## 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 31 may 2021
- 2. Member State: ITALY
- 3. Name of the disease<sup>1</sup>

Infection with MTBC

- 4. Contact details
  - a. E-mail: r.lomolino@sanita.it
  - b. Responsibility within the competent authority

Veterinary of the Ministry of Health

- c. Name: Roberto Lomolino
- 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.

This program covers the following regions:

ABRUZZO: only the Provinces of Aquila, Teramo and Chieti, BASILICATA only the Province of Potenza, CALABRIA, CAMPANIA, LAZIO: only the Provinces of Roma and Latina, MARCHE: only the Province of Macerata, PUGLIA, SARDEGNA only the Province Sassari, Olbia, Nuoro e Lanusei and SICILIA.

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

This template is to be used for the submission of the following eradication programmes for the following listed diseases:

- 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;

### **Bovine kept Population**

MEMBER STATE: ITALY - YEAR 2020

DISEASE (a):

BOVINE

TUBERCULOSIS

STATUS OF THE ESTABLISHMENT UNDER PROGRAM (c)							
REGIONS	number of establishm Unkown(d) ent under		last control	free last control negative (f)	suspended (g)	status free (i)	
		Establishm ent	Establishm ent	Establishme nt	Establishme nt	Establishm ent	
ABRUZZO: only Provinces of L'Aquila, Teramo, Chieti	2331	0	0	0	1	2330	
BASILICATA: all region	2396	0	1	0	0	2395	
CALABRIA: all region	5206	3	3	25	18	5157	
CAMPANIA: all region	5809	14	14	20	17	5744	
LAZIO: only Provinces of Roma, Latina	2290	0	1	4	3	2282	
MARCHE: only Provinces of Macerata	497	0	0	5	1	491	
MOLISE: all region	1367	0	0	0	0	1367	
PUGLIA:all region	3664	0	0	6	0	3658	
SARDEGNA: only Provinces of Sassari, Nuoro	5740	0	2	0	9	5729	
SICILIA: all region	8988	1	29	109	41	8808	
Total	38288	18	50	169	90	37961	

### Buffalo kept population in Campania Region.

MEMBER STATE: ITALY - FINAL REPORT 2020

DISEASE (a): BUFFALO TUBERCULOSIS

STATUS ESTABLISHMENT AND ANIMALS UNDER PROGRAM (c)								
	Total number of	Unkow n(d)	not	free	suspendedo (g)	status free (i)		
REGIONS	establishment under program	` '	last control positive (e)	last control negative (f)	suspendedo (g)			
	Establishment	Establishment	Establishment	Establishment	Establishment	Establishment		
CAMPANIA: all region	1069	3	46	16	26	978		
Total	1069	3	46	16	26	978		

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

### **Bovine population**

MEMBER STATE: ITALY YEAR: 2020

FINAL REPORT

DISEASE (a):

BOVINE
TUBERCULOSIS

STATUS ESTABLISHMENT AND ANIMALS UNDER PROGRAM (c)						
REGIONS	Total number		not	free	suspende d (g)	status free (i)
	of establishment under program	Unkow n(d)	last control positive (e)	last control negative (f)		
	Animals (j)	Animals (j)	Animals (j)	Animals (j)	Animals (j)	Animals (j)
ABRUZZO: only Provinces of L'Aquila, Teramo, Chieti	50394	0	0	0	4	50390
BASILICATA: all region	96566	0	30	0	0	96536
CALABRIA: all region	108065	54	215	586	183	107027
CAMPANIA: all region	141865	91	439	367	346	140622
LAZIO: only Provinces of Roma, Latina	131335	0	82	129	22	131102
MARCHE: only Provinces of Macerata	17563	0	0	175	23	17365
MOLISE: all region	32989	0	0	0	0	32989
PUGLIA:all region	179346	0	0	226	0	179120
SARDEGNA: only Provinces of Sassari, Nuoro	157305	0	132	0	577	156596
SICILIA: all region	349129	6	2766	6437	1240	338680
Total	1264557	151	3664	7920	2395	1250427

