibility of drawing up and implementing the national strategy on the control and eradication of existing diseases in Romania, in line with the Community principles of disease control. Subsequently, after the official request of Romania's Accession to the European Union was sent to the Commission on June 22, 1995, discussions were carried out to conclude an equivalence agreement for sanitary veterinary measures between Romania and the European Commission, including the equivalence of methods of surveillance, prevention and control of animal diseases, a relevant point being bovine brucellosis.

Since 1998, Romania has transposed into the national legislation the specific legislation on the control and eradication of transmissible animal diseases, including regulations for bovine brucellosis.

In 1998, the "Central Sanitary Veterinary Diagnostic Laboratory" was transformed in "Institute for Diagnosis and Animal Health", and substantial changes took place in the structure and functioning of the institution and in particular of the laboratories whose field of activity was the laboratory surveillance of animal herds in Romania, including that on bovine brucellosis. In the meantime, the serology laboratory became the immunodiagnostic laboratory and finally, in 2008, the Immunology Laboratory.

Also, substantial improvements on laboratory facilities, approval, validation and accreditation of official surveillance methods and laboratory diagnostic implicitly for brucellosis took place, and also was nominated the National Reference Laboratory for Animal Brucellosis, which collaborates closely with the Brucellosis European Reference Laboratory, participating in different comparative interlaboratory tests organised by the Brucellosis European Reference Laboratory within the French Agency for Food, Environmental and Occupational Health & Safety (ANSES), Maisons-Alfort, France, as well as by other European-laboratories authorized to organize such tests between countries.

Each year, Romania included in its "strategic programme of sanitary veterinary actions for the surveillance, prevention and control of animal disease" bovine brucellosis, and the results were communicated to the European Commission by the "Annual report on certain diseases of bovine animals and swine, in accordance with the provisions of the Art. 8 of Council Directive 64/432/EEC." So far, all results were negative.

2. The legal basis, in order to support the obtaining of official bovine brucellosis free country status, represents the community legislation transposed into the national legislation, as follows:

- Transposed community legislation which establishes the intracommunity trade in animals from bovine species:

The NSVFSA Order no. 61/13.03.2006 for the approval of sanitary veterinary Norm regarding the animal health problems which affect the intracommunity trade in animals from bovine and swine species, which transpose the Council Directive 64/432/EEC regarding the animal health problems which affect the intracommunity trade in animals from bovine and swine species, with subsequent amendments;

- Transposed community legislation which establishes the intracommunity trade in bovine semen, ova and embryos:
 - a) The NSVFSA Order no. 205/25.08.2006 for the approval of the sanitary veterinary Norm which establishes the animal health requests applicable to the intracommunity trade and import of

- semen coming from domestic animals from bovine species, which transpose the Council Directive 88/407/EEC, with subsequent amendments;
- b) The NSVFSA Order no. 134/16.06.2006 for the approval of the sanitary veterinary Norm regarding animal health conditions, which establishes intracommunity trade and import from third countries of embryos coming from domestic animals from bovine species, which transpose the Council Directive. 89/556/EEC, with subsequent amendments.
- Transposed community legislation which establishes the import from third countries of animals from bovine species and their products:
 - a) The NSVFSA Order no. 53/26.05.2005 for the approval of the sanitary veterinary Norm on the list including third countries or parts of third countries and animal and public health veterinary certification conditions, in order to import into the European Community of certain live animals and fresh meat thereof and taking over these lists and conditions for the import into Romania, which transpose Commission Decision 79/542/EEC;
 - b) The NSVFSA Order no. 136/13.12.2005 regarding the amendment and completion of Order no. 53/2005 for the approval of the sanitary veterinary Norm on the list including third countries or parts of third countries and the animal and public health veterinary certification conditions, in order to import into the European Community certain live animals and fresh meat thereof and taking over of these lists and conditions, which transpose the Commission Decision 05/753/EEC;
 - c) The NSVFSA Order no. 152/22.06.2006 regarding the amendment and completion of the NSVFSA Order no. 53/2005 for the approval of the sanitary veterinary Norm on the list including third countries or parts of third countries and the animal and public health veterinary certification conditions, in order to import into the European Community of certain live animals and fresh meat thereof and taking over of these lists and conditions for the import into Romania, with subsequent amendments, which transpose the Commission Decision 79/542/EEC;
 - d) The NSVFSA Order no. 1/1.04.2004 for the approval of the sanitary veterinary Norm on implementing the inspections on the spot which must be carried out relating to the import of animals from bovine and swine species and of fresh meat thereof, originary from third countries, which transpose the Commission Decision 86/474/EC;
 - e) The NSVFSA Order no. 125/24.11.2004 regarding the approval of the sanitary veterinary and food safety Norm on the import into Romania of live animals, fresh meat and their meat products, coming from the Federal Republic of Yugoslavia and Groenlanda, which transpose the European Commission Decision 97/736/EC.
 - Transposed community legislation which establishes the import from third countries of bovine semen, ova and embryos:
 - a) The NSVFSA Order no. 205/25.08.2006 for the approval of the sanitary veterinary Norm which establishes animal health requirements applicable to the intracommunity trade and import of semen coming from domestic animals from the bovine species transposing The Council Directive. 88/407/EEC, with subsequent amendments;
 - b) The NSVFSA Order no. 105/11.03.2002 for the approval of the sanitary veterinary Norm regarding animal health conditions and veterinary certification for the import from third countries of semen coming from Bovines, transposing the Commission Decision 94/577/EC;

