



**EUROPEAN COMMISSION**  
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Crisis preparedness in food, animals and plants  
**Animal health**

**SUBMISSION OF ERADICATION PROGRAMMES FOR CATEGORY B AND C  
DISEASES OF TERRESTRIAL ANIMALS BASED ON GRANTING DISEASE-FREE  
STATUS AT ESTABLISHMENT LEVEL**

**Template in accordance with Article 10 of  
Commission Implementing Regulation (EU)  
2020/2002**

1. Date of submission 09.12.2021
2. Member State : ROMANIA
3. Name of the disease<sup>1</sup> *Infection with Mycobacterium tuberculosis complex*
4. Contact details
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  - b. Responsibility within the competent authority – Head of the Disease Control Service within Animal Health Directorate - National Sanitary Veterinary and Food Safety Authority
  - c. Name: Ioana Alexandra NEGHIRLĂ
5. Territorial scope with a description and demarcation of the geographical and administrative areas covered by the eradication programme and the names of the zones and regions, if more than one region is included in the territorial scope of the programme.

The purpose of the eradication program is for Romania to obtain the status free from infection with MTBC.

The eradication program will be applied throughout Romania, in all geographical areas represented by counties.

The program will be implemented by:

- annual testing of the population of bovine animals kept (over 6 weeks old throughout the country) on all establishment (commercial, including commercial type A and non-professional);
- annual testing of the additional animal population represented by buffaloes (over 6 weeks old throughout the country) on all establishment (commercial, including commercial type A and non-professional);

**6. A description of the epidemiological situation for each zone or region, if more than one region is included in the territorial scope of the programme:**

- (a) the number of establishments keeping animals of the targeted animal population by health status (Disease-free, infected or unknown) excluding establishments falling under the derogation referred to in point (6)(f) at 31 December;

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<sup>1</sup> This template is to be used for the submission of the following eradication programmes for the following listed diseases:

Category B-diseases

- a) Infection with *Brucella abortus*, *B. melitensis* and *B. suis*
- b) Infection with *Mycobacterium tuberculosis complex*

Category C-diseases

- a) Enzootic bovine leukosis
- c) Infectious bovine rhinotracheitis/infectious pustular vulvovaginitis
- d) Infection with Aujeszky's disease virus
- e) Bovine viral diarrhoea



Annex\_I\_TBC  
31.12.2020.doc

**(b) the number of animals of the targeted animal population kept in the establishments referred to in point (a) by health status;**

Please see Annex no I above.

**(c) maps indicating the density of the targeted animal population referred to in point (b) by health status;**



MTBC\_map\_of\_programme\_ROMANIA\_2021.jpg



Bovine\_TBC\_status\_ROMANIA\_31\_dec\_2020.jpg

**(d) timeline with prevalence, incidence data and, where relevant, vaccination history covering at least the past 5 years; and**

The situation of positive cases of complex Mycobacterium Tuberculosis infection for the period 2016-2020 is as follows:

- years 2016 were identified 208 positive cases of MTBC (prevalence 0.0096%)
- years 2017 were identified 381 positive cases of MTBC (prevalence 0.0184%)
- years 2018 were identified 262 positive cases of MTBC (prevalence 0.0136%)
- years 2019 were identified 187 positive cases of MTBC (prevalence 0.0099%)
- years 2020 were identified 89 positive cases of MTBC (prevalence 0.0048%)

**(e) information as regards the epidemiological situation in additional animal populations, where relevant.**

**7. A description of the disease control strategy of the eradication programme in accordance with Article 16 of Commission Delegated Regulation (EU) 2020/689 including at least:**

**(a) the sampling schemes and diagnostic methods to be used in accordance with Annex IV to Delegated Regulation (EU) 2020/689:**

**(i) for the granting of the disease-free status to establishments and the maintenance of that status;**

In Romania, the qualification of the holdings was carried out according to the requirements of Council Directive 64/432 / EEC implemented in national legislation by the Order of the President of ANSVSA no. 49/2010 on the qualification of farms in relation to bovine tuberculosis.