### Buffalo population in Campania Region: Province of Caserta and Salerno.

MEMBER STATE: ITALY

YEAR:
2020

FINAL REPORT

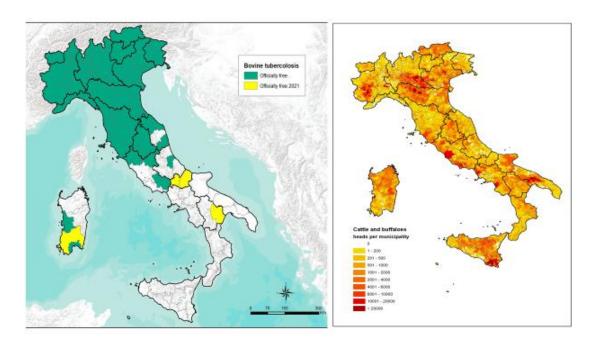
DISEASE (a):

BUFFALO

TUBERCULOSIS

STATUS OF ANIMALS UNDER PROGRAM (c)							
REGIONS	Total number of animals under program	Unkow n(d)	last control negative (f)		suspende d (g)	status free (i)	
	Animali (j)	Animali (j)	Animali (j)	Animali (j)	Animali (j)	Animali (j)	
CAMPANIA: all region	294272	573	17153	9784	8125	258637	
Total	294272	573	17153	9784	8125	258637	

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



In Green the territories OTBF, in white and yellow the territories not OTBF in 2020, in yellow the territories OFTBF declared OTBF with Decision 385/2021.

The right figure shows the density of the bovine-buffalo population on the Italian territories.

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

TABLE 1 – TIMELINE OF PREVALENCE OF BOVINE TUBERCULOSIS					
ABRUZZO REGION	2018	2019	2020	TARGET 2021	TARGET 2022
TERAMO	0,00 %	0,00 %	0,00 %	0,00 %	0,00 %
AQUILA	0,00 %	0,09 %	0,00 %	0,00 %	0,00 %
CHIETI	0,00 %	0,00 %	0,00 %	0,00 %	0,00 %
BASILICATA REGION	2018	2019	2020	TARGET 2021	TARGET 2022
POTENZA	0,34%	0,21 %	0,11%	0,00 %	<mark>0,00 %</mark>
CALABRIA REGION	2018	2019	2020	TARGET 2021	TARGET 2022
CROTONE	1,72 %	1,40 %	0,37 %	0,68 %	0,00 %
VIBO VALENTIA	0,10 %	0,10 %	0,11 %	0,00 %	0,00 %
COSENZA	0,41 %	0,21 %	0,05 %	0,11 %	0,00 %
CATANZARO	0,00 %	0,21 %	0,00 %	0,00 %	<mark>0,00 %</mark>
REGGIO CALABRIA	0,32 %	0,33 %	0,00 %	0,14 %	<mark>0,00 %</mark>
CAMPANIA REGION - b		2019	2020	TARGET 2021	TARGET 2022
AVELLINO	0,53 %	0,00 %	0,10 %	0,19 %	0,00 %
BENEVENTO	0,12 %	0,13 %	0,00 %	0,00 %	0,00 %
CASERTA	2,18 %	3,93 %	1,35 %	0,89 %	0,00 %
NAPOLI	0,37%	0,38%	0,00 %	0,00 %	0,00 %
SALERNO	0,22%	0.05%	0,44%	0,05 %	0,19 %
CAMPANIA REGION -bu		2019	2020	TARGET 2021	TARGET 2022
AVELLINO	0,00 %	0,00 %	0,00 %	0,00 %	0,00 %
BENEVENTO	0,00 %	0,00 %	0,00 %	0,00 %	0,00 %
CASERTA	7,30 %	13,69 %	11,27 %	5,12 %	7,22 %
NAPOLI	0,00 %	0,00 %	0,00 %	0,00 %	0,00 %
SALERNO	0,58%	0,58%	0,29%	0,29 %	0,00 %
LAZIO REGION	2018	2019	2020	TARGET 2021	
ROMA	0,60%	0,14%	0,14	0,00 %	0,00%
LATINA	0,19%	0,00%	0,00%	0,00 %	0,00%
MARCHE	2018	2019	2020	TARGET 2021	TARGET 2022
MACERATA	0,56%	1,16%	1,2%	0,58 %	0,40 %
PUGLIA REGION	2018	2019	2020	TARGET 2021	TARGET 2022
BRINDISI	0,48 %	0,28 %	0,00 %	0,00 %	0,00 %
TARANTO	0,14 %	0,15 %	0,00 %	0,00 %	0,00 %
BARLETTA ANDRIA TRA		0,00 %	0,00 %	0,00 %	0,00 %
BARI	0,08 %	0,00 %	0,00 %	0,00 %	0,00 %
FOGGIA	2,37 %	0,61 %	0,30 %	0,41 %	0,20 %
LECCE	0,34 %	0,17 %	0,00 %	0,00 %	0,00 %
SARDEGNA	2018	2019	2020	TARGET 2021	0.00.04
A.S.L. SASSARI	0,00 %	0,00 %	0,18 %	0,00 %	0,00 %
A.S.L. NUORO	0,05 %	0,00 %	0,19 %	0,00 %	0,00 %
SICILY REGION	2018	2019	2020	TARGET 2021	TARGET 2022
AGRIGENTO	0,22 %	0,88 %	0,22 %	0,00 %	0,00 %
CALTANISSETTA	6,01 %	2,29 %	0,59 %	0,00 %	0,00 %
CATANIA	1,87 %	1,23 %	3,44 %	1,08 %	1,56 %
ENNA	1,75 %	2,98 %	2,50 %	1,53 %	2,19 %
MESSINA	1,71 %	0,78 %	1,16 %	0,56 %	0,06 %
PACHSA	0,59 %	2,32 %	2,20 %	1,63 %	1,68 %
RAGUSA	0,50 %	0,22 %	0,07 %	0,16 %	0,00 %
SIRACUSA	1,59 %	0,99 %	1,24 %	0,89 %	0,85 %
TRAPANI	1,94 %	0,81 %	0,00 %	0,00 %	<mark>0,00 %</mark>

