



**submitted for obtaining EU financial contribution**

**Annex I.b: Programme for the eradication of bovine tuberculosis, bovine brucellosis or sheep and goat brucellosis (*B. melitensis*)**

Member States seeking an EU financial contribution for national programmes for eradication, control and surveillance of animal diseases and zoonosis shall submit online this document completely filled out by the 31 May of the year preceding its implementation (part 2.1 of Annex I to the Single Market Programme Regulation).

**If encountering difficulties:**

- concerning the information requested, please contact [HADEA-VET-PROG@ec.europa.eu](mailto:HADEA-VET-PROG@ec.europa.eu).
- on the technical point of view, please contact [SANTE-BI@ec.europa.eu](mailto:SANTE-BI@ec.europa.eu), include in your message a printscreen of the complete window where the problem appears and the version of this pdf:

**Protection of Your Personal Data:**

For consultation about the processing and the protection of your personal data, please click to follow this link

[Privacy Statement](#)

**Instructions to complete the form:**

- 1) You can attach documents (.docx, .xlsx, .pdf, etc) to complete your report.  
Using the button "Add attachments" on the last page of the form.
- 2) Before submitting this form, please use the button "Verify form"(bottom right of each page).  
If needed, complete your pdf document as indicated.
- 3) When you have finished completing this pdf document, save it on your computer.
- 4) Verify that your internet connection is active and then click on the "Submit notification" button and your pdf document will be sent to our server. A submission number will appear on your document.  
Save this completed document on your computer for your record.
- 5) For simplification purposes you are invited to submit multi-annual programmes.
- 6) You are invited to submit your programmes in English.

Document version number: 2022 1.0

Member state : ITALIA

Disease : Bovine Brucellosis

Species : Bovines and buffalo

This program is multi annual :

Request of the Union co-financing from beginning of:

First year of implementation of the programme described in this document:

1. Contact data

Name	Phone
Email	Your job type within the CA :

**Submission Date**  
**07/12/2022 09:55:47**

**Submission Number**  
**1670403351760-19167**



# Standard requirements for the submission of programme for eradication, control and surveillance

## 2. Historical data on the epidemiological evolution of the disease

Describe timeline with prevalence, incidence data and, where relevant, vaccination history covering at least the past 5 years.

(max. 32000 chars) :

The programme 2021 for the eradication of *Brucella abortus*, *B. melitensis* and *B. suis* without vaccination

from the establishment keeping bovine-buffaloes animals has the following objectives:

- to continue with, and step up, animal health measures to prevent brucellosis in bovine and buffalo;
- to intensify disease eradication in infected establishments so they can be declared officially brucellosis-free or,

for establishments where vaccination could be applied, brucellosis-free;

- to retain the disease-free status without vaccination (or disease-free status where vaccination has been applied) for establishments that have already achieved this qualification.

The planned and achievable objective for 2021, was for other Italian provinces and regions to acquire (or retain) the requirements to qualify for the disease-free status without vaccination (or disease-free status where vaccination is applied) as regards brucellosis in bovine and buffalo.

The 21 of April 2021 the Animal Health Law has entered in force in Europe. For Italy start a time of transition from the national legislation to European legislation. In any case, the Ministry of health has prolonged the

Ministerial Ordinance 28 May 2015, until 26 June 2022 to give to the local veterinary services the instruments to continue the process of eradication in the regions where the disease is still present.

The Ordinance is applied in the not free territories as well as in the free territories at the aim of obtain a uniform control of the disease in Italy.

20220419-RE76PCV7, output on 2022/04/29 15:47 (Europe/Luxembourg) Page 2/8

The Ordinance provide for an obligation for all the Regions to insert in the Italian Veterinary Informatic System (VETINFO), a list of the establishments that are plan to control during the year.

The upload of the planning of controls in VETINFO is the base of calculation of a DASHBOARD, that compare

the planning, with the data of the veterinary activities performed during the implementation of the program, producing statistic, refreshed weekly, in form of indicators, useful at local, regional and national

level to monitoring of the correct application of the plan.

The Ordinance considered also the frequency and the modalities of the controls on dealers. The local veterinary service must check, at least every three months the dealers on site and every month on the veterinary informatics system, (VETINFO). In case the checks on the informatic system reveal unconformity, the local veterinary service control the dealer on site.

Following the synthesis of the measures contained in the Ordinance (ANNEX 2, Ministerial Order 28 may 2015):

- 1) Responsibility of the Chief of local Veterinary service on the control of 100% of the establishments;
- 2) Registration of pastures;
- 3) Controls of Dealers;
- 4) Control of fattening establishments;
- 5) Controls on animals before and after movement;
- 6) Electronic identifications of animals of the outbreak (rumen bolus);
- 7) Electronic identifications of animals subjected to movement;

## Standard requirements for the submission of programme for eradication, control and surveillance

8) Capture and control of animals at pasture that have no owner or that have an owner that does not assure capture and the restraint of animals;

9) Guidelines for stamping-out;

10) Elaboration, already at the suspect, of the epidemiological investigations, following the guidelines of the Ministry of health (ANNEX 3);

11) Compulsory use of the database, SANAN and SIMAN;

12) Sanctions and withdrawal of the status of OTF of the establishments in case of fraud;

13) Control of the efficacy and efficiency by local and regional veterinary service.

Regarding this last point, to support the enforcement of the verification of the efficacy and efficiency of the controls by the local veterinary authority, in the dashboard has been provided a function that permit at the chief of the veterinary service to:

1) verify, one by one, all the indicator of the disease;

2) indicate the corrective actions that decides to implement to recovery the unconformities detected.

All the data of the verification of the efficacy and efficiency are then saved in changeless way and made available to the Regional and Central Authority for Audit session and other verification.

*Brucella abortus* has been eradicate from most part of the Italian territory. Out of 19 Regions and 2 Autonomous provinces, 13 of them and 9 Provinces of the Regions: Abruzzo, Campania, Molise and Puglia have been declare Officially *B. abortus*, *melitensis* and *suis* - Free according to EU legislation (ANNEX 1 MAP AND GRAPHICS).

In the year 2021, the prevalence recorded for the disease in Italy, calculated all in the establishments under control has been of 0.48% while in 2017 has been 0.50%, (ANNEX 8). This this decrease is more evident looking at the data registered in the 7 Regions still not declared FREE that shown a prevalence and incidence of 0,97 % and 0,68 % respect at the result of 2017 1.47%, and 1.24% (ANNEX 8).

The number of establishments present in 2021 at national level (93433) is decreased respect the stablishments present in 2017 (100003) instead the outbreaks occurred in the 2021 (316) are decreasing respect at the 457 registered in 2017.

The higher prevalence in Italy is reported from Puglia region with an overall prevalence of 3.14% establishments infected on the controlled, and with the Province of Foggia (cluster of brucellosis in the Gargano Area) recording the highest value among all provinces still not free (Foggia e Taranto), i.e. 5.38%.

More in detailed of 55 outbreaks registered in Puglia in 2021, 52 occurred in Foggia. (ANNEX 5 AND 7).

In Sicily the prevalence registered in 2021 is 2.20 % decreasing respect the year 2017 2.91%. Also the outbreaks are decreasing 223 respect 276 in 2017.

In Campania region the buffalo population have registered an increasing of the prevalence in the establishments in the year 2021 13.07% respect the 2020 (3.76 %) – (ANNEX 4 and 6). This increasing of the prevalence regard in particular the province of Caserta (18.71%), considered that of 137 outbreak registered in buffaloes in the Provinces still not free of Campania Region, 131 have been confirm in province of Caserta, the other 6 in province of Salerno.

The Campania Region ascribe this increase of the prevalence in Province of Caserta at problems of biosecurity of the farms. Environmental contamination with *brucella* of the area that mixed with the particular attitude of the buffaloes to stay in the water facilitate the diffusion of the infection. Farms near each other and contiguity as cause of the persistence of the disease. Suspect irregular movement of the animals that jeopardize the health status of the establishments. To solve this last critical point the Region has proposed a genetic plan for the certain identification of the animals.

To face all this critical points the Campania region has prepared in 2021, with the contribution of the

## Standard requirements for the submission of programme for eradication, control and surveillance

stakeholders, a specific plan for the resolution of the cluster of infection in Province of Caserta, that include the vaccination on the young buffaloes to limit the circulation of the disease between the animals but also the environmental contamination.