With the entry into force of Reg. 429/2016 and the Delegated Regulation (EU) 2020/689, for the maintenance of MTBC-free status, testing of bovine animals on officially qualified bovine tuberculosis-free holdings with a certificate of indemnity, performing intradermal tuberculin by TCS, once a year, in all bovine animals and

buffaloes over 6 weeks of age. The testing is planned before the immunoprophylactic actions, being necessary the prophylactic deworming of the animals.

In the case of establishments with unknown status, granting of the status free from infection with MTBC is performed according to the provisions of Annex IV, Part II, Chap. 1, Section 1 of Delegated Regulation (EU) 2020/689.

**(ii) to confirm or rule out the disease in the event of a suspected case;**

TCS-positive animals shall be disposed of from the livestock, by control slaughtering for diagnostic purposes within a maximum of 30 days from the official notification to the owner or to the person responsible for the test results, and the holding shall be suspended as official TB-free status.

TCS inconclusive animals are retested after mandatory internal deworming, within 21 days before retesting, in the presence and responsibility of the official veterinarian, and the holding is suspended as official TB-free status until the status of the holding is clarified by a TCS performed within 42 days after the first tuberculin test.

Animals with two inconclusive TCS results are considered positive and must be removed from the holding by slaughtering for diagnostic purposes within 30 days from the official notification to the owner or to the person responsible for the test results.

Laboratory examinations for the determination of the MTBC diagnosis are performed at SVFSL designated, under the coordination and, if necessary, with the support of LNR-IDAHA.

The designated laboratory which carry out histopathological and bacteriological examinations (bacterioscopic and culture exams), and, in case of isolating species from the Mycobacterium Tuberculosis complex, the designated laboratories submit strains to IDAH-LNR for Tuberculosis and Paratuberculosis in view of genotypic and phenotypic identification (diagnostic methods for disease confirmation).

The NSVFSA may approve the use of alternative methods to increase the diagnosis confidence regarding suspicious animals, such as ELISA- $\gamma$ -IFN test carried out by IDAH-LNR.

**(b) disease control measures to be applied in the event of a confirmed case;**

When bovine tuberculosis is confirmed in a holding, there shall be applied control measures in conformity with the provisions of Art. 24 - 31 of Delegated Regulation (EU) 2020/689:

- the disease-free status of the infected holding is withdrawn;
- the epidemiological investigation is carried out;
- the removal of animals from the holding is prohibited, unless there is authorized their immediate slaughter in a designated slaughterhouse;
- in order to control the risk of spreading the disease, it is necessary to isolate suspected cases on the holding, to restrict the entry of animals into the holding and to restrict the removal or introduction of bovine products into the establishment;

- after the disease confirmation, the competent authority shall require that all bovine animals over 6 weeks of age on the holding be tested by TCS, as follows:
- the first test shall be performed two months after the disposal of the last confirmed case and of the last animal that tested positive for a TCS test;
- the second test shall be performed after two months and no later than 12 months from the date of the first test;
- milk originated from confirmed cases is given for consumption only to animals from the same establishment after processing to ensure the inactivation of the pathogen, or is disposed of;
- the official tuberculosis-free status of a holding must remain withdrawn until the premises and tools have been cleaned and disinfected;
- manure, straw, fodder or any other substances and materials which have come into contact with a confirmed case or contaminated matter are collected and disposed of as soon as possible or, after carrying out an adequate risk assessment, they should be stored and processed to reduce the risk of spreading the disease to an acceptable level;
- the competent authority shall supervise the cleaning and disinfection, re-establish and grant disease-free status for the concerned holding, when it considers that the cleaning and disinfection operations have been completed.