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

When a epidemiological enquire performed by veterinary local service identifies as possible cause of an outbreak, the presence in the territory of wild animals, the service has the duty to put in place a plan of monitoring to verify the prevalence of the disease in the wild species involved and after that decide the right measures to control the dissemination of the infection by these specie.

- 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:

The tests that will be use for the diagnosis of MTBC are the ones listed in the EU Reg. 689/2020:

- 8. 1. Tuberculin skin tests
- 9. (a) the single intradermal tuberculin test (SITT)
- 10. (b) the comparative intradermal tuberculin test (CITT)
- 2. Gamma-interferon assay.

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

All establishments including the fattening units must obtain MTBC free status in accordance with the requirements laid down in Section 1, Chapter 1, Part. II of Annex IV to Reg. 2020/689 as modified with the Reg. 881/2021.

- 1. The status free from infection with Mycobacterium tuberculosis complex (Mycobacterium bovis, Mycobacterium tuberculosis, Mycobacterium caprae) (MTBC) may only be grant to an establishment keeping bovine animals if:
- (a) during the past 12 months there has been no confirmed case of infection with MTBC in bovine animals kept in the establishment;
- (b) the bovine animals over 6 weeks of age present in the establishment at the time of testing or sampling have tested negative to immunological test on two occasions as follows:
- (i) the first test must be carried out on bovine animals or samples taken from bovine animals not earlier than 6 months after the removal of the last confirmed case and of the last animal that tested positive in an immunological test;
- (ii) the second test must be carried out on bovine animals or on samples taken from bovine animals not earlier than 6 months and not later than 12 months following the date of testing of the bovine animal or taking of the samples referred to in point (i);

- c) since the beginning of the testing or sampling referred to in point (b)(i), all bovine animals introduced into the establishment originate from establishments free from infection with MTBC and:
  - (i) originate from a Member State or a zone free from infection with MTBC; or
  - (ii) are bovine animals over 6 weeks of age and have tested negative in an immunological test:
  - during the 30 days prior to their introduction into the establishment; or
  - during the 30 days after their introduction provided they have been kept isolated during this period; and';

By way of derogation from point 1, the status free from infection with MTBC may be granted to an establishment if all bovine animals originate from establishments free from infection with MTBC and:

- (a) originate from a Member State or a zone free from infection with MTBC; or
- (b) if they are bovine animals over 6 weeks of age, they have tested negative to an immunological test:
- (i) during the 30 days prior to their introduction into the establishment; or
- (ii) during the 30 days after their introduction provided they have been kept in isolation during this period.

The status free from infection with MTBC of an establishment keeping bovine animals may only be maintained if:

- (a) the requirements set out in points (a), (c) and (d) of point 1 of Section 1 continue to be fulfilled;
- (b) any suspected case of infection with MTBC in a bovine animal kept on that establishment or introduced from that establishment into a slaughterhouse is notified to the competent authority and investigated; and
- (c) an immunological test has been carried out, with negative results, on all bovine animals over 6 weeks of age, at intervals of not more than 12 months.

