



**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

2. Member State :

**Bulgaria**

3. Name of the disease<sup>1</sup>

**Mycobacterium tuberculosis complex**

4. Contact details

a. E-mail

AHW@bfsa.bg

b. Responsibility within the competent authority

**Bulgarian Food Safety Agency**

c. Name :

**Anna Zdravkova – Director of Animal Health and Welfare Directorate**

**Daniel Denev – chief expert, Animal Health and Welfare Directorate**

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 regional structures of the BFSA correspond to the administrative districts of the country — the Republic of Bulgaria is administratively divided into 28 districts, each of them will implement the surveillance and control programme for Tuberculosis in large ruminants.

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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

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;

<b>Blagoevgrad</b>	3 760
<b>Burgas</b>	2 160
<b>Varna</b>	727
<b>Veliko</b>	920
<b>Vidin</b>	282
<b>Vratsa</b>	1 581
<b>Gabrovo</b>	341
<b>Dobrich</b>	660
<b>Kardjali</b>	9 119
<b>Kjustendil</b>	585
<b>Lovech</b>	756
<b>Montana</b>	597
<b>Pazardjik</b>	2 388
<b>Pernik</b>	630
<b>Pleven</b>	1 142
<b>Plovdiv</b>	2 270
<b>Razgrad</b>	1 119
<b>Russe</b>	546
<b>Silistra</b>	782
<b>Sliven</b>	1 226
<b>Smolyan</b>	3 284
<b>Sofia town</b>	260
<b>Sofia-</b>	1 520
<b>Stara</b>	1 066
<b>Targovishte</b>	1 306
<b>Haskovo</b>	3 994
<b>Shumen</b>	2 175
<b>Yambol</b>	796
<b>Total</b>	49 992

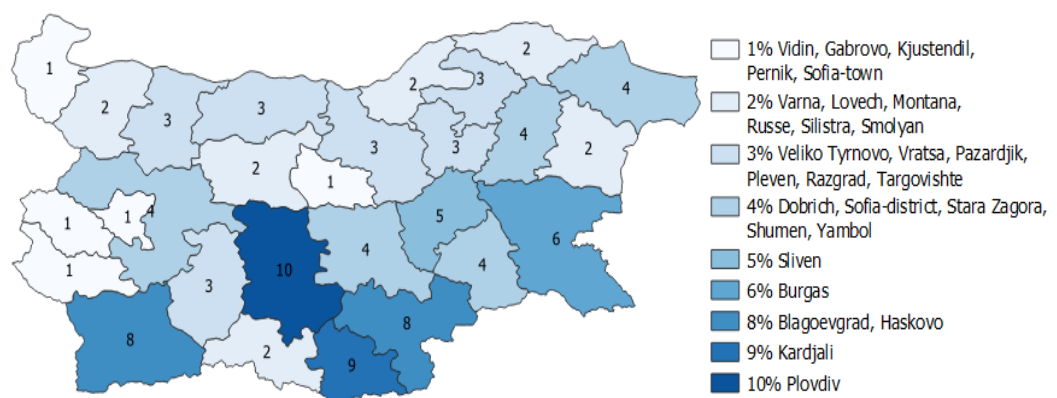
(b) the number of animals of the targeted animal population kept in the establishments referred to in point (a) by health status;

Total number of bovines in Bulgaria, by regions:

<b>Blagoevgrad</b>	53 772
<b>Burgas</b>	41 290
<b>Varna</b>	13 813
<b>Veliko Tarnovo</b>	24 930
<b>Vidin</b>	5 992
<b>Vratsa</b>	26 041
<b>Gabrovo</b>	8 384