- c) The NSVFSA Order no. 189/29.04.2002 for the approval of the List including third countries and centers for the collection of embryos coming from domestic animals from bovine species approved for the import into Romania, transposing the Commission Decision 92/452 /EEC;
 - d) The NSVFSA Order no. 38/20.02.2007 regarding the approval of the sanitary veterinary Norm on establishing the requirements concerning animal health and veterinary certification for the import into the European Community of bovine embryos, transposing the Commission Decision 06/168/EEC.
- Transposed community legislation which establishes the identification and registration of bovines;
 - a) The Commission Regulation no. 509/8.03.1999 regarding an extent of the maximum period which establishes the application of ear tags in bisons (*Bison bison* spp.), published in JO L 60, 9.03.1999, p. 53-53;
 - b) The Regulation of the European Parliament no. 1760/17.07.2000 of establishing a system for bovine identification and registration regarding the labelling of beef meat and beef meat products and repealing the Council Regulation no. 820/1997;
 - c) The Commission Regulation no. 2680/17.12.1999 of approving a certain system for the identification of the bulls intended for cultural and sporting events;
 - d) Commission Regulation (EC) No 911/2004 of 29 April 2004 implementing Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards ear tags, passports and holding registers, with further amendments;
 - e) The NSVFSA Order no. 40/2010 on the approval sanitary veterinary Norm regarding the implementation process of identification and registration of swine, bovine, sheep and goat, with further amendments.
 - Data regarding the identification of the cattle

The identification of the cattle in Romania started in January 2005 respecting the rules established by Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) and by Regulation (EC) No 911/2004 of 29 April 2004 implementing Regulation (EC) No 1760/2000 of the European Parliament and of the Council as regards ear tags, passports and holding registers, transposed into national legislation by OUG 113/2002 regarding the approval for the identification and registration of cattle and Order No. 5/2005 regarding the approval for the identification and registration of animals.

Thus, since with January 2005 the cattle are identified before the age of 20 days after birth or, in any event, before leaving the farm of origin, depending on which event took place first. This is done by applying two ear tags, one in each ear, which are printed with the same unique identification code. For each identified cattle, a passport is issued in which all the owners are enrolled, and this, together with the movement documents will accompany the cattle during movement, ensuring traceability.

The owner of the cattle is obliged to notify to the official empowered veterinarian all the movements of the cattle (born, sale/purchase, death, slaughter, ear tag loss). The official empowered veterinarian is required to give the owner the movement documents and the passports for those cattle and to record the movements in National Database.

This system was kept after January 1, 2007 (also the date of Romania's accession).

The total number of the existing bovines can be seen in the Annual report for 2019 on certain diseases of bovine animals and swine, sent by Romania to European Commission on 14.05.2020. ([Annex 1](#))

3. Presentation of tests and category of bovine for surveillance concerning the *Brucella abortus*

Romania developed a mandatory national program for the control of *Brucella abortus*. The tests provided in the program are as follows:

1. Serological surveillance by Rose Bengal Test (RBT)/ iELISA in:
 - a) bovines aged over 24 months are controlled once a year but not later than 12 months since the precedent control;
 - b) breeding bovines, in cases of sales- purchase, concerning the seller no later than 30 days before delivery, if they were not examined in the current calendar year.
 - c) cows, water buffaloes and heifers that aborted or which show clinical signs leading to the suspicioning of brucella infection.
2. Bulk milk surveillance iELISA, in dairy cattle farms, three times in interval of 12 month,
3. *Serological testing* of domestic and wild animals introduced by intra-Community trade or import from third countries over the age of 1 year is made in 1% percent, but not less than 5 samples per batch.
4. *Bacteriological and serological surveillance*, compulsory for susceptible species from wildlife, for all hunted animals.
5. Anatomopathological examination and laboratory complex:
 - a) From all the animals that aborted, there are sent slinks to laboratory, placenta, foetal fluids and blood serum samples from 14 to 21 days after abortion;
 - b) For confirmation/invalidation of serological and clinical suspicions of Brucellosis, after slaughtering perform the culture and isolation from head, mammary and genital lymph nodes and spleen.

([Annex 1](#) and [Annex 2](#) and [Annex 3](#)).

The laboratory tests for Brucellosis surveillance complies with the OIE Manual and with Annex C of the Council Directive 64/432/EEC.

The veterinary services of Romania performed in 2010 the qualification of the bovine holdings as official free of bovine brucellosis, based on tests carried out according to Council Directive no. 64/432/EEC and officially certified as free of disease.