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

The status free from infection with MTBC of an establishment keeping bovine animals must be suspended if:

- (a) one or more of the requirements above mentioned are not fulfilled; or
- (b) a case of infection with MTBC is suspected in a bovine animal kept in the establishment.

The status free from infection with MTBC of an establishment keeping bovine animals must be withdrawn if the requirements for the maintenance are not fulfilled and/or in a case of infection with MTBC has been confirmed in a bovine animal kept in the establishment; or it is justified by other needs to control infection with MTBC.

The status free from infection with MTBC may only be rul out, if:

the requirements for granting the status are fulfilled and the results of further investigations

substantiate absence of infection with MTBC and the status of all suspected cases has been determined. In case, suspected bovine animals are slaughtered in that context, investigations must include examination of samples with direct diagnostic methods.

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

If the status free from infection with MTBC of an establishment keeping bovine animals have been withdrawn it may only be regained if:

The animals kept in the infected establishment are subjected to 2 subsequent controls;

- 1) a first test, with negative results, must be carried out on bovine animals or samples taken from bovine animals not earlier than 6 months after the removal of the last confirmed case and of the last animal that tested positive in an immunological test;
- 2) a second test, with negative results, must be carried out on bovine animals or on samples taken from bovine animals not earlier than 6 months and not later than 12 months following the date of first test.

An epidemiological enquire must be performed to individuate the possible cause of the disease.

### (iii) biosecurity and risk mitigating measures to be implemented;

To maintain the status of OTBF are putted in place proportionate risk mitigating measures (annual surveillance on the establishment and controls at the slaughterhouse) to prevent the reinfection in the establishments taking into account relevant risk factors as indicated by the results of the epidemiological data (Section 2 of Chapter 2 of Part II of Annex IV for status free from infection with MTBC). These measures take in account the persistence of the disease agent in the environment or in wild animals and the biosecurity measures that are adapted to the specificities of the establishments.

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

No measures are provided for.

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

Apposite biosecurity measures will be performed in function of the information provided from the results of the epidemiological enquire.

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

No measures provided for.

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

No measures provided for.

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

Bovines, Buffaloes and goats in case of isolation of Mycobacterium caprae

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;

Central Authority: Ministry of Health;

Regional Authority: Regions and Autonomous Provinces;

Local Veterinary Authorities: ASL (Azienda Sanitaria Locale);

Laboratories: Istituti Zooprofilattici Sperimentali;

National Reference Centre of Tuberculosis: Istituto Zooprofilattico Sperimentale di Lombardia and Emilia Romagna.

(b) responsibilities of all stakeholders involved.

The responsibilities of the stakeholders involved in the eradication program of MTBC is essentially to collaborate with the local competent Authority at the correct implementation of the eradication program. In particular, the farmer association, private veterinarians, milk collector, cheese factories, dealers, etc should, informed by the competent veterinary Authority on the danger for the public and animals health of the zoonosis, give their contribution on the circulation of the information regarding the risk of spreading the disease and on its prevention.

(iii) The estimated duration of the eradication programme.

10 years.

- (iv) The intermediate targets of the eradication programme including at least:
- (a) the expected annual decrease of the number of infected establishments;

Bovine herds

In 2020 have been registered 185 outbreaks, in 2022 the regionals Authorities are expecting 94 outbreaks (expected reduction of 50%).

Buffalo herds (in Campania region)

In 2020 has been registered 81 outbreaks, in 2022 the regionals Authority are expected 50 outbreaks (expected reduction of 39%).

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

Bovine herds

In the 2020 on 39188 herds under program at the beginning of the year 38861 have resulted OBF by December 31st (327 herds with suspension or withdrawal of the status).

In the 2022 is expected that on 34908 herds under program at the beginning of the year 34777 should resulted OBF by December 31st (131 herds with suspension or withdrawal of the status – reduction of 39%).

Buffalo herds (province of Caserta in Salerno in Campania region)

In the 2020 on 1069 herds under program at the beginning of the year 978 have resulted OBF by December 31st (90 herds with suspension or withdrawal of the status).

In the 2022 is expected that on 1078 herds under program at the beginning of the year 1020 should resulted OBF by December 31st (58 herds with suspension or withdrawal of the status – reduction of 36%).

#### (c) the expected vaccination coverage, where relevant.

No relevant for MTBC.