The plan has been applied at the beginning of 2022 and transmitted at the Commission for approval of the vaccination tool. The vaccination will be applied only after the approval of the EU. For the monitoring of the plan, there is a Group of Monitoring, composed by representatives of: Ministry of Health; Campania Region, Reference National Centre of brucellosis, Laboratory of Analysis (IZS Mezzogiorno), Veterinary National Informatics System. At the meeting of the Group are also invited to participate the local veterinary service of Caserta Province and officers of the Ministry of Agriculture. This Group of Monitoring has the duty to control the advancing of the plan and eventual difficulties, propose solutions and elaborate a report to inform the Stakeholder of the result of application of the plan.

### 3. Description of the submitted programme

*Describe 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;*
- (ii) to confirm or rule out the disease in the event of a suspected case;*
- (b) the disease control measures to be applied in the event of a confirmed case;*
- (c) the biosecurity and risk mitigating measures to be implemented;*
- (e) the measures to be implemented as regards additional animal populations, if relevant;*
- (f) the derogations to be applied in accordance with Article 19 of Delegated Regulation (EU) 2020/689, if relevant;*
- (g) coordinated measures with other Member States or third countries, if relevant.*

*(max. 32000 chars) :*

The programme 2021 for the eradication of *Brucella abortus*, *B. melitensis* and *B. suis* without vaccination from the establishment keeping bovine-buffaloes animals has the following objectives:

- to continue with, and step up, animal health measures to prevent brucellosis in bovine and buffalo;
- to intensify disease eradication in infected establishments so they can be declared officially brucellosis-free or, for establishments where vaccination could be applied, brucellosis-free;
- to retain the disease-free status without vaccination (or disease-free status where vaccination has been applied) for establishments that have already achieved this qualification.

The planned and achievable objective for 2021, was for other Italian provinces and regions to acquire (or retain) the requirements to qualify for the disease-free status without vaccination (or disease-free status where vaccination is applied) as regards brucellosis in bovine and buffalo.

The 21 of April 2021 the Animal Health Law has entered in force in Europe. For Italy start a time of transition from the national legislation to European legislation. In any case, the Ministry of health has prolonged the Ministerial Ordinance 28 May 2015, until 26 June 2022 to give to the local veterinary services the instruments to continue the process of eradication in the regions where the disease is still present. The Ordinance is applied in the not free territories as well as in the free territories at the aim of obtain a



## Standard requirements for the submission of programme for eradication, control and surveillance

uniform control of the disease in Italy.

20220419-RE76PCV7, output on 2022/04/29 15:47 (Europe/Luxembourg) Page 2/8

The Ordinance provide for an obligation for all the Regions to insert in the Italian Veterinary Informatic Sistem (VETINFO), a list of the establishments that are plan to control during the year.

The upload of the planning of controls in VETINFO is the base of calculation of a DASHBOARD, that compare

the planning, with the data of the veterinary activities performed during the implementation of the program, producing statistic, refreshed weekly, in form of indicators, useful at local, regional and national

level to monitoring of the correct application of the plan.

The Ordinance considered also the frequency and the modalities of the controls on dealers. The local veterinary service must check, at least every three months the dealers on site and every month on the veterinary informatics system, (VETINFO). In case the checks on the informatic system reveal unconformity, the local veterinary service control the dealer on site.

Following the synthesis of the measures contained in the Ordinance (ANNEX 2, Ministerial Order 28 may 2015):

- 1) Responsibility of the Chief of local Veterinary service on the control of 100% of the establishments;
- 2) Registration of pastures;
- 3) Controls of Dealers;
- 4) Control of fattening establishments;
- 5) Controls on animals before and after movement;
- 6) Electronic identifications of animals of the outbreak (rumen bolus);
- 7) Electronic identifications of animals subjected to movement;
- 8) Capture and control of animals at pasture that have no owner or that have an owner that does not assure capture and the restraint of animals;
- 9) Guidelines for stamping-out;
- 10) Elaboration, already at the suspect, of the epidemiological investigations, following the guidelines of the Ministry of health (ANNEX 3);
- 11) Compulsory use of the database, SANAN and SIMAN;
- 12) Sanctions and withdrawal of the status of OTF of the establishments in case of fraud;
- 13) Control of the efficacy and efficiency by local and regional veterinary service.

Regarding this last point, to support the enforcement of the verification of the efficacy and efficiency of the

controls by the local veterinary authority, in the dashboard has been provided a function that permit at the

chief of the veterinary service to:

- 1) verify, one by one, all the indicator of the disease;
- 2) indicate the corrective actions that decides to implement to recovery the unconformities detected.

All the data of the verification of the efficacy and efficiency are then saved in changeless way and made available to the Regional and Central Authority for Audit session and other verification.

*Brucella abortus* has been eradicate from most part of the Italian territory. Out of 19 Regions and 2 Autonomous provinces, 13 of them and 9 Provinces of the Regions: Abruzzo, Campania, Molise and Puglia

have been declare Officially *B. abortus*, *melitensis* and *suis* - Free according to EU legislation (ANNEX 1).

In the year 2021, the prevalence recorded for the disease in Italy, calculated all in the establishments under control has been of 0.48% while in 2017 has been 0.50%, (ANNEX 1). This this decrease is more evident looking at the data registered in the 7 Regions still not declared FREE that shown a prevalence and incidence of 0,97 % and 0,68 % respect at the result of 2017 1.47%, and 1.24% (ANNEX 1).

## Standard requirements for the submission of programme for eradication, control and surveillance

The number of establishments present in 2021 at national level (93433) is decreased respect the establishments present in 2017 (100003) instead the outbreaks occurred in the 2021 (316) are decreasing respect at the 457 registered in 2017.

The higher prevalence in Italy is reported from Puglia region with an overall prevalence of 3.14% establishments infected on the controlled, and with the Province of Foggia (cluster of brucellosis in the Gargano Area) recording the highest value among all provinces still not free (Foggia e Taranto), i.e. 5.38%.

More in detailed of 55 outbreaks registered in Puglia in 2021, 52 occurred in Foggia. (ANNEX 5 AND 7). In Sicily the prevalence registered in 2021 is 2.20 % decreasing respect the year 2017 2.91%. Also the outbreaks are decreasing 223 respect 276 in 2017.

In Campania region the buffalo population have registered an increasing of the prevalence in the establishments in the year 2021 13.07% respect the 2020 (3.76 %) – (ANNEX 4 and 6). This increasing of the prevalence regard in particular the province of Caserta (18.71%), considered that of 137 outbreak registered in buffaloes in the Provinces still not free of Campania Region, 131 have been confirm in province of Caserta, the other 6 in province of Salerno.

The Campania Region ascribe this increase of the prevalence in Province of Caserta at problems of biosecurity of the farms. Environmental contamination with brucella of the area that mixed with the particular attitude of the buffaloes to stay in the water facilitate the diffusion of the infection. Farms near each other and contiguity as cause of the persistence of the disease. Suspect irregular movement of the animals that jeopardize the health status of the establishments. To solve this last critical point the Region has proposed a genetic plan for the certain identification of the animals.

To face all this critical points the Campania region has prepared in 2021, with the contribution of the stakeholders, a specific plan for the resolution of the cluster of infection in Province of Caserta, that include

the vaccination on the young buffaloes to limit the circulation of the disease between the animals but also

the environmental contamination.

The plan has been apply at the beginning of 2022 and transmitted at the Commission for approval of the vaccination tool. The vaccination will be apply only after the approval of the EU. For the monitoring of the

plan, there is a Group of Monitoring, composed by representing of : Ministry of Health; Campania Region, Reference National Centre of brucellosis, Laboratory of Analysis (IZS Mezzogiorno), Veterinary National informatics System. At the meeting of the Group are also invite to participate the local veterinary service of

Caserta Province and officers of the Ministry of Agriculture. This Group of Monitoring as the duty to control

the advancing of the plan and eventual difficulties, propose solution and elaborate a report to inform the Stakeholder of the result of application of the plan.