<b>Dobrich</b>	26 626
<b>Kardjali</b>	61 109
<b>Kjustendil</b>	10 155
<b>Lovech</b>	14 270
<b>Montana</b>	17 256
<b>Pazardjik</b>	23 197
<b>Pernik</b>	7 515
<b>Pleven</b>	21 827
<b>Plovdiv</b>	73 580
<b>Razgrad</b>	19 079
<b>Russe</b>	14 195
<b>Silistra</b>	13 891
<b>Sliven</b>	38 707
<b>Smolyan</b>	12 976
<b>Sofia town</b>	6 058
<b>Sofia-district</b>	28 662
<b>Stara Zagora</b>	34 239
<b>Targovishte</b>	22 807
<b>Haskovo</b>	61 375
<b>Shumen</b>	26 505
<b>Yambol</b>	27 498
<b>Total</b>	735 749

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



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

	2011	2012	2013	2014	2015	2016	2017	2018	2019	2020
Blagoevgrad	0	0	0	0	0	0	0	0	0	0
Burgas	1	0	0	0	0	0	0	0	0	0
Varna	0	0	0	0	0	0	0	0	0	0
Veliko Tarnovo	0	0	0	0	0	0	0	0	0	0
Vidin	0	0	0	2	1	0	0	0	0	0
Vratsa	0	0	0	0	0	0	0	0	0	0
Gabrovo	0	0	0	1	1	1	1	0	1	0
Dobrich	0	0	0	0	0	0	1	0	0	0
Kardjali	0	0	0	2	2	0	0	1	1	0
Kjustendil	0	0	0	1	1	0	0	1	0	0
Lovech	0	0	0	0	0	0	0	0	0	0
Montana	0	0	0	0	0	0	0	0	0	0
Pazardjik	0	0	0	0	0	0	1	2	1	0
Pernik	0	0	0	0	0	0	0	0	0	0
Pleven	0	0	0	1	0	0	0	0	0	0
Plovdiv	0	0	0	0	0	4	11	3	3	0
Razgrad	0	0	0	5	15	15	6	0	0	0
Russe	0	0	0	0	0	0	0	0	0	0
Silistra	0	0	0	0	0	2	2	0	0	0
Sliven	0	0	0	0	0	0	0	0	0	0
Smolyan	0	0	0	0	0	0	0	0	0	0
Sofia town	0	0	0	0	0	0	0	0	0	0
Sofia-district	0	0	0	0	0	0	0	0	0	0
Stara Zagora	0	0	0	0	0	0	3	1	1	0
Targovishte	0	0	0	0	0	0	0	0	0	0
Haskovo	0	0	0	0	0	0	0	0	0	0
Shumen	0	0	0	0	0	2	3	0	0	0
Yambol	0	0	0	0	0	0	0	0	0	0
Total	1	0	0	12	20	24	28	8	7	0

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

N/A

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 herds, free of tuberculosis in large ruminants** — an annual, single intradermal tuberculinisation with Bovine purified protein derivative (PPD) of all large ruminants aged 42 days (6 weeks) is performed;

✓ **In herds with diagnosed tuberculosis found in large ruminants** - frequent intradermal examinations every 2 months, from the date of slaughter of the last responding animal, of all large ruminants over 42 days of age. In case of negative tuberculosis results from the intradermal or laboratory test for all large ruminants in the herd, the next test is performed after 6 months and in case of negative results the herd is considered free from the disease.

✓ **single intradermal tuberculinisation** with Bovine purified protein derivative (PPD) of all bovine animals over 42 days of age, imported from third countries (the examination is paid by the owner of the imported animals).

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

✓ **In herds, free of tuberculosis in large ruminants** - differential tuberculinisation is performed (with bovine and avian tuberculin, on the 42nd day after the initial tuberculinisation) of the large ruminants with a suspicious reaction in the previous single examination with bovine tuberculin.

✓ The positively reacted animals in the single intradermal test shall be subjected to a diagnostic/sanitary slaughter, except for animals suspected of a false positive reaction or an intervening reaction. Differential tuberculinisation is carried out on the same animals (with bovine and avian tuberculin 0.1 ml on the 42nd day after initial tuberculinisation).

✓ Single intradermal tuberculinisation with bovine PPD (between 45th and 60th days after the differential tuberculinisation) at a dose of 0.2 ml of all large ruminants reacted with a suspicious reaction to the differential tuberculinisation.