**(c) biosecurity and risk mitigating measures to be implemented;**

The biosecurity measures implemented on cattle farms are regulated in NSVFSA Order No 34/2009 on general biosecurity rules for cattle farms, as follows:

**1. General biosecurity rules for cattle farming in commercial holdings:**

Keepers of cattle on commercial cattle holdings have the following obligations:

- (a) to be registered/approved for veterinary purposes in accordance with the legal provisions in force;
- (b) to provide sanitary veterinary health care by a free practice veterinarian;
- (c) to ensure the application of sanitary veterinary rules on the population, protection and welfare of bovine animals and their health surveillance programme, the keeping of records required by sanitary veterinary rules and the application of measures ordered by the National Sanitary Veterinary and Food Safety Authority;
- (d) to provide facilities for changing clothes and street shoes with protective equipment, hand washing and disinfection facilities for persons entering and leaving the premises;
- (e) to prohibit access to the holding by persons not directly involved in the production process; exceptions are the supervisory and control bodies of the county and municipal sanitary veterinary and food safety directorates and of The National Sanitary Veterinary and Food Safety Authority, which may enter only in accordance with the provisions of the legislation in force;
- (f) to provide separate housing for newly-entered cattle until the health status has been clarified;

(g) to ensure that bovine animals are bred by natural mounting or artificial insemination only with bulls approved for sanitary veterinary purposes or with appropriate semen;

(h) to provide facilities for the storage of carcasses and other animal waste for disposal;

(i) to provide facilities for the carrying out of disinfection, disinfection and pest control by an approved commercial company or by its own team coordinated by the free practice veterinarian of the commercial cattle farm;

(j) to ensure the storage and preparation of feed as an integral activity of the holding;

(k) to ensure the disposal and storage of manure and litter in such a way that they do not constitute a source of spreading diseases;

l) to notify the county and Bucharest municipality sanitary veterinary and food safety directorates, via the TRACES system, of the intention to introduce/remove cattle into/from the holding and other internal movements of cattle;

(m) to notify without delay the veterinarian authorized by the county and Bucharest municipality sanitary veterinary and food safety directorates of any changes in the health status of the cattle; to take measures to isolate sick and suspect animals, dead animals or animals that have been killed in emergency situations and not to allow the use, sale or distribution of animal products from these animals, or the removal of feed, litter and other materials from the farm.

In order to prevent the introduction of infectious diseases, the holder of the registered/ sanitarily veterinary approved holding may draw up and implement his own biosecurity programme, based on procedures that rely on general biosecurity rules specific to the holding and approved by the county or Bucharest municipality sanitary veterinary and food safety directorates.

## **2. General biosecurity rules for cattle rearing on non-commercial holdings:**

Keepers of cattle on non-commercial holdings have the following obligations:

(a) to comply with the legal provisions in force concerning the breeding of cattle on the holding only by the use of sanitary veterinary authorized breeders;

(b) declare their cattle to the free practice veterinarian authorized by the county or Bucharest municipality sanitary veterinary and food safety directorates and to the town hall, by breed, sex and age category;

(c) not to introduce newly purchased cattle into herds for at least 15 days; these animals shall be kept for 15 days only on their own holding;

(d) to keep bovine animals and their shelters in accordance with animal protection and welfare rules;

(e) at the request of the empowered free practice veterinarian, to present animals for compulsory sanitary veterinary surveillance on the established date, time and place;

(f) to allow the staff of the competent sanitary veterinary and food safety directorate and of Bucharest municipality to check the health status of the animals on the holding and to assist him in carrying out the sanitary veterinary actions laid down in the methodological rules for the implementation of the programme of measures for the

surveillance, prevention, control and eradication of animal diseases, of diseases transmissible from animals to humans, animal protection and environmental protection, annually approved by Order of the President;

(g) to notify without delay the county sanitary veterinary and food safety directorate, respectively of the municipality of Bucharest, through the empowered free practice veterinarian of the occurrence of signs of disease in bovine animals, of the first cases of death or emergency slaughter, and until the arrival of the sanitary veterinary staff to isolate the sick animals, to keep the corpses, meat, organs or other products resulting from the emergency slaughtered animals, taking measures to ensure that they are not used or sold;

(h) comply with the provisions of the sanitary veterinary legislation in force on the conditions for the slaughter and sale of bovine animals.

