



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 31 may 2021**
2. *Member State:* ITALY
3. **Name of the disease¹** Infection with Brucella abortus, B. melitensis and B. suis
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 abortus: ABRUZZO: Province of l'Aquila, Teramo and Chieti, BASILICATA: all region, CALABRIA: all region, CAMPANIA: provinces of Caserta and Salerno, MOLISE: province of Isernia, PUGLIA: province of Foggia and Taranto and for SICILIA: all region.

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

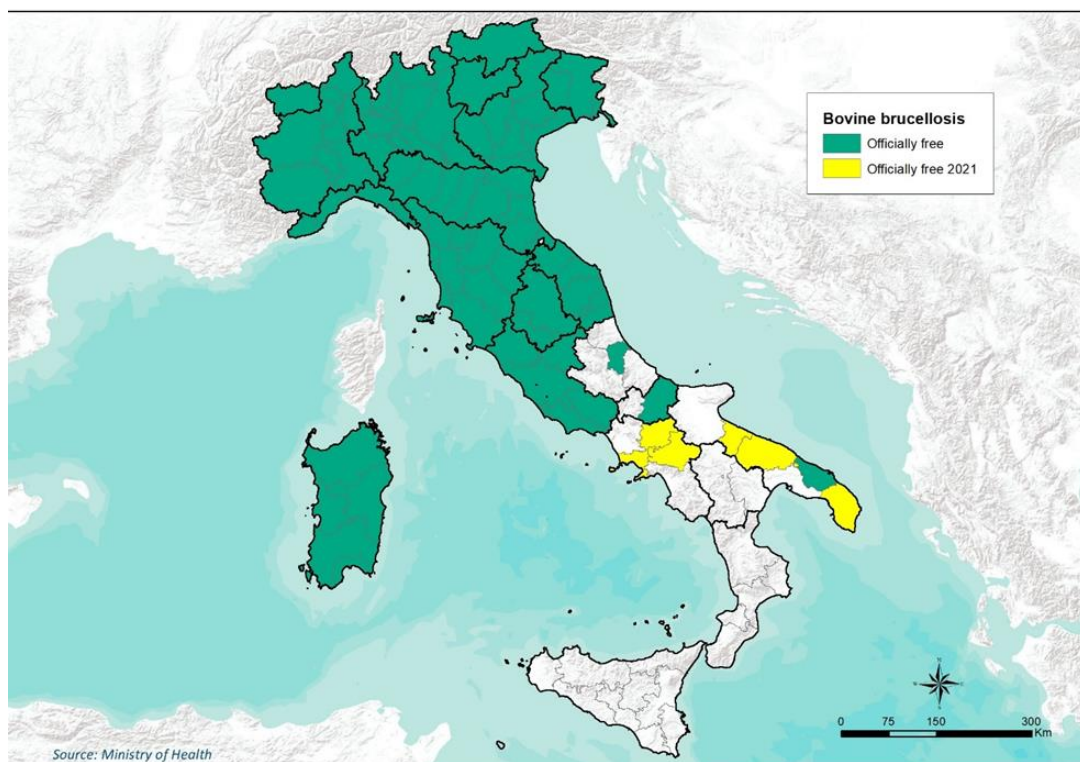
Category B-diseases

- 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

ITALY. BOVINE – BUFFALO BRUCELOSIS - MAP with territories OBF and not OBF.



In green the Regions BF, in yellow and white the Regions not OBF in 2020, in yellow the Regions declared BF 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 result at 31 December 2020.

Bovine brucellosis – data on establishment – year 2020

STATO: ITALY - YEAR 2020

DIESASE (a): BOVINE BRUCELLOSIS

REGIONS	Status (c)						
	Total number of establishment under proogram	Unknown (d)	Free and not Free		Free without vaccination suspended (g)	Free with vaccination (h)	Free without vaccination (i)
			Last control positive (e)	Last control negative (f)			
	Establishment	Establishment	Establishment	Establishment	Establishment	Establishment	Establishment
1	2	4	6	8	10	12	14
ABRUZZO: only province of L'Aquila, Teramo, Chieti	1839	0	0	1	1	0	1837
BASILICATA: all region	2290	0	1	0	0	0	2289
CALABRIA: all region	5192	3	1	30	9	0	5149
CAMPANIA: all region	5801	11	10	35	2	0	5743
MOLISE: only province of Isernia	448	0	2	2	0	0	444
PUGLIA: Only province of Foggia, Bari, Taranto, Lecce, Barletta-Andria-Trani	3309	0	11	35	0	0	3263
SICILIA: all region	9037	1	42	187	48	0	8759
Total	27916	15	67	290	60	0	27484