### 3. Description of the submitted programme

Describe 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;

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

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

## Standard requirements for the submission of programme for eradication, control and surveillance

- (c) the biosecurity and risk mitigating measures to be implemented;
- (e) the measures to be implemented as regards additional animal populations, if relevant;
- (f) the derogations to be applied in accordance with Article 19 of Delegated Regulation (EU) 2020/689, if relevant;
- (g) coordinated measures with other Member States or third countries, if relevant

The programme is annual and covers the following objectives:

- to continue with, and step up, animal health measures and measures to prevent brucellosis in bovine and buffalo;
- to intensify disease eradication on infected establishments so that they can be designated free without vaccination or free with vaccination;
- to retain officially disease-free status without vaccination (or disease-free status with vaccination) for establishments that have already achieved that objective.

The planned and achievable objective for 2023 is for other Italian provinces and regions to meet (or retain) the requirements to qualify for officially disease-free status without vaccination or disease-free status with vaccination as regards brucellosis in bovine and buffalo.

In particular, for the 2023 the prevalence and incidence expected are respectively: 0.56% and 0.43%.

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

In particular:

- a) twice a year in the territories not free, rapid serum agglutination test with Rose Bengal antigen (RBT) to be performed on all blood samples collected;
- b) the complement fixation test (CFT) to be carried out on all RBT positive samples and on all animals in the establishment in the case of establishments that are not free and controlled for the acquisition of the status free.

In bovine buffalo establishments, CFT is also performed on all animals in the establishment if one or more animals have reacted positively to RBT. The CFT test is considered positive at a titer equal to or greater than 20 UIFC / ml.

- c) milk-ELISA can be used as a screening test in unvaccinated free establishments, present in unvaccinated free provinces, on a bulk milk sample from farms in which at least 30% of dairy cows are lactating. If this method is used, it must be ensured that the samples taken for analysis make it possible to trace the individual animals from which the tested milk comes.

Interpretation of test results:

- a) In the event that the serum of an animal tested gives negative results to RBT and CFT, the animal is to be considered not positive;
- b) if the serum of an animal tested gives a positive result to the CFT (greater than or equal to 20 UIFC / ml) and negative or positive to the RBT, the animal is to be considered positive;
- c) in the event that the serum of an animal tested gives a positive result for RBT and negative for CFT, the result is considered doubtful and the animal suspected of infection. The health qualification is suspended at the farm of origin and the control on the animal will be repeated.

In the event that this result is obtained on sera from animals present in infected farms, the animals with positive RBT are considered infected in any case.

For non-infected farms in which doubtful results are repeated during subsequent checks, the Region may request the intervention of the IZS competent for the area and the National Reference Center for

## Standard requirements for the submission of programme for eradication, control and surveillance

Brucellosis for any diagnostic investigations.

In case of positivity of the mass milk examined, further confirmatory tests must be carried out on serum samples taken from the individual animals present on the farm that had constituted the milk pool. The batches of kits used on the national territory are controlled by the national reference laboratory for brucellosis, which verifies the suitability with respect to the analytical sensitivity established with international standard sera and the number of samples making up the pool compatible with acceptable levels of diagnostic sensitivity.

### Granting of the status

1. The status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* without vaccination may only be granted to an establishment keeping bovine, ovine or caprine animals if:

(a) during the past 12 months there has been no confirmed case of infection with *Brucella abortus*, *B. melitensis* and *B. suis* in bovine, ovine or caprine animals kept in the establishment;

(b) during the past 3 years none of the bovine, ovine or caprine animals in the establishment has been vaccinated against infection with *Brucella abortus*, *B. melitensis* and *B. suis*;

(c) the entire bovine animals over 12 months of age and the entire ovine or caprine animals over 6 months of age present in the establishment at the time of sampling have tested negative to serological test, on two occasions as follows:

(i) the first test must be carried out on samples taken not earlier than 3 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 samples taken not earlier than 6 months and not later than 12 months following the date of sampling referred to in point (i);

(d) animals showing clinical signs consistent with infection with *Brucella abortus*, *B. melitensis* and *B. suis*, such as abortions, have been subjected to investigations with negative results;

(e) since the beginning of the sampling referred to in point (c)(i) all bovine, ovine or caprine animals introduced into the establishment originate from establishments free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* without vaccination, or free with vaccination and have not been vaccinated against infection with *Brucella abortus*, *B. melitensis* and *B. suis* during the past 3 years, and (i) originate from a Member State or a zone free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* for the relevant animal population;

(ii) are entire bovine animals over 12 months of age or entire ovine or caprine animals over 6 months of age and must have tested negative in a serological test carried out on a sample taken:

— during the 30 days prior to their introduction into the establishment; or

— during the 30 days following their introduction provided they have been kept isolated during this period;

or

(iii) are post-parturient females kept in isolation since their introduction into the establishment until they have tested negative in a serological test carried out on a sample taken not earlier than 30 days after parturition; and

(f) since the beginning of the sampling referred to in point (c)(i), all germinal products of bovine, ovine or caprine origin introduced into or used in the establishment originate from:

(i) establishments free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* without vaccination; or

(ii) approved germinal product establishments.

### Granting of the status

1. The status free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* with vaccination may only be granted to an establishment keeping bovine, ovine or caprine animals if:



## Standard requirements for the submission of programme for eradication, control and surveillance

- (a) the requirements set out in points (a), (c) and (d) of point 1 of Section 1 of Chapter 1 are fulfilled;
- (b) since the beginning of the sampling referred to in point (c)(i) of point 1 of Section 1 of Chapter 1, all bovine, ovine, or caprine animals introduced into the establishment originate from establishments free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* without vaccination or free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* with vaccination and:
- (i) originate from a Member State or a zone free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* for the relevant animal population; or
  - (ii) are entire bovine animals over 12 months of age and have tested negative in a serological test on a sample taken
    - during the 30 days prior to their introduction into the establishment; or
    - during the 30 days following their introduction into the establishment provided they have been kept isolated during this period; or
  - (iii) are post-parturient females kept in isolation since their introduction into the establishment until they have tested negative in a serological test carried out on a sample taken not earlier than 30 days after parturition; and
- (c) since the beginning of the sampling referred to in point (c)(i) of point 1 of Section 1 of Chapter 1, all germinal products of bovine, ovine or caprine origin introduced into or used in the establishment originate from:
- (i) establishments free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* without vaccination or free from infection with *Brucella abortus*, *B. melitensis* and *B. suis* with vaccination; or
  - (ii) approved germinal product establishments.

To confirm or rule out the disease in the event of a suspected case.

The confirmation of a suspected case of *B. abortus*, *melitensis* and *suis* in establishment with or without vaccination occur when there are the condition listed in annex 4 - Chapter 1/2, section 4 point 1 (a,b,c and d) of the EU Reg. 689/2021.

In case of no confirmation of *B. abortus*, *melitensis* and *suis* in establishment with or without vaccination the status free from infection with *B. abortus*, *melitensis* and *suis* and without vaccination may only be restored if, there are the condition prescribed at Chapter 1/2, section 3, point 2 of the Reg. 689/2020:

- (a) the requirements set out in points (b), (d), (e) and (f) of point 1 of Section 1 and in point (b) of Section 2 are fulfilled;
- (b) the results of further investigations substantiate absence of infection with *Brucella abortus* and the status of all suspected cases has been determined.

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

If the status free from infection with *B. abortus*, *melitensis* and *suis* without vaccination is withdrawn in case the infection of *B. abortus*, *melitensis* and *suis* has been confirmed in bovine-buffalo animal kept in the establishment;

it may only be regained if all confirmed cases and all animals that have tested non-negative have been removed and the remaining bovine-buffalo over 12 months of age present in the establishment at the time of sampling have tested negative to serological test, on two occasions as follows:

- (i) the first test must be carried out on samples taken not earlier than 3 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 samples taken not earlier than 6 months and not later than 12 months following the date of sampling referred to in point (i);

In case the test is overdue, the Italian informatics system by apposite functionality (VETINFO) report this information to the local veterinary authority that have maximum six months to perform the control. After this time the status is withdrawn.

# Standard requirements for the submission of programme for eradication, control and surveillance

The biosecurity and risk mitigating measures to be implemented;  
For mitigating the risk of geopardization fo the b.abortus in the Ministerial Order 28 may of 2015 and his prorogation is provided for strenght meausures for the animal moving for pasture (control 30 days befor moving, identification with endoruminal bolus and geo- referentation of the pastures) and controls on dealers (monthly on the veterinary informatic sistem VETINFO and in case of not conformity controls in place).  
The closed herds are monitored by the competent local veterinary service by the DASHBORD present in the Italian veterinary system.

## 4. Measures of the submitted programme

### 4.1 Summary of measures under the programme

Duration of the programme: 2023 - 2023

- Eradication
- Testing
- Slaughter of animals tested positive
- Vaccination

*Other, please specify*

#### 4.1.1 Timeline for the eradication

*Describe the timeline with prevalence, incidence data and, where relevant, vaccination history covering at least the past 5 years and the estimated duration of the eradication programme*

The Italian target for the program 2023 bovine -buffalo brucellosis is to continue to achieve the status of free for further territories. In 2022 the provinces of Teramo in Abruzzo Region and Vibo Valentia in Calabria Region have present the request at the Commission to be for the status free, that has been accepted.

Listed below the regions not free and the result of prevalence achieved in 2021 compared with the results of 2020/2019 and the target 2023 proposed:

## Standard requirements for the submission of programme for eradication, control and surveillance

Abruzzo: prevalence on establishments registered in 2019 – 0.09; in 2020 – 0.11%; in 2021 – 0.12%, target 2023= 0.00%.

Basilicata: - prevalence on establishments registered in 2019 – 0.86%; in 2020 – 0.74%; in 2021, 0.07% target 2023 = 0.00%,

Calabria: - prevalence on establishments registered in 2019 – 0.39 %; in 2020 – 0.10%; 2021, 0.73%; target 2023= 0.00%

Campania bovine: - prevalence on establishments registered in 2019 – 0.67%; in 2020 – 0.41%; 2021= 0.45 % -target 2023 = 0.24%,

Campania buffalo: - prevalence on establishments registered in 2019 – 8.56%; in 2020 – 10.08%; 2021= 12.15 % -target 2022 = 9,08 %

Molise: - prevalence on establishments registered in 2019 – 2.97%; in 2020 – 5.80%; in 2021= 0.12 %, target 2023 = 0.00%.

Puglia: - prevalence on establishments registered in 2019 – 1.36%; in 2020 – 1.15%; in 2021= 3.14 %-target 2023 = 1,75 %

Sicilia: prevalence on establishments registered in 2019 -2.36 %; in 2020 – 3.05%; in 2021= 2.20 % - target 2023 = 0.87 %.

### 4.1.2 Interim targets in relation to the timeline for eradication

Describe 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.

(max. 32000 chars) :

Relatively at the intermediate target of this program of eradication of *B. abortus*, *melitensis* and *suis* is expected the following annual decrease of the number of infected establishments: in 2021 has been registered 316 outbreaks, for the 2023 the regional Authority expect 129 outbreaks (reduction of 59% of case).

As consequence of the reduction of outbreaks is expected the following proportional increase of the number of disease-free establishments:

In the 2021 on 27.938 establishments under program at the beginning of the year 27484 have resulted free by December 31st (210 establishments with suspension or withdrawal of the status end 70 establishments unknown);

In the 2023 is expected that on 23.137 establishments under program at the beginning of the year 22.969 should result OBF by December 31st (101 establishments with suspension or withdrawal of the status end 11 establishments unknown).

Relatively at the above mentioned eradication progresses of *brucella abortus*, *melitensis* and *suis* regarding the establishments keeping bovine-buffalo population, the Regions with territories where the program is applied have declared the following targets:

ABRUZZO Region: the Provinces of Teramo, L'Aquila and Chieti have registered in the last three years the following results of prevalence and established the below indicate target:

2019 – 0.00%, 2020 - 0.00% 2021 0.00, target 2023 0.00%;

2019 - 0.11%, 2020 – 0.12%, 2021 – 0.37%, target 2023 0.00%;

2019 - 0.21%, 2020 – 0.36%, 2021 – 0.39%, target 2023 0.00%;

Teramo request in 2022 has been assessed by the Commission and is in course of achieving the free status.

## Standard requirements for the submission of programme for eradication, control and surveillance

BASILICATA Region: the Provinces of Potenza and Matera have registered in the last three years the following results of prevalence and established the below indicate target:

2019 - 1.04%, 2020 – 0.90%, 2021 – 0.09%, target 2023 0.00%;

2019 - 0.20%, 2020 – 0.20%, 2021 – 0.00%, target 2023 0.00%;

2) CALABRIA Region: the Provinces of Crotona, Vibo Valentia, Cosenza, Catanzaro e Reggio Calabria have registered in the last three years the following results of prevalence and established the below indicate target:

2019 0.51%- 2020 - 0.18%, 2021 – 0.00%, target 2023 – 0.00%;

2019 – 0.00%, 2020 – 0.00%, 2021 0.08%, target 2023 0.00%;

2019 0.56%, 2020 - 0.20%, 2021 – 0.19%, target 2023 0.00%;

2019 0.63%, 2020 - 0.00%, 2021 – 0.24%, target 2023– 0.00%;

2019 0.24%, 2020 - 0.00%, 2021 – 0.00%, target 2023– 0.00%;

CAMPANIA Region BOVINE, the Provinces of Salerno and Caserta have registered in the last three years the following results of prevalence and established the below indicate target

2019 1.71 % 2020 – 0.78%, 2021 – 1.23%, target 2023 – 0.71%;

2019 0.93 %- 2020 – 0.58%, 2021 – 0.11%, target 2023 – 0.06%;

CAMPANIA Region BUFFALO, the Provinces of Salerno and Caserta have registered in the last three years the following results of prevalence and established the below indicate target

2019 11.47%- 2020 - 14.83%, 2021 – 17.70%, target 2023 – 13.51%;

2019 3.18%- 2020 - 0.88%, 2021 – 1.55%, target 2023 – 0.76%;

3) MOLISE the Provinces of Isernia have registered in the last three years the following results of prevalence and established the below indicate target:

2019 2.97%- 2020 – 5.80%, 2021 – 0.12%, target 2023 – 0.00%; INSERIRE TARGET

4) PUGLIA Region: the Province of Taranto and Foggia have registered in the last three years the following results of prevalence and established the below indicate target:

2019 - 0.15%, 2020 – 0.14%, 2021 – 0.42%, target 2023 - 0.00%,

2019 - 4.00%, 2020 – 3.68%, 2021 – 5.03%, target 2023 -3.00%.

5) SICILY Region: the Provinces of Agrigento, Caltanissetta, Catania, Enna, Messina, Palermo, Ragusa, Syracuse and Trapani have registered in the last three years the following results of prevalence and established the below indicate target:

2019 – 0.22%, 2020 – 0.00%, 2021- 0.00%, target 2023 0.00 %;

2019 – 1.72%, 2020 – 0.58%, 2021- 0.35%, target 2023 0.00 %;

2019 – 2.76%, 2020 – 5.01%, 2021- 5.29%, target 2023 2.21 %;

2019 – 2.15%, 2020 – 2.82%, 2021- 0.92%, target 2023 0.77 %;

2019 – 7.76%, 2020 – 9.85%, 2021- 6.24%, target 2023 1.85 %;

2019 – 0.32%, 2020 – 0.52%, 2021- 0.62%, target 2023 0.28 %;

2019 – 0.44%, 2020 – 0.00%, 2021- 0.00%, target 2023 0.00 %;

2019 – 1.75%, 2020 – 2.62%, 2021- 2.57%, target 2023 1.63 %;

2019 – 0.80%, 2020 – 0.00%, 2021- 0.00%, target 2023 0.00 %;

The process of the eradication of brucella abortus in bovine - buffalo is going forward in Italy also in territories of some regions considered "hot spot", as the Province of Cosenza in Calabria as shown by the



## Standard requirements for the submission of programme for eradication, control and surveillance

data of the last five years (prevalence 0.19% in 2021, 0,20% - 2020, 0,56% - 2019, 0.67% - 2018, 1,17% - 2017, 1,01%- 2016,) in Messina in Sicily (6,24% - 2021, 9,85% - 2020, 7,76 % - 2019, 5,69 % - 2018, 9,70% - 2017, 8,71% - 2016) and for the bovine population in Province of Salerno in Campania (0,58% - 2020, 0,93 % - 2019, 2,15 % - 2018, 1,80 % - 2017, 3,02%- 2016). Different the situation in Campania region for the buffalo population in the Province of Caserta where is registered an increasing of the prevalence (17.70%-2021, 14,83% - 2020, 11,47 % - 2019, 6,29 % - 2018, 3,76 % - 2017, 3,06 - 2016) for bovine of the Provinces in the area of Gargano in Puglia (prevalence 5,03% in 2021 3,68% - 2020, 4,0% - 2019, 4,09% - 2018, 4,79% 2017, 6,79 %- 2016)

The Sicily Region, has registered a general improvement, but still has the highest value of prevalence of Italy.

Considered the prevalence of *Brucella abortus melitensis* and *suis* registered in 2021 in Province of Caserta in the buffaloes population, the Campania Region after consultation of the Stakeholders has decide to use the vaccination to front off the further diffusion of the infection. The protocol of vaccination has been elaborate by the National Centre of Reference and the Ministry of Health transmitted it to the Commission for approval. The DGSANTE with letter 3402468 of 03 May 2022 have communicate at The Ministry of Health that has taken note of these changes to the already approved eradication programme 2022 and that find acceptable that them to become part of the Italian approved programme that now includes vaccination in the cluster of infection in Province of Caserta.

### 4.2 Organisation, supervision and role of all stakeholders involved in the programme

*Describe 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.

(max. 32000 chars) :

Following the description of the organization and the roles of the parties involved in the eradication program:

- 1) Ministry of Health: this is the central body of the National Health Service. It is responsible for health policy and planning, setting targets for improving the health of the population, and determining the uniform levels of care to be provided to all citizens throughout the country. The Directorate-General for Animal Health and Veterinary Medicine has responsibility for the Animal Health area.
- 2) Regional Health Departments (Assessorati Regionali alla Sanità): these are the bodies responsible for health protection services and activities within their region. They are also responsible for planning the measures to be implemented by coordinating the activities of the ASLs and monitoring their work.
- 3) Local veterinary service (Aziende Sanitarie Locali – ASLs, Aziende Sanitarie Provinciali - ASP) are the units operating on the ground. They ensure the levels of assistance in their geographical areas by means of their own services. They are under the administrative and financial control of the Regions but enjoy wide operational autonomy.
- 4) Laboratories (Istituti Zooprofilattici Sperimentali – IZSS): these are public-law health bodies with operational and administrative autonomy and are the technical and operational arm of the national health service, particularly as regards animal health, monitoring the quality and fitness for consumption of foodstuffs of animal origin, farm hygiene and the proper relationship between human settlements, animals and the environment.

## Standard requirements for the submission of programme for eradication, control and surveillance

By means of ring trials involving the main laboratory and the provincial diagnostic centres, each IZS ensures that brucellosis is diagnosed in a uniform manner in its geographical area. The National Reference Centre for Brucellosis organises annual ring trials involving Italy's ten IZSs. By means of the Ministerial Decree of 4 October 1999, Abruzzo and Molise IZS, which has its headquarters in Teramo, was designated the National Reference Centre for Brucellosis. Further information on the Ministry of Health and, in particular, on the Directorate-General for Animal Health and Veterinary Medicine is available at <http://www.salute.gov.it/>

In Italy, the eradication plan for *brucella abortus*, *melitensis* and *suis* for what concern the bovine-buffalo population kept in establishments is compulsory. The information and programming from the operators are carried out by local veterinary authorities operating in the area. In some Region the official vet involve liberal vets to collect the blood samples in the field with conventions and different contracts depending on the Regions concerned. Farmers collaborating to the program, creating favorable conditions for the work of veterinary (animal capture, restraint, etc.).

The supervision of traceability monitored by the competent local veterinary service by the DASHBOARD present in the Italian veterinary system (VETINFO) based on the electronic certificate for movement of bovine-buffalo provided for in the Italian Legislative Decree 5 August 2022, n. 134 art. 10.

### 4.3 Description and demarcation of the geographical and administrative areas in which the programme is to be implemented

*Describe territorial scope with a description and demarcation of the geographical and administrative area 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.*

(max. 32000 chars) :

The programs will be apply to the whole of Italy, taking account of the epidemiological differences found in the various areas of the country. Regions and provinces that have obtained officially disease-free status will adopt specific regional surveillance and control programmes. Although these specific surveillance programmes are part of this national plan for the eradication of brucellosis in bovine-buffalo no EU cofinancing has been requested for them. The 7 regions that are still performing the eradication program to obtain the status of free are indicated in the maps. (ANNEX 1 maps).

### 4.4 Description of the measures of the programme

*A comprehensive description needs to be provided of all measures and detailed reference must be made to Union legislation. The national legislation in which the measures are laid down is mentioned.*

#### 4.4.1 Notification of the disease

(max. 32000 chars) :

As consequence of the application of the 21 April 2021 of the EU Animal health Law, required notification is provided for in Article 18(1) of Regulation (EU) 2016/429; and by Reg. 689/2020 as indicated in PART II SURVEILLANCE, ERADICATION PROGRAMMES, DISEASE-FREE STATUS, CHAPTER 1,

## Standard requirements for the submission of programme for eradication, control and surveillance

Surveillance, Section 1, Design of surveillance, Targeted animal population and diagnostic methods, Article 3, point 1 (i).

The Ministry of Health has put in place a veterinary general surveillance system (VETINFO) for the notification and investigations of outbreaks in targeted animal population for the bovine buffalo brucellosis program.

In particular regarding the notification of the *b.abortus*, *melitensi* and *suis* for what concern the bovine buffalo population kept in establishments, the extension of 6 June 2017, of the Ministerial Ordinance of 28 May 2015, has provided that in the event of suspicion or confirmation of the presence of *brucella abortus* in an establishment with "status free without vaccination" or "status free with vaccination", the veterinary service, excluding the application of what provided for in the European veterinary health measures currently in force, provides for that:

- a) within two days of the suspension of officially free herd status without or with vaccination following suspicion of positivity for bovine-buffalo brucellosis in establishment, starts the epidemiological investigation, inserts in the national information system for the notification of animal diseases (SIMAN), the reason for the suspicion of positivity and any other data available;
- b) after starting the epidemiological investigation, acquires the first findings relating to clinical and/or pathological examinations and/or serological checks and/or microbiological tests and/or epidemiological links, inserts them in SIMAN, confirms or not the outbreak and, if confirmed, continues the investigations using the collaboration of the regional epidemiological observatory, where present, or the competent Laboratory (IZS) for territory to identify strategies for the rapid extinction of outbreak and containment of the infection and to determine the causes of its origin;
- c) within two days from the confirmation of positivity, it withdrawn the status of establishment free without vaccination or free with vaccination or, in case of confirmation not preceded by suspicion, starts the epidemiological investigation in the SIMAN and, in any case, continues the epidemiological investigation with the collaboration of the regional epidemiological observatory, where present, or the Laboratory competent for the territory;
- d) simultaneously with the withdrawal of the status, orders the notification of the withdrawal to the breeder and the obligation to slaughter the animals declared infected within 15 days;
- e) Reports the measures adopted to the "human public health office" of the territorially competent local health authority to inform them of the case of a zoonosis outbreak;
- f) within two days from the exclusion of the suspicious or from the extinction of the outbreak, it inserts the deletion in the SIMAN of the unconfirmed suspicion or the extinction of the outbreak and give the status of establishment free without vaccination or with vaccination in accordance with current European legislation.

### 4.4.2 Target animals and animal population

*Describe 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 to be applied in accordance with Article 19 of Delegated Regulation (EU) 2020/689 at 31 December;*

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

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

*(d) information as regards the epidemiological situation in additional animal populations, where relevant. (max. 32000 chars) :*

The *B. abortus*, *melitensis* and *suis*, *melitensis* and *suis* is still present in seven regions of Italy (see ANNEX maps).

ABRUZZO: Province of l'Aquila, and Chieti, BASILICATA: all region, CALABRIA: all region, CAMPANIA: provinces of Caserta and

# Standard requirements for the submission of programme for eradication, control and surveillance

Salerno, MOLISE: province of Isernia, PUGLIA: province of Foggia and Taranto and SICILIA: all region.

a) The number of establishments (year 2021) keeping bovine buffalo by health status are the following:

ABRUZZO: total number of establishment - 2.733, free establishments- 2.726, infected 0, Unknown 6;  
BASILICATA: total number of establishment - 2.518, free establishments - 2.518, infected 0, Unknown 0;  
CALABRIA: total number of establishment - 6.910, free establishments - 6.809, Infected 2, Unknown 45;  
CAMPANIA bovine: total number of establishment - 4.149, free establishments - 4.095, Infected 13, Unknown 10;  
CAMPANIA buffalo: total number of establishment - 1.058, free establishments - 965, Infected 47, Unknown 1;  
MOLISE: total number of establishment - 593, free establishments - 593, Infected 0, Unknown 0;  
PUGLIA: total number of establishment - 1.655, free establishments - 1.600, Infected 13, Unknown 7;  
SICILIA: total number of establishment - 9.380, free establishments - 9.234, Infected 50, Unknown 2;

b) Status of the establishment and the animals under program (year 2020):

ABRUZZO: total number of animals under the program - 54.950, free animals - 54.903, infected 0, Unknown 32;  
BASILICATA: total number of animals under the program - 101.738, free animals- 101.738, infected 0, Unknown 0;  
CALABRIA: total number of animals under the program – 119.246, free animals- 118.244, infected 233, Unknown 216;  
CAMPANIA: total number of bovine under the program 90.046 , free animals - 88.565, infected 688, Unknown 101;  
CAMPANIA: total number of buffalo under the program 296.459, free animals - 264.228, infected 16.996, Unknown 196;  
MOLISE: total number of animals under the program 16.658, free animals - 16.658, infected 0, Unknown 0;  
PUGLIA: total number of animals under the program - 98.473, free animals- 95.841, infected 519, Unknown 447;  
SICILIA: total number of animals under the program 342.056, free animals - 335.840, infected 2.635, Unknown 6;

c) See annex (1 MAPS)

d) no relevant.

## 4.4.3 Identification of animals and registration of holdings including detailed reference to relevant Union legislation and its implementation in the Member State for this disease

(max. 32000 chars) :

Until the publication of the implementing Italian legislative decree and the operating manual, and therefore until the reorganization of the entire Identification & Registration system, continue to be apply the following indications:

- i) the provisions currently in force for the identification of cattle, approved before 21 April 2021, as permitted by Article 20 of the Implementing Regulation (EU) 2021/520 which, until 21 April 2023, provides for the possibility of maintaining identification means provided before the application of the Regulation;
- ii) as regards the maximum recording time in the computer database set up for cattle of the information referred to in Article 112, letter d) and 113, paragraph 1, letter c) of the Regulation, the provisions of referred to in Article 3, paragraph 1, of the aforementioned Regulation referred to in document SANCO / 11123 2018 CIS published in the Official Journal of the EU;
- iii. the provisions currently in force for registries other than those referred to in the previous point;
- iv. the sanctions provided for by the current provisions on the zootechnical registry of the various species as well as, as applicable, the measures provided for by articles 137 and 138 of Regulation (EU) 2017/625 and the provisions of the legislative decree of February 2, 2021 n. 27.

### ANIMALS

Regulation (EC) No 21/2004 defines the procedures for identifying bovine and buffalo.

The Local Veterinary Service (ASL/ASP) assign an identification code to holdings and take care of their registration. Animals are identified individually, except those intended to be slaughtered before the age of 12 months, which are identified by the holding's code only.



## Standard requirements for the submission of programme for eradication, control and surveillance

When animals are moved, electronic Form 4 must be completed (Ministerial Decree 28 June 2016). This form contains information on the origin and destination of the consignment, the necessary health information and, where relevant, any health restrictions that apply to the animals or to their holding of origin.

In implementing the eradication programme, the official veterinarians check on the correct registration of holdings and identification of animals.

### HOLDINGS

Decree No 317/96, transposing Directive 92/102/EEC, lays down the rules for the compulsory registration of all bovine- buffalo holdings with more than three animals of these species. However, it should be noted that Ministerial Decree No 453/92 requires disease prevention operations to be carried out on all holdings, even those not subject to compulsory registration.

The ASL veterinary service allocates the farms an identification number and takes care of the relevant registration. +++"Each animal is identified by an individual number made up of the identification number of the holding, on an ear tag or by electronic disposal (ear tag/endoruminal bolus)".

In implementing the eradication programme, the official veterinarians check on the correct registration of holdings and identification of animals.

Reg. 1505/2006 provides a minimum level of annual inspections of at least 3% of farms and at least 5% of the animals in the area of competence, for the purposes of verifying the correct application of the system of identification and registration of bovine-buffalo. The control registers is carried out by ASL during operations prophylaxis.

With a note of DGVA.VIII / 22577 / PI.5.i / 8 of 13 June 2006 the Ministry of Health has confirmed the minimum level of checks required by the said Regulation and issued a specific check list in order to standardize the methods for carrying out farm controls as bovine and buffalo.

The selection of the establishments that are inspected annually shall be based on risk analysis and is based on the following risk criteria:

- Number of animals
- Implications for human and animal health, in particular the existence of previous outbreaks
- Amount of annual premiums required and / or paid to the holding, compared with the amount paid the previous year;
- Significant changes in comparison with situations in previous years.

### 4.4.4 Qualifications of animals and herds including detailed reference to relevant Union legislation and its implementation in the Member State for this disease

(max. 32000 chars):

In accordance with the Reg. (UE) 429/2016 and with the Reg. (UE) 689/2020 all establishment must achieve disease-free status without vaccination or disease-free status with vaccination (in provinces in which vaccination will be eventually planned, if vaccinated animals are present).

In particular the Annex IV of the Reg. (UE) 689/2020 at the part 1, chapter 1, section 1 specify the rule for the granting of the status of Establishment free from infection with *B. abortus*, *melitensis* and *suis* without or with vaccination:

1. The status free from infection with *B. abortus*, *melitensis* and *suis*, *melitensis* and *suis* without or with vaccination may only be granted to an establishment keeping bovine-buffalo animals if:

- (a) during the past 12 months there has been no confirmed case of infection with *B. abortus*, *melitensis* and *suis* in bovine or buffalo animals kept in the establishment;
- (b) the entire bovine-buffalo animals over 12 months of age present in the establishment at the time of sampling have tested negative to serological test, on two occasions as follows:

## Standard requirements for the submission of programme for eradication, control and surveillance

- (i) the first test must be carried out on samples taken not earlier than 3 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 samples taken not earlier than 6 months and not later than 12 months following the date of sampling referred to in point (i);
- (c) animals showing clinical signs consistent with infection with *B. abortus*, *melitensis* and *suis*, such as abortions, have been subjected to investigations with negative results;
- (d) since the beginning of the sampling referred to in point (b)(i) all bovine-buffalo introduced into the establishment originate from establishments free from infection with *B. abortus*, *melitensis* and *suis* without vaccination, or free with vaccination and have not been vaccinated against infection with *B. abortus*, *melitensis* and *suis* during the past 3 years, and
  - (i) originate from a Member State or a zone free from infection with *B. abortus*, *melitensis* and *suis*, *melitensis* and *suis* for the relevant animal population;
  - (ii) are entire bovine-buffalo over 12 months of age and must have tested negative in a serological test carried out on a sample taken:
    - during the 30 days prior to their introduction into the establishment; or
    - during the 30 days following their introduction provided they have been kept isolated during this period; or
    - (iii) are post-parturient females kept in isolation since their introduction into the establishment until they have tested negative in a serological test carried out on a sample taken not earlier than 30 days after parturition; and
- (e) since the beginning of the sampling referred to in point (c)(i), all germinal products of bovine-buffalo origin introduced into or used in the establishment originate from:
  - (i) establishments free from infection with *B. abortus*, *melitensis* and *suis*, *melitensis* and *suis* without vaccination; or
  - (ii) approved germinal product establishments.

### 4.4.5 Rules of the movement of animals including detailed reference to relevant Union legislation and its implementation in the Member State for this disease

*Please detail also the rules existing for transhumance and common grazing areas, if any.*

*(max. 32000 chars) :*

The animal movements are in accordance with the Reg. (UE) 429/2016 and with the Reg. (UE) 688/2020 about the rules for the prevention and control of animal diseases transmissible to animals or to humans as regards movements within the Union of kept terrestrial animals.