**(d) type of vaccine(s) to be used and the vaccination scheme, if relevant;**

It isn't relevant.

**(e) measures to be implemented as regards additional animal populations, if relevant;**

It isn't relevant.

**(f) derogations to be applied in accordance with Article 19 of Delegated Regulation (EU) 2020/689, if relevant;**

It isn't relevant.

**(g) coordinated measures with other Member States or third countries, if relevant.**

In case of confirmation of infection with the Mycobacterium Tuberculosis complex in animals from intra-Community trade or from third countries, the country of origin shall be notified in order to carry out further investigations.

**(h) targeted animal populations and when applicable, additional animal populations**

The program to eradicate the infection with the Mycobacterium Tuberculosis complex targets the bovine and buffalo population.

*Active surveillance*

The eradication program will be applied throughout Romania, in all geographical areas represented by counties.

The program will be implemented by:

- annual testing of the population of bovine animals kept (over 6 weeks old throughout the country) on all establishment (commercial, including commercial type A and non-professional);

- annual testing of the additional animal population represented by buffaloes (over 6 weeks old throughout the country) on all establishment (commercial, including commercial type A and non-professional);

Intradermal tuberculin test will be used. Intradermal tuberculin controls are thus planned and performed before immunoprophylactic actions.

The technical specifications of the manufacturer of the diagnostic test used must be observed during execution.

The holding maintains its official tuberculosis-free status if the animals have reacted negatively to the test.

The positive animals shall be removed from the herd by slaughter for diagnostic purposes within 30 days of the official notification to the owner or to the person responsible for the test results, and the holding shall be suspended as tuberculosis-free status.

Inconclusive animals at tuberculin test shall be retested after compulsory internal deworming, 21 days before retesting, in the presence and responsibility of the official veterinarian, and the holding shall be suspended as tuberculosis-free status until the status of the holding is clarified by a intradermal tuberculin test 42 days after the first tuberculin test.

#### *Passive surveillance*

The animals intended for intra-Community trade / export to third countries shall be tested for bovine tuberculosis prior to movement, in collection centers or on the holding of origin authorized for intra-Community trade or export to third countries by a free practice veterinarian authorized, under the control and responsibility of the official veterinarian, within 30 days, when the bovine animals are dispatched from the holding of origin or, during their stay in the collection center, then when the shipment is made of it.

The animals imported from third countries shall be sampled at border inspection posts for the purpose of verifying compliance with the health rules in the accompanying certificate.

*The notification of the disease* is made in accordance with the provisions of the veterinary sanitary legislation in force.

According the legislation in force, the animals 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 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 suspicioned. 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).

The animals owner has the obligation 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.

A description of the organisation, supervision and roles of the parties involved in the eradication programme including at least:

- (a) the authorities in charge of coordinating and supervising the implementation of the programme;
- (b) responsibilities of all stakeholders involved.

The program is put into place through the developing a figure plan which is prepared by each County Sanitary Veterinary and Food Safety Authority (CSVFSA) and its fulfilment is monitored by National Sanitary Veterinary and Food Safety Authority (NSVFSA).

The estimated duration of the eradication programme. – 6 years;

The intermediate targets of the eradication programme including at least:

- (a) the expected annual decrease of the number of infected establishments;
- (b) the expected annual increase of the number of disease-free establishments;
- (c) the expected vaccination coverage, where relevant.

Taking into consideration that in 2020 at the level of the entire country there were 24 outbreaks (ANNEX II), the expected annual decrease of the number of infected establishments is 3 and the expected annual increase of the number of disease-free establishments is 2.