Buffalo brucellosis – data on establishment – years 2020

STATO: ITALY - YEAR 2020

DIESASE (a): BUFFALO BRUCELLOSIS

REGIONS	Status (c)						
	Total number of establishment under proogram	Unknown (d)	Free and not Free		Free without vaccination suspended (g)	Free with vaccination (h)	Free without vaccination (i)
			Last control positive (e)	Last control negative (f)			
	Establishment	Establishment	Establishment	Establishment	Establishment	Establishment	Establishment
1	2	4	6	8	10	12	14
CAMPANIA: all region	1071	3	45	40	1	5	977
Totale	1071	3	45	40	1	5	977

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

Bovine brucellosis – data on the animal population years 2020

STATO: ITALY

YEAR: 2020

DIESASE (a): BOVINE BRUCELLOSIS BOVINE

REGIONS	Status (c)						
	Total number of animal under proogram	Unknown (d)	Last control positive (e)	Last control negative (f)	Suspended (g)	Free with vaccination (h)	Free without vaccination (i)
	Animals (j)	Animals (j)	Animals (j)	Animals (j)	Animals (j)	Animals (j)	Animals (j)
1	3	5	7	9	11	13	15
ABRUZZO: Only province of L'Aquila, Teramo, Chieti	35203	0	0	27	4	0	35172
BASILICATA: all region	76794	0	279	0	0	0	76515
CALABRIA: all region	87713	54	6	347	32	0	87274
CAMPANIA: all region	123299	127	1064	784	59	0	121265
MOLISE: Only province of Isernia	11288	0	63	37	0	0	11188
PUGLIA: Only province of Foggia, Bari, Taranto, Lecce, Barletta-Andria-Trani	144942	0	651	2127	0	0	142164
SICILIA: all region	271897	11	2781	7707	597	0	260801
Totale	751136	192	4844	11029	692	0	734379

Buffalo brucellosis – data on animal population years 2020

STATO: ITALY

Anno: 2020

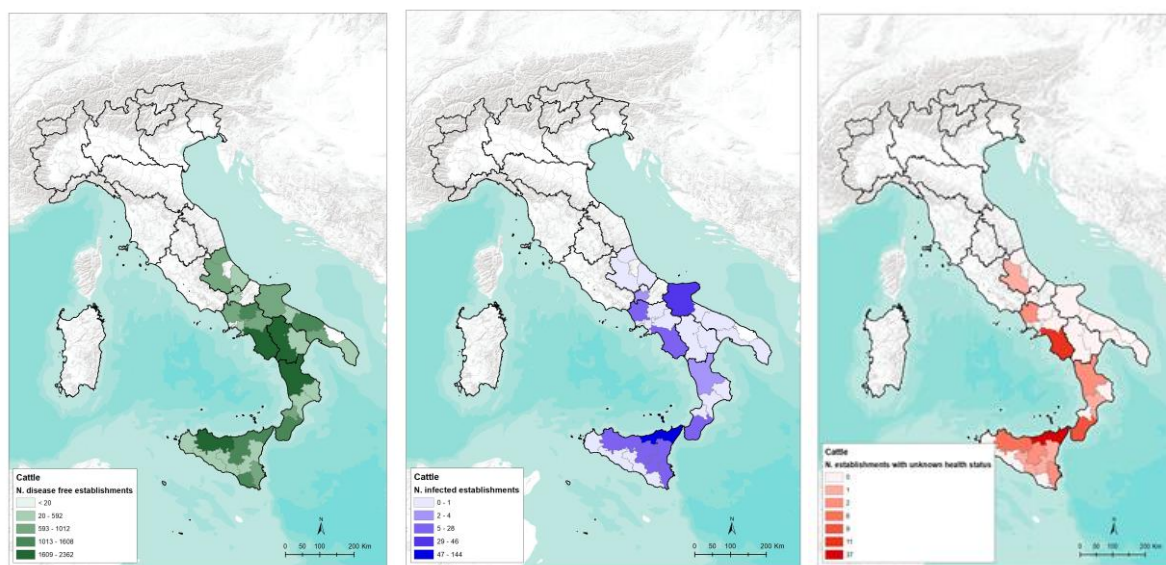
YEAR 2020

DIESASE (a): BUFFALO BRUCELLOSIS BUFFALO

REGIONS	Status (c)						
	Total number of animal under proogram	Unknown (d)	Last control positive (e)	Last control negative (f)	Suspended (g)	Free with vaccination (h)	Free without vaccination (i)
	Animals (j)	Animals (j)	Animals (j)	Animals (j)	Animals (j)	Animals (j)	Animals (j)
1	3	5	7	9	11	13	15
CAMPANIA: all region	275508	524	15834	12368	44	3617	243121
Totale	275508	524	15834	12368	44	3617	243121

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

In the following maps: in green the density of the disease free status establishment; in blue the density of infected status establishment, in red the density of the establishment with unknown status.



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

The table 1 and 2 show the prevalence registered in the last 3 years, in the territories not OBF, where the program has been applied in the bovine population and in sheep and goats population and the related target expected for the 2022. In green are highlighted the territories that have achieved the condition of prevalence, required in the Reg. 689/2020, to submit a request at the Commission for the declaration of OBF. In yellow are highlighted the territories that have registered in the last 2 years a favourable prevalence condition.

REGIONS	TABLE 1 – TIMELINE %PREVALENCE AND %INCIDENCE OF BOVINE BRUCELLOSIS										
	2016		2017		2018		2019		2020		TARGET 2022
	I	P	I	P	I	P	I	P	I	P	
ABRUZZO											
TERAMO Province	0.00	0.00	0.12	0.12	0.13	0.13	0.00	0.00	0,00	0,00	0.00
AQUILA Province	0.35	0.35	1.13	1.13	0.12	0.59	0.11	0.11	0,12	0,12	0.00
CHIETI Province	0.00	0.56	0.0	0.0	0.31	0.31	0.21	0.21	0,00	0,36	0.00
BASILICATA											
POTENZA Province	0.31	0.62	0.15	0.21	0.64	0.69	1.04	1.04	0,90	0,90	0.00
MATERA Province	0.92	0.92	1.55	1.75	1.20	1.81	0.20	0.20	0,20	0,20	0.00
CALABRIA											
CROTONE Province	1.23	1.58	1.37	1.54	0.69	0.69	0.51	0.51	0,18	0,18	0.00
V. VALENTIA Province	0.54	0.54	0.0	0.0	0.10	0.10	0.00	0.00	0,00	0,00	0.00
COSENZA Province	0.96	1.01	1.17	1.17	0.76	0.76	0.51	0.56	0,20	0,20	0.00
CATANZARO Province	0.2	0.2	0.41	0.61	0.63	0.63	0.63	0.63	0,00	0,00	0.00
REGGIO CAL. Province	0.76	0.83	0.43	0.50	1.22	1.22	0.24	0.24	0,00	0,00	0.00
CAMPANIA BOVINE											
AVELLINO Province	0.08	0.08	0.17	0.17	0.0	0.0	0.19	0.19	0,00	0,00	FREE
BENEVENTO Province	0.11	0.11	0.18	0.18	0.0	0.0	0.00	0.0	0,20	0,20	FREE
CASERTA Province	0.30	0.52	0.72	0.88	0.17	0.34	1.35	1.71	0,58	0,78	0.49
NAPOLI Province	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0,4	0,4	FREE
SALERNO Province	2.49	3.31	1.24	1.80	1.52	2.15	0.74	0.93	0,53	0,58	0.30
CAMPANIA BUFFALO											
AVELLINO Province	0.0	0.0	11.11	11.11	0.0	0.0	0.00	0.00	12,50	12,50	FREE
BENEVENTO Province	0.0	0.0	0.0	0.0	0.0	0.0	0.00	0.00	0,00	0,00	FREE
CASERTA Province	3.30	4.07	4.15	5.19	5.73	7.87	8.50	11.47	10,49	14,83	6.49
NAPOLI Province	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0,00	0,00	FREE

SALERNO Province	1.13	1.13	0.60	0.60	3.19	3.48	2.60	3.18	0.59	0.88	0.57
MOLISE											
ISERNIA Province	0.58	0.58	0.0	0.2	0.20	0.20	2.76	2.97	3.57	5.80	0.00
PUGLIA											
TARANTO Province	0.0	0.0	0.56	0.56	0.88	1.02	0.15	0.15	0.14	0.14	0.00
BAT Province	0.0	0.0	0.0	0.0	0.0	0.0	0.00	0.00	0.00	0.00	FREE
BARI Province	0.0	0.0	0.0	0.0	0.17	0.17	0.35	0.35	0.09	0.09	FREE
FOGGIA Province	5.75	6.79	3.54	4.79	2.99	4.09	2.98	4.00	2.86	3.68	3.27
LECCE Province	0.0	0.0	0.22	0.22	0.0	0.0	0.00	0.00	0.00	0.00	FREE
SICILY											
AGRIGENTO Province	0.63	0.63	0.21	0.21	0.87	0.87	0.22	0.22	0.00	0.00	0.00
CALTANISSETTA Province	0.0	0.0	0.0	0.0	1.09	1.09	1.15	1.72	0.58	0.58	0.00
CATANIA Province	2.12	2.87	3.42	4.17	3.27	3.73	2.30	2.76	3.76	5.01	1.56
ENNA Province	1.22	1.37	1.15	1.38	1.15	1.76	1.69	2.15	2.19	2.82	2.50
MESSINA Province	6.54	8.71	8.14	9.13	5.12	5.73	6.76	7.76	8.31	9.85	7.10
PALERMO Province	0.54	0.62	0.86	0.94	0.63	0.63	0.32	0.32	0.44	0.52	0.42
RAGUSA Province	2.32	2.53	1.41	1.90	1.14	1.50	0.37	0.44	0.00	0.00	0.00
SIRACUSA Province	2.06	2.43	1.33	1.58	2.09	2.33	1.63	1.75	2.37	2.62	2.20
TRAPANI Province	2.21	2.21	0.0	0.0	0.39	0.39	0.80	0.80	0.00	0.00	0.00

In Italy the vaccination is not in use from more than last 5 years, but is not excluded that in some cluster of infection, like the buffalo population in Campania (Province of Caserta), the bovine population in the area of Gargano (Puglia Region) and the bovine population in Province of Messina (Sicily region) this tools can be used in future, to reduce the dissemination of brucella abortus in this areas 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.

In particular sampling schemes and diagnostic methods to confirm a case (art. 9 of Reg. 689/2020) of brucella abortus, melitensis and suis in one animal or group of animal is the following:

The screening is performed with SAT, the SAT positive are check with CFT and then the CFT positive are controlled by BST. When an animal if positive at: SAT, CFT and BST the case is confirmed and the suspect establishment is declared outbreak with status withdrawn. In the outbreak all the animal positive at the serological tests are slaughtered. At the time of the suspicious start an epidemiological investigation to find the source of the infection and for that is performed bacteriological analysis, on the organs of the animals slaughtered, to try to isolate and genotyped the brucella responsible of the disease.

(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 1 and 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 1 and 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).

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

In case of confirmation of *Brucella abortus*, *B. melitensis* and *B. suis* in establishment with or without vaccination, 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 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 bovine, ovine or caprine animals fulfil the requirements set out in point 1(c) of Section 1 of Chapter 1.

(b) 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 bovine animals 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 are providing a specific indications on biosecurity for the clusters of infection as the one registered for bovine buffalo brucellosis in Province of Caserta.

(c) 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.

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

No measures provided for.

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

No measures provided for.

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

No measures provided for.

- (g) targeted animal populations and when applicable, additional animal populations.**

Bovines, Buffaloes 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;

Bovine herds

In 2020 have been registered 394 infected establishment, for the year 2021 the regionals Authority are expected 210 infected establishment (reduction of 46,6% of the infected establishment respect the year 2020), for the year 2022 the regionals Authority are expected 180 infected establishment (reduction of 14% of the infected establishment respect the year 2021).

Buffalo herds (present in the provinces of Caserta and Salerno in Campania region)

In 2020 has been registered 110 infected establishment, for the year 2021 the regionals Authority are expected 65 infected establishment (reduction of 41% of the infected establishment respect the year 2020), while for the year 2022 the regionals Authority are expected 47 infected establishment (reduction of 27% of the infected establishment respect the year 2021).

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

Bovine herds

In 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 23882 establishment under program at the beginning of the year 23641 should result with free status by December 31st (241 establishment with suspension or withdrawal of the status). An increase of 44% more establishment with free status respect the year 2020.

In the 2022 is expected that on 22170 establishment under program at the beginning of the year 21932 should resulted OBF by December 31st (238 establishment with suspension or withdrawal of the status). An increase of 1% more establishment with free status respect the year 2021.

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

In the 2020 on 1071 herds under program at the beginning of the year 977 have resulted OBF by December 31st (94 herds with suspension or withdrawal of the status).

In the 2021 is expected that on 1081 establishment under program at the beginning of the year 1033 should result OBF by December 31st (48 establishment with suspension

or withdrawal of the status). An increase of 45% more of establishment with free status respect the year 2020.

In the 2022 is expected, that on 1043 herds under program at the beginning of the year 1009 should resulted OBF by December 31st (34 herds with suspension or withdrawal of the status). An increase of 29% more establishment with free status respect the year 2021.

(c) the expected vaccination coverage, where relevant.

At the present, no program of vaccination have been present officially at the attention of the central Authority. However, the Campania Regional Authority have requested at the National Reference Centre for Brucellosis (IZSAM) the correct protocol for the application of vaccination with RB51 on the buffalo population in Caserta Province. Discussion with the Stakeholders is still in course and no feedback is arrived at moment at the CA. 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.