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

✓ Positively reacted animals in differential tuberculinisation are subjected to the diagnostic/sanitary slaughter, with the exception of animals suspected of a false positive reaction or an intervening reaction. The same animals are subject to a single intradermal tuberculinisation with bovine PPD (between 45 and 60 days after the differential tuberculinisation) at a dose of 0.2 ml.

✓ Single tuberculinisation of all pigs (with bovine and avian PPD tuberculin — at the same time on the two ears) which are grown in conjunction with large ruminants in which tuberculosis has been detected.

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

- ✓ The main biosecurity measures in the livestock farms, including those for bovine animals are described in detail in Ordinance № 44 of 20.04.2006 on the veterinary requirements for the livestock farms.
- ✓ Link to the ordinance: chrome-extension://efaidnbmnnnibpcajpcgclefindmkaj/viewer.html? Pdfurl = https% 3A% 2F% 2Fwww.bfsa.bg% 2Fuserfiles% 2Ffiles% 2Fnaredbi% 2FNAREDBA\_\_\_\_ve\_\_\_\_\_
- ✓ In addition, in case of tuberculosis diagnosed, the following measures will be enforced:
  - An animal movement ban – no animals are allowed to enter or leave the herd, excluding animals intended for immediate slaughter;
  - Isolation of the herd with animals suspected of being infected;
- ✓ thermal processing of the milk from the infected herd, intended for feeding animals from the same herd, in a way, guaranteeing the destruction of the infectious agent;
- ✓ delivery of the milk from the infected herd to milk processing enterprises is allowed only for thermal processing;
- ✓ prohibition for the use for animal feed of carcasses of slaughtered animals, parts of carcasses and by-products without thermal processing, guaranteeing the destruction of the infectious agent;
- ✓ prevention of the spread of the disease in the process of collection and transportation and disposal of carcasses in sites for disposal of animal by-products;
- ✓ disposal of the manure from the premises for animals by biothermal decontamination, which shall be carried out in places inaccessible to the animals, for not less than 3 weeks after preliminary treatment of the manure with disinfectant; no disinfectant may be used when covering the fertilizer with a layer of uncontaminated fertilizer or soil.
- ✓ after the slaughter of animals which have reacted positively, before the introduction of new animals into the herd under official control:

1. mechanical cleaning and disinfection of dishes, equipment and other objects in the premises for animals and the yards around them is performed under the control of an official veterinarian;

2. all means of transport and containers carrying infected or suspected infected animals, materials or articles from infected farms, places and equipment for loading animals are subjected to mechanical cleaning and disinfection.

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

**N/A**

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

**N/A**

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

**N/A**

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

If positive cases of animals originating from other Member States or third countries are found, the same shall be notified in a timely manner to carry out traceability in the country of origin of the animals.

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

**Number of Edges of ruminants in Bulgaria to be tested for tuberculosis (*based on estimated number of animals as at 12.2021*)**

Region	Total number of cattle	
	Bovine animals	Buffalo
Blagoevgrad	45317	181
Burgas	33850	648
Varna	11000	150
Veliko Tarnovo	23700	216
Vidin	4900	58
Vratsa	17400	1179
Gabrovo	7950	692
Dobrich	25200	124
Kardzhali	57450	10
Kyustendil	7150	139
Lovech	12500	335
Montana	16150	290
Pazardzhik	18200	172



Pernik	7300	156
Pleven	20245	698
Plovdiv	67240	1009
Razgrad	18000	128
Ruse	13 870	375
Silistra	13300	124
Sliven	32868	441
Smolyan	12500	38
Sofia city	5890	28
Sofia district	23340	427
Stara Zagora	31350	872
Targovishte	20100	538
Haskovo	50590	771
Shumen	23970	137
Yambol	23250	760
<b>Total:</b>	<b>644580</b>	<b>10696</b>

8. 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;

1. Bulgarian Food Safety Agency
2. Bulgarian Veterinary Union (Registered Veterinarians)
3. National Reference Laboratory “Tuberculosis” at the National Diagnostic and Research Veterinary Institute (NDRVI) in Sofia

(b) responsibilities of all stakeholders involved.