Since 2010, the surveillance programme for bovine brucellosis provides and tests on milk samples in dairy cattle farms, according to Council Directive no. 64/432/EEC. In case of positive results of milk ELISAs the animals are serologically tested on samples of serum taken from individual animals.

In case of suspicion, the officially free status of farm is suspended and remains suspended until negative results to the serological tests carried out in accordance with the provisions of NSVFSA President Order no. 61/2006, with subsequent amendments, which transpose the Council Directive 64/432/EEC.

According to the COMMISSION DECISION of 23 June 2003 establishing the official tuberculosis, brucellosis, and enzootic-bovine-leukosis-free status of certain Member States and regions of Member States as regards bovine herds (2003/467/EC) Romania is free from bovine brucellosis.

4. Surveillance of *Brucella abortus*

The bovine brucellosis monitoring programme is a fulfilment of the OIE – *Terrestrial Code* Article 8.4.3 – Article 8.4.4. (See Annex 2 and Annex 3 for a detailed activity on surveillance).

Vaccination. In Romania, on the entire territory of the country, the vaccination against bovine brucellosis never was applied (Order of the President of NSVFSA no. 35/2016).

The disease is mandatorily notifiable and subject to quarantine measures, but the disease was eradicated in 1969. No cases of bovine brucellosis were detected during the last 57 years. The notification is carried out according to national Order no.77/2005 for the approval of the Sanitary Veterinary Norm regarding the notification of animal diseases, with all subsequent amendments, published in the Official Journal of Romania, no.964//31 October 2005. This Order represents the official transposition of Council Directive 82/894/EEC on the notification of animal diseases within the European Community.

As an OIE Member, Romania has the obligation to notify bovine brucellosis using the WAHIS system.

According to the legislation in force, the animal owner has the obligation to notify any alteration of the health status of the animals or any case of mortality registered, to the empowered free practice (authorised private veterinarian) or official veterinarian. The empowered free practice veterinarian has the obligation to communicate to the official veterinarian any situation in which a transmissible animal disease is suspected. The official veterinarian communicates, by any means, the suspicion of disease to the county sanitary veterinary and food safety directorate (local sanitary veterinary competent authority).

In the case of wild ruminants hunted under natural conditions or hunted because they show clinical signs it is compulsory for the wildlife officers of the hunting area to notify the authorised private veterinarian regarding any alteration of the status of wild animals or any lesions noticed in dead animals. The Institute for Diagnosis and Animal Health (IDAH), which is the unit with the jurisdiction and operates as a public institution of national interest, subordinated to National Sanitary Veterinary and Food Safety Authority (NSVFSA), had never received requests from the General Association of Sport Hunters and Fishermen in Romania for suspected brucellosis investigations in wild ruminants.

5. Measures implemented to maintain freedom in the country

Romania implement each year a national Program of surveillance, prevention, control and animal disease eradication, of those transmissible from animal to human, animal protection and environment protection. This program comprises 72 animal and zoonotic diseases for which samples are sent to the laboratory for diagnosis. This program is approved by Order of the President of NSVFSA no. 35/2016 for the methodological norms approval in order to implement the program of surveillance, prevention, control and eradication of animal diseases, of those which are transmissible from animals to humans, the animal and environment protection, the bovine, ovine, swine, goats identification and registration and methodological norms of implementing of surveillance and control program on food safety, with subsequent amendments.

Please see the National Surveillance Program at NSVFSA website: <http://www.ansvsa.ro/legislatie/programul-strategic-al-ansvsa/>

The program is put into place by developing a figure plan which is prepared by each County Sanitary Veterinary and Food Safety Authority and its fulfillment is monitored by National Sanitary Veterinary and Food Safety Authority.

In the case of animals coming from other countries, clinical inspection and verification of relevant data, including sanitary veterinary documents and other documents accompanying susceptible animal consignments coming from other member states of European Union or third countries, before

unloading at destination are performed according to the NSVFSA and Agricultural and Rural Development Ministry order no.129/566/2007 approving sanitary veterinary norm regarding veterinary and zootechnical controls applicable to intra community trade with certain live animals and animal products. For ruminants coming from third countries all animals are tested.

6. Conclusions

Considering that:

- the eradication of the disease took place in 1963, since then Romania being officially free,
- based on the surveillance programme, in accordance with Chapter 1.4 and Article 1.4.6 of the *Terrestrial Code*, no evidence of infection with *Brucella abortus* in the country during the past 50 years,

The OIE Delegate of Romania declares that the country complies with the requirements for historically free from infection with *Brucella* in bovids as of 1 January 2020, in compliance with the provisions of Chapter 1.4.6. and Article 8.4.3. of the OIE *Terrestrial Code* (2019 edition) and consistent with the information provided in WAHIS.



Annex I

Statement to be included in the self-declaration document.

I, the undersigned, DR. ROBERT VIOREL CHIOVEANU - CVO

Delegate of ROMANIA

to the World Organisation for Animal Health (OIE), takes responsibility for the self-declaration of freedom from

BRUCELLOSIS IN BOVIDS (disease)

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Drawn up on 17/08/2020

Signature of the Delegate:

