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 disease¹ Infection with Brucella abortus, B. melitensis and B. suis on

Sheep & Goat animal population.

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:

Regarding brucella melitensis: BASILICATA: all region; CALABRIA: provinces of Reggio Calabria, Crotone and Vibo Valentia; CAMPANIA: provinces of Caserta, Napoli, Avellino and Salerno; PUGLIA: provinces of Foggia and Lecce; SICILIA: all region as indicated in the following map.

Category B-diseases

a) Infection with Brucella abortus, B. melitensis and B. suis

b) Infection with Mycobacterium tuberculosis complex

Category C-diseases

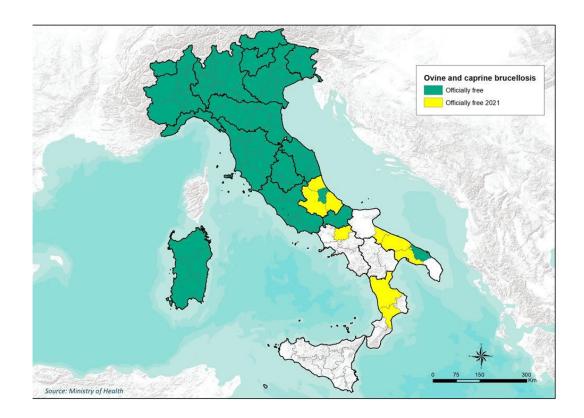
a) Enzootic bovine leukosis

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:



In green the Regions with free status, in yellow and white the Regions with not free status in 2020, in yellow the Regions declared with status free in the year 2021 (Decision 385/2021).

- 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;

The data of the following tables refer to the data registered in the year 2020.

MEMBER STATE: ITALY - YEAR 2020									
DISEASE (a): S&G BRUCELLOSIS									
STATUS OF THE ESTABLISHMENT									
REGIONS	Total number of establishment under program	Unknow n (d)		accination or with ination	suspended (g)	Free with	Free without vaccination (i)		
			Last check positive (e)	lLast check negative (f)	odoponaca (g)	vaccination(h)			
	Establishmnent	Establishmnent	Establishmnent Establishmnent		Establishmnent	Establishmnent	Establishmnent		
1	2	4	6	8	10	12	14		
ABRUZZO: Only Provinces of L'Aquila, Teramo, Chieti	3390	o	0	14	2	0	3374		
BASILICATA: all region	5465	0	1	0	0	0	5464		
CALABRIA: all region	7491	9	4	67	37	0	7374		
CAMPANIA:all region	6216	324	5	168	13	0	5706		
PUGLIA: Only Provinces of Foggia, Bari, Taranto, Lecce, Barletta-Andria- Trani	2871	0	0	2	3	0	2866		
SICILIA: all region	8346	1	17	108	155	7	8058		
Total	33779	334	27	359	210	7	32842		

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

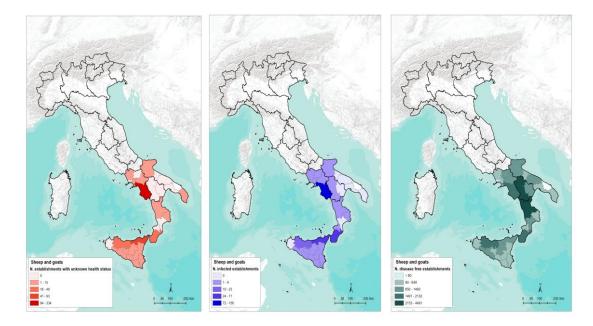
S&G brucellosis – data on animal population years 2020

MEMBER STATE: ITA	LY	YEAR: 2020							
	8&G BRUCELLO		- CAPRI						
STATUS of animals under program									
REGIONS	Total number of animals Unknow n under program		vaccinati	without on or with ination Last check negative	Suspended	Free w ith vaccination	Free w ithout vaccination		
	Animals(j)	Animals(j)	Animals(j) Animals(j)		Animals(j)	Animals(j)	Animals(j)		
1	3	5	7	9	11	13	15		
ABRUZZO: Only Provinces of L'Aquila, Teramo, Chieti	146874	o	0	69	28	o	146777		
BASILICATA: all region	, ,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,,								
	138765	0	222	0	0	0	138543		
CALABRIA: all region	138765 322847	0 150	222 1176	0 2866	0 2166	0	138543 316489		
CALABRIA: all region	322847	150	1176	2866	2166	0	316489		
CALABRIA: all region CAMPANIA: all region PUGLIA: Only Provinces of Foggia, Bari, Taranto, Lecce, Barletta-Andria-	322847 225028	150 819	1176 525	2866 3324	2166 637	0	316489 219723		

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

DENSITY

Sheep and goat establishment: in red the density of the establishments with unknown status, in blue the density of the infected establishments and in green the density of establishments with free status.



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

The table 1 show the prevalence registered in the last 6 years, in the territories not with no free status, where the program has been applied in the sheep and goats

population and the related target expected for the 2022. Are also indicated the Provinces that in these five years have achieved the free status.

TABLE 1 – TIMELINE OF PREVALENCE OF SHEEP AND GOATS BRUCELLOSIS												
REGIONS												
	2016		2017		2018		2019		2020		Target 2022	
	P%	1%	P%	1%								
ABRUZZO												
TERAMO	0.0	0.0	0.15	0.15	0,00	0,00	0,00	0,00	0,00	0,00	FREE	
L'AQUILA	0.0	0.0	0.0	0.0	0,13	0,13	0,13	0,13	0,07	0,07	FREE	
CHIETI	0.0	0.0	0.0	0.0	0,00	0,00	0,00	0,00	0,00	0,00	FREE	
BASILICATA												
POTENZA	0.02	0.0	0.32	0.28	0.40	0.25	0,39	0,37	0,18	0,18	0,00	0,00
MATERA	0.18	0.18	0.48	0.48	0.41	0.30	0,41	0,41	0,00	0,00	0,00	0,00
CALABRIA												
CROTONE	1.56	1.11	0,68	0,68	0,69	0,69	0,50	0,50	0,91	0,60	0,95	0,71
VIBO V.	2.31	2.31	0,92	0,69	0,27	0,27	0,00	0,00	0,00	0,00	0,00	0,00
COSENZA	0.21	0.18	0,21	0,19	0,17	0,17	0,15	0,15	0,00	0,00	FREE	
CATANZARO	0.10	0.10	0,42	0,42	0,53	0,53	0,10	0,10	0,10	0,10	FR	EE
REGGIO C.	2.42	1.87	1,66	1,24	1,48	1,31	0,55	0,55	0,41	0,41	0,09	0,00
CAMPANIA												
AVELLINO	0.56	0.44	0,26	0,26	0,53	0,53	0,14	0,07	0,07	0,07	0,00	0,00
BENEVENTO	0.07	0.07	0,00	0,00	0,00	0,00	0,00	0,00	0,17	0,17	FREE	
CASERTA	0.40	0.27	0,14	0,00	0,14	0,14	0,29	0,29	0,31	0,31	0,00	0,00
NAPOLI	0.22	0.22	0.73	0.48	0,00	0,00	0.27	0.27	0,00	0,00	0,00	0,00
SALERNO	0.41	0.36	0,41	0,37	0,49	0,49	0,19	0,15	0,31	0,31	0,12	0,12
PUGLIA												
BRINDISI	0.0	0.0	0,00	0,00	0,00	0,00	FR	EE				
TARANTO	0.0	0.0	0,00	0,00	0,62	0,62	0,00	0,00	0,21	0,00	FR	EE
BAT	0.0	0.0	0,00	0,00	1,08	1,08	1,14	1,14	0,00	0,00	FREE	
BARI	0.11	0.11	0,00	0,00	0,12	0,12	0,37	0,37	0,00	0,00	FREE	
FOGGIA	1.50	1.26	1,05	1,05	0,75	0,66	0,60	0,60	0,27	0,27	0,18	0,18
LECCE	1.90	1.67	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00	0,00
SICILIA												
AGRIGENTO	2.71	2.31	1,35	1,04	1,06	0,74	0,43	0,43	0,55	0,44	0,33	0,11
CALTANISSETTA	4.20	3.10	4,40	3,30	4,76	3,85	2,30	0,92	1,84	1,61	0,23	0,00
CATANIA	4.26	2.44	1,99	1,69	0,92	0,61	0,93	0,62	1,08	0,93	0,78	0,62
ENNA	1.82	1.21	0,78	0,43	0,43	0,09	1,12	1,12	0,61	0,52	0,43	0,35
MESSINA	7.68	4.00	6,53	5,21	5,52	4,54	3,60	2,75	2,34	1,98	1,68	1,38
PALERMO	1.42	1.11	1,78	1,38	1,20	0,93	0,71	0,67	0,44	0,27	0,37	0,18
RAGUSA	1.76	1.58	1,76	0,88	1,45	1,27	0,55	0,55	0,19	0,19	0,00	0,00
SIRAGUSA	2.38	1.32	4,64	3,55	3,65	3,09	3,51	1,46	1,52	0,30	1,16	0,58
TRAPANI	7.69	5.61	4,75	2,78	4,75	3,56	3,47	2,60	0,54	0,36	0,36	0,36

In Italy the vaccination is not in use from more than last 5 years, but is not excluded that in some cluster of infection in Sicily this tool can be used in future, to reduce the dissemination of brucella spp. in this area and speed up the eradication of the disease.

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

In Toscana has been reported some case of animal positive at brucella suis in the Cinta Senese breed, a typical race of pork originates in Province of Siena and bred at pasture. A possible plan of control of the disease could be put in place by the Toscana Region in the 2022.

- 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 used for the diagnosis of brucella abortus, melitensis and suis will be the one listed in the REG 689/2020:

- 1. Serological tests
- (a) tests for blood samples
- (i) buffered Brucella antigen tests;
- (ii) complement fixation test (CFT)
- (iii) indirect enzyme-linked immunosorbent assay (I-ELISA)
- (iv) fluorescence polarisation assay (FPA)
- (v) competitive enzyme-linked immunosorbent assay (C-ELISA)
- (b) tests for milk samples
- (i) ring test (MRT)
- (ii) I-ELISA
- 2. Brucellin skin test (BST)

For the testing as referred to in section 1 and 2 of Chapter 1 of Part I of Annex IV, Brucellin skin test (BST) shall only be used in ovine and caprine animals.

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

For the granting and the maintenance of the status free from infection with Brucella abortus, B. melitensis and B. suis without vaccination we will refer at EU Reg. 689/2020, annex 4 - Chapter 1, section 1 and 2.

For the granting and the maintenance of the status free from infection with Brucella abortus, B. melitensis and B. suis with vaccination we will refer at EU Reg. 689/2020, annex 4 - Chapter 2, section 1 and 2.

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

Measures to be applied by the competent authority to confirm or rule out the disease in the event of a suspected case are set out in Article 20 - 23 of Reg. (EU) 2020/689.

In case of suspected case to confirm the disease of Brucella abortus, B. melitensis and B. suis in establishment with or without vaccination we refer at EU Reg. 689/2020, annex 4 - Chapter 2, section 4.

In case of no confirmation of Brucella abortus, B. melitensis and B. suis in establishment with or without vaccination as prescribed at the EU Reg. 689/2020, annex 4 - Chapter 2, section 3 point 2 (b), the disease is rule out.