In respect of what prescribed in the art. 10, chapter 2, section 1, point 1 (a,b,c) the Reg. (UE) 688/2020, operators shall only move kept bovine-buffalo to another Member State when the following requirements are fulfilled:

a) the animals have been continuously resident in the establishment for at least 30 days prior to departure, or since birth, if they are younger than 30 days of age, and during this period they have not been in contact with kept bovine animals of a lower health status or subject to movement restrictions for animal health reasons or with kept animals coming from an establishment which did not fulfil the

## Standard requirements for the submission of programme for eradication, control and surveillance

requirements set out in point (b);

(b) any animals entering the Union from a third country or territory during the last 30 days prior to the departure of the animals referred to in point (a), and introduced into the establishment where those animals were resident, are kept separate so as to prevent direct and indirect contact with all other animals on that establishment;

(c) the animals come from an establishment free from infection with *Brucella abortus*, *melitensis* and *suis*, without vaccination regarding bovine-buffalo animals, and one of the following conditions is fulfilled:

(i) the establishment is situated in a Member State or zone thereof with the status free from infection with *Brucella abortus*, *melitensis* and *suis* regarding the bovine- buffalo population;

or

(ii) the animals have been subjected to a test for infection with *Brucella abortus*, *melitensis* and *suis* with one of the diagnostic methods provided for in Part 1 of Annex I, carried out, with negative results, on a sample taken during the last 30 days prior to departure, and in the case of post-parturient females taken at least 30 days after parturition;

or

(iii) the animals are less than 12 months old;

or

(iv) the animals are castrated;

At integration of the above mentioned legislation for the animals movement Italy has provided for specific rules.

Only the electronic Form 4, available in the national database, authorizes all the animal's movements. Apart from being sent for slaughter, animals may be moved only if they come from establishment brucellosis-free without vaccination and brucellosis-free establishment with vaccination accompanied by Form 4. In all cases where the animals are not being sent to the slaughterhouse, the official veterinarian will fill the Form 4, indicating the date of the last inspection of the animals and the holding of origin, in addition to the health status of the establishment of origin.

Penalties are applied in the event of irregularities.

Each movement in the summer fields and communal grazing field is authorized by the Veterinary Services and all the authorization procedure is managed through the Information System.

The prorogation of the Ministerial Order 28 May 2015 states that only animals, originating from establishment brucellosis-free without vaccination or with vaccination, negative at the SAR and Fdc test for brucellosis, electronically identified and registered in the National Database, can be moved and in the not brucellosis-free territories, the animals are submitted to a diagnostic test for brucellosis during the previous 30 days.

In all the national territory and on a risk-based evaluation, the animals can be test for brucellosis during the 30 days before the re-entry from grazing too.

The Veterinary Services upon authorization verifies that territories destined to grazing are identify, geo-referenced and registered in the National Database.

In 2022, an accord between Regions has been approve for the regulation of movements of bovine-buffalo from territories not free to territories free (ANNEX 9). A special list is in preparation in National Data Base to insert all the data of the establishments that have the characteristics and the permission to move animals from territories not free to territories free.

The provision to be satisfied to be list are:

1. Favorable animal identification and registration situation (correct identification of all animals on the farm) at the last annual official control;
2. Uninterrupted possession of the free status of the establishment concerned in the last 2 calendar years;

## Standard requirements for the submission of programme for eradication, control and surveillance

3. Correct identification with endorumenal bolus of all bovine-buffalo on the establishment and their individual registration in National Data Base;
4. Checks on establishments: screening tests (RBT and CFT) negative for brucellosis carried out on all animals of the establishment (if these coincide with the scheduled date for a prophylaxis check, the test is valid for both purposes), in addition to the annual tests provided for in the eradication plan.

### 4.4.6 Tests used and sampling and testing schemes including detailed reference to relevant Union legislation and its implementation in the Member State for this disease (including herd frequency per region, animal coverage in each herd, interpretation rules of the test,...)

*For bovine tuberculosis, please detail how the quality/reliability of the skin-testing is ensured/verified (training and supervision of field veterinarians, recheck of some officially-free herds by the official veterinarians, quality insurance system in force if any, etc. ...)*  
*Please detail also how the surveillance of bovine tuberculosis is monitored in slaughter houses (Training of vets, monitoring of the lesions submission rates and positivity rates, link with the field vets in case of positive results, etc. ...)*

(max. 32000 chars) :

The official tests used in Italy are listed in the ANNEX III Section 1 of the Reg. (UE) 689 /2020. The antigen used for the Rose Bengal test is the same throughout Italy and is produced by Abruzzo and Molise IZS. The antigen used for the complement fixation test is the same throughout Italy, and is produced by Lombardy and Emilia-Romagna IZS. The quality of antigens is checked by the National Reference Centre for Brucellosis. The standardization of the antigens is carried out in accordance with the relevant Community provisions.

The Veterinary Medicine Laboratory (Istituti Zooprofilattici Sperimentali) are accredited according to ISO 17025 by the independent organization "Accredia" responsible for verifying the quality of the tests performed in Italy.

All official tests are performed at the Veterinary Medicine Laboratory responsible for each geographical area.

The procedure for the interpretation of the test SAR and CFT for bovine-buffalo brucellosis are summarize in ANNEX 1 of the prorogation of the Ministerial Order 28 may 2015.

The Rose Bengal test is used for screening bovine and buffalo herds in order to establish the status of establishment as officially brucellosis-free. The CFT is used as individual animal test in order to establish the suspension of the status of establishment in case of positivity to RBT.

In other terms the diagnostic procedure provides for performing of Rose Bengal test on all the animals in the establishment. The animals resulted positive to Rose Bengal test are tested with CFT in order to confirm the positivity.

If one or more animals result positive to the CFT, the holding is declared suspected, the status of the establishment is suspended the local veterinary service start the epidemiological investigation and perform other clinical, serological, antigenic, bacteriological investigations to confirm or not the outbreak (art. 7, 8 and 9 of EU Reg, 689/2020).

The bacteriology is used for the differential diagnosis in case of abortion or with the aim of isolating the circulating B. abortus, melitensis and suis, melitensis and suis strain strain.

In addition the animal positive slaughtered are sampled for a bacteriological examination.

The results of all the above examination are considered in an epidemiological investigation that, has provided for in the art. 5 of the M.O. 28 may 2015, the local veterinary service started already at the suspect of the outbreak following apposite guide line (ANNEX 3).

The epidemiological investigation consider:

- a) clinical signs\*;
- b) the results of the laboratory analysis (serological e microbiological);



## Standard requirements for the submission of programme for eradication, control and surveillance

c) the analysis of the data, present in the informatic veterinary system (VetINFO) related to status of the establishment, identification of the animals, movement of the animals, persons, tools, epidemiological link with other establishment, link with the dealers, food and water supply.

\*The clinical surveillance for bovine-buffalo brucellosis in Italy is based on the detection of abortion. The net of surveillance is based on:

a) the competent veterinary services distributed in all the 107 Italian Provinces;

b) The 10 Public Laboratory (Istituti Zooprofilattici) that cover all the 20 Italian Regions.

The clinical surveillance of brucellosis starts with the communication of abortion by the breeder, as provided for in art. 11 of the Italian Decree 5 August 2022 n° 136, to the competent veterinary service that samples (foetus, organs and lochia) and sends to the laboratory for analysis and isolation of brucella. In case of positive result the competent veterinary authority performs the serological control of all the animals susceptible to the disease present in the establishment.

### 4.4.7 Vaccines used and vaccination schemes including detailed reference to relevant Union legislation and its implementation in the Member State for this disease

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

*(max. 32000 chars) :*

The use of vaccination with the RB51 strain in the Campania Region, is specific to the infection cluster municipalities of Cancellaro and Arnone, Castel Volturno, Grazzanise and Santa Maria la Fossa, municipalities in which 84% of the outbreaks occurred are concentrated in the past 6 years. Subsequently, in the closer municipalities, which act as a "buffer" to the infection cluster municipalities, and identified in the municipalities of Villa Literno, Pignataro Maggiore, Carinola, Capua, Francolise, Mondragone and San Tammaro, the vaccination is applied voluntarily always with the strain RB51. The plan, elaborated by the Campania Region, to front off the cluster of infection of brucella abortus, melitensis and suis in the kept buffalo population in the cluster of Caserta Province, has been submitted and approved by the EU Commission.

As part of the mandatory program for the eradication of infectious diseases of the bovine and buffalo species pursuant to art. 54 of the Reg. Del. 689/2020 "Vaccination", the Campania Region includes in the eradication program, under its supervision:

a) compulsory vaccination with the RB51 strain of subjects aged between 6 and 9 months of the buffalo species present in establishments falling within the common infection clusters;

b) the optional vaccination with the RB51 strain of subjects aged between 6 and 9 months of the buffalo species present in the establishments falling within the "buffer" municipalities around the common infection clusters.