## **1. Bulgarian Food Safety Agency**

### **1.1. BFSA Headquarters**

✓ The BFSA is a central competent authority that monitors the implementation of the control of the infectious diseases and their mandatory notification;

✓ certifies the status of the country / districts / sites as free from bovine tuberculosis;

✓ interact with other Member States and ensure the health status of animals and animal products in international trade;

✓ certifies to the international institutions the restoration of the status of the individual districts and the country as a whole, as free from bovine tuberculosis.

Animal Health and Welfare Directorate:

- ✓ develop a disease control strategy and implement the control of the implementation of the program;
- ✓ coordinates the actions of all authorities involved in the program;
- ✓ collects information and prepare reports on the results of the program;
- ✓ sends an annual report to the European Commission on the activities carried out in relation to the disease.

Food Control Directorate:

- ✓ carries out controls on establishments engaged in meat production and processing activities.

### **1.2. Regional Food Safety Directorates**

- ✓ control the implementation of the program;
- ✓ control the activities of all registered veterinarians at regional level to ensure the program and report the data to the BFSA Central Office;
  - ✓ summarize data on the positive/suspiciously reacted ruminants in regular tuberculinisation, differential tuberculinisation, tuberculinisation with bovine PPD at 0.2 ml and rapid tuberculinisation in the region and send information to the Animal Health and Welfare Directorate at the Headquarters of the BFSA;
  - ✓ control the results of the disease surveillance in the database provided by the registered veterinarians;
    - ✓ the official veterinarians (OV) for animal health perform the differential tuberculinisation, tuberculinisation with bovine PPD in a dose of 0.2 ml and increased tuberculinisation;
    - ✓ the official veterinarians (OV) for animal health take samples for laboratory tests from slaughtered bovine animals suspected of having tuberculosis;
    - ✓ the official veterinarians (OV) for animal health prepare a list of positive/suspiciously responsive ruminants for regular, differential tuberculinisation with bovine PPD in a dose of 0.2 ml;
    - ✓ the official veterinarians controlling meat production establishments (OV for food control) carry out meat inspection of all slaughtered animals;
    - ✓ the official veterinarians (OV) for food control carry out sampling of all suspect animals at slaughter of necessity;

✓ the official veterinarians (OV) for food control shall report immediately in case of ascertained, during the slaughter meat inspection, pathological changes characteristic of the disease.

### **1.3. Registered veterinarians:**

✓ perform regular tuberculinisation with bovine PPD in a dose of 0.1 ml;  
✓ enter into the Integrated Information System of the BFSA (VetIS) data for the performed tuberculinisation.

### **2 National Reference Laboratory “Tuberculosis” at the NDRVI in Sofia:**

✓ performs laboratory examination (microbiological and molecular biological) of animal samples, in case of suspicion;  
✓ inform the AHW Directorate at the Headquarters of the BFSA of the results of the performed laboratory tests;  
✓ sends samples for confirmation to the EU Reference Laboratory if necessary to perform additional tests;  
✓ participates in the "ring" tests organized by the European Reference Laboratory;  
✓ cooperates with the National Reference Laboratories of other Member States on the necessary studies.

Laboratory diagnostic tests are performed according to the methods specified in the OIE Manual of Standards for Diagnostic Tests and Vaccines.

9. The estimated duration of the eradication programme.

2022-2024

10. The intermediate targets of the eradication programme including at least:

(a) the expected annual decrease of the number of infected establishments;

**Single (sporadic) outbreaks of the disease would be expected to be confirmed. It is expected that during the implementation of the program, no more than 2 affected enterprises will be confirmed positive per year, which is less than 0.0001% of all registered establishments in the country.**

(b) the expected annual increase of the number of disease-free establishments;

**It is expected 99,999 % establishments to be confirmed disease-free.**

(c) the expected vaccination coverage, where relevant.

N/A