The maximum period referred to in Article 20(3)(b) of Reg. (EU) 2020/689 during which the disease-free status may be suspended before is taken the decision to withdraw or regain the disease-free status is related to the time necessary for performing bacteriological test. In this case are necessary in total 9 weeks with the following timeline: a) slaughter the animal (15 days); b) isolation the bucella spp. on organs of the positive animals slaughtered with the bacteriological test (6 weeks); c) transmission of the result of the from the Laboratory diagnosis to the local veterinary service (1 week).

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

Measures to be applied by the competent authority in the event of a confirmed case are set out in Articles 20 and 24 - 31 of Reg. (EU) 2020/689.

In case of confirmation of Brucella abortus, B. melitensis and B. suis in establishment with or without vaccination, according with the EU Reg. 689/2020, annex 4 - Chapter 1 and 2, section 4 point 1 (c), the status is withdrawn at may it only be regained if all confirmed cases and all animals that have tested non-negative have been slaughtered and the remaining ovine or caprine animals fulfil the requirements set out in point 1(c) of Section 1 of Chapter 1.

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

The EU Reg. 689/2020 at the article 81 specify the criteria on surveillance and biosecurity measures for the maintenance of disease-free status. In: Section 2 of Chapter 3 of Part I of Annex IV for status free from infection with Brucella abortus, B. melitensis and B. suis as regards kept S&G animal population or Section 2 of Chapter 4 of Part I of Annex IV for status free from infection with Brucella abortus, B. melitensis and B. suis as regards kept ovine and caprine animals are provided the specific requirements as regards surveillance and biosecurity measures that are implemented to achieve a good level of biosecurity and lower the risk of dissemination of the infection.

Furthermore, to provide at the measures specified at the Article 10 or Reg. (EU) 2016/429 we will provide a guide line on biosecurity for the zone with not free status.

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

In case of vaccination program will be used: RB51 for bovine and buffalo and REV1 for sheep and goat.

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

No measures provided for.

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

No measures provided for.

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

No measures provided for.

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

Sheep and goats. In Toscana a control program could be applied in future in pigs. At the moment the plan for pigs is not available.

- 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;

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 Brucellosis: Istituto Zooprofilattico Sperimentale di Abruzzo and Molise.

(b) responsibilities of all stakeholders involved.

The responsibilities of the stakeholders involved in the eradication program of brucella abortus, melitensis and suis 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. A real responsibility of the stakeholders is the notification at the local veterinary authority of every case of abortion registered in the herds to permit the checks of the animals involved.

The estimated duration of the eradication programme.

10 years.

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

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

Establishments with Sheep and Goat population.

In 2020 have been registered 120 infected establishment, for the year 2021 the regionals Authority are expected 113 infected establishment (reduction of 5.5% of the infected establishment respect the year 2020), for the year 2022 the regionals Authority are expected 67 infected establishment (reduction of 45% of the infected establishment respect the year 2021).

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

Establishments Sheep and Goat population.

n the 2020 on 27916 establishment under program at the beginning of the year 27484 have resulted OBF by December 31st (432 herds with suspension or withdrawal of the status).

In the 2021 is expected that on 27158 establishment under program at the beginning of the year 26760 should result with free status by December 31st (230 establishment with suspension or withdrawal of the status). A decrease of 46,6% of establishment with suspension or withdrawal of the status respect the year 2020 that show a favourable increasing of the number of establishment free.

In the 2022 is expected that on 23257 establishment under program at the beginning of the year 23051 should resulted OBF by December 31st (101 establishment with suspension or withdrawal of the status). A decrease of 56% of the establishment with suspension or withdrawal of the status respect the year 2021 that show a favourable increasing of the number of establishment free.

(c) the expected vaccination coverage, where relevant.

At the present no program of vaccination has been presented officially at the attention of the central Authority. In case is decided at a later stage to use vaccination to eradicate the disease we will make an amendment of our programme, specifying the vaccination area and the expected vaccination coverage and will resubmit the amended programme for approval.