The Campania Region, on the basis of the epidemiological trend, can extend the vaccination compulsory at establishments that result infected in buffer zones that could become a clustered area of infection over time as in any other cluster area that should occur in the province of Caserta.

The brucella infection control strategy in the eradication program set out in Chapter II is based on:

c) on the implementation of specific measures for disease referred to in Articles 18 to 31 of Reg. Ce 689/2020, until all the establishments concerned achieve disease-free status;

d) on the granting, suspension and withdrawal by the competent authority of the disease-free status of all the establishments concerned;

## Standard requirements for the submission of programme for eradication, control and surveillance

- e) on the implementation of biosecurity measures and other risk reduction measures;
- f) on the implementation of vaccination programs.

With regard to the use of vaccination with the RB51 strain as a tool to reduce the spread of Brucella in areas with a high level of prevalence and incidence, the provisions of Chapter 4.4 of the International Animal Health Code (OIE) are respected; therefore an eradication plan with vaccination will be prepared, in compliance with the "zoning / compartmentalisation" criterion.

The decision to introduce vaccination takes into account some fundamental concepts, namely:

- For the purposes of acquiring the qualification of "BRC-free area", an interruption of the vaccination program for at least three years will be necessary (Annex IV, Chapter 3, section 1, letter d) of EC regulation 2020/689).

### 4.4.8 Information and assessment on bio-security measures management and infrastructure in place in the holdings involved.

*Please detail also the situation as regard to this disease in the wildlife, and explain the surveillance and control measures in wildlife if any, and the coordination between the stakeholders involved (hunters, farmers, official service labs, vets, etc ...)*

*(max. 32000 chars) :*

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, melitensis and 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, melitensis and suis as regards kept bovine-buffalo 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.

2. The status of a Member State or a zone free from infection with Brucella abortus, as regards kept bovine and buffalo is not affected by the confirmation of infection of Brucella abortus in an animal population other than kept bovine and buffalo provided that effective measures have been implemented, and are periodically assessed, to prevent transmission of infection with Brucella abortus, to kept bovine and buffalo animals.

The local competent veterinary service elaborate a specific risk assessment/management in other species depending on the type of production, type of breeding, prevalence registered in the area, movement, status, distance from cluster of infection, presence of other species susceptible, presence of wild animal.

To harmonize the measure of biosecurity of the establishment of bovine-buffalo in all National territories, the Ministry of Health is preparing a specific Decree on biosecurity art 10 Legislative Decree n° 136 – 5 August 2022.

### 4.4.9 Measures in case of a positive result including detailed reference to relevant Union legislation and its implementation in the Member State for this disease

*A description is provided of the measures as regards positive animals and detailed reference to the Union legislation provisions (slaughter, destination of carcasses, use or treatment of animal products, the destruction of all products which could transmit the disease or the treatment of such products to avoid any possible contamination, a procedure for the disinfection of infected holdings, a procedure for the restocking with healthy animals of holdings which have been depopulated by slaughter. A definition of a suspicion and of a confirmation should be provided, with detailed measures implemented in both situation and how the herd is requalified as free after a positive result. Detailed information should also be provided as regard the epidemiological investigations done, and the additional laboratory tests foreseen (culture, PCR, IFGamma, etc ...). Please mention if national guidelines are available.*

# Standard requirements for the submission of programme for eradication, control and surveillance

(max. 32000 chars) :

Following the synthesis of the measures put in place in case of positive animals and detailed reference to the union legislation provisions.

Slaughter.

As provided for in the prorogation of the Ministerial Order 28 May 2015, the animals testing positive will be identified within two days of notification, of a positive result, by means of a rumen bolus and then be slaughtered within 15 days of the official notification of a positive result.

Destination of carcasses.

The carcasses after veterinary inspection are designate to human consumption.

Use or treatment of animal products.

As provided for in the art. 28 of the (EU) REG. 689/2021 the milk from confirmed cases shall either be fed only to animals in the same establishment after it has been processed to ensure the inactivation of the disease agent, or it shall be disposed of;

Destruction of all products, which could transmit the disease.

In according to the art. 28 of the (EU) REG. 689/2021 point 1 (b), manure, straw, feed or any other matter and substance which has come into contact with a confirmed case or with contaminated material is collected and disposed of as soon as possible or, following an appropriate risk assessment, stored and processed to reduce to an acceptable level the risk of spreading of the disease.

Furthermore according the art. 28 of the (EU) REG. 689/2021 point 2 in the event of infection with B. abortus, melitensis and suis, melitensis and suis, the competent authority order that in all infected establishments fetuses, still-born animals, animals which have died from the disease after birth and placentae must be collected and disposed of.

A procedure for the disinfection of infected holdings.

In according with the art. 30 of the (EU) REG. 689/2021, the local veterinary authority order the operators of all infected establishments and those receiving animals from infected establishments the cleaning and disinfection or, where relevant, the safe disposal of:

- (a) all parts of the establishments that may have been contaminated after the removal of the confirmed and suspected cases and before repopulation;
- (b) any feed, materials, substances, husbandry related equipment, medicinal equipment and production related equipment that may have been contaminated;
- (c) any protective clothing or safety equipment used by operators and visitors;
- (d) all means of transport, containers and equipment after the transport of animals or products from infected establishments;
- (e) loading areas for animals after each use.

2. The local veterinary authority approve the protocol for the cleaning and disinfection.

3. The local veterinary authority supervise the cleaning and disinfection, or where relevant, the safe disposal and do not restore or grant again disease-free status to the establishment until it considers that the cleaning and disinfection, or where relevant, the safe disposal, has been completed.

4. The local veterinary authority may, based on a risk assessment, regard a pasture as contaminated and prohibit its use for kept animals of higher health status than that of the targeted animal population or, if epidemiologically relevant, additional animal populations, for a period of time sufficient to consider the risk of persistence of the disease agent to be negligible.

A procedure for the restocking with healthy animals of establishment which have been depopulated by

## Standard requirements for the submission of programme for eradication, control and surveillance

slaughter.

The prorogation of Ministerial Order at the annex 2 has provided for specific indications, to the region, for apply the stamping out. These indications should take in account the clinical signs (abortion), the prevalence of serological positivity, the isolation of *Brucella* spp., the recrudescence of the positivity in the herds.

"Guidelines stamping-out".

In case of an outbreak of bovine-buffalo brucellosis the stamping out, can be applied considered the following items:

- h. a positivity rate of animals more than 5% at the time of the check;
- i. positivity in two consecutive controls, after the opening of the outbreak;
- j. the livestock health situation in the last two years, paying attention in particular to the causes of the persistence of the infection and the origin of the infection;
- k. the isolation of *Brucella* spp.;
- l. the risk of spreading to other farms, also in relation to the type of handling of animals or in relation to the type of farming (pasture stray and / or tethering);
- m. failure to comply with current regulations related to: the frequency of tests; the movimentation to mountain grazing / pasture / grazing/ wandering animals; the animals identification, the controls, the lack of cooperation in the activities of prophylaxis prescribed by this decree; as well as the killing of Positive animals within the prescribed period.
- n. the health status of the adjacent territory.

After culling of all the infected animals and before the farm is restocked, the pens and other buildings used to house the animals, as well as the containers, equipment and tools used for the animals, must be cleaned and disinfected under official supervision; the veterinarian will issue the certificate of disinfection. The pasture previously used by those animals cannot be reused for 60 days after they have been removed. All means of transport, containers and equipment must be cleaned and disinfected, under official supervision.

The bovine-buffalo for the repopulation of the establishment should originate from establishments free from infection with *Brucella abortus* without vaccination, or free with vaccination and have not been vaccinated against infection with *B. abortus*, *melitensis* and *suis* during the past 3 years, and (i) originate from a Member State or a zone free from infection with *Brucella abortus*, for the relevant animal population; or

(ii) are entire bovine buffalo animals over 12 months of age and must have tested negative in a serological test carried out on a sample taken:

— during the 30 days prior to their introduction into the establishment; or

— during the 30 days following their introduction provided they have been kept isolated during this period;

or

(iii) are post-parturient females kept in isolation since their introduction into the establishment until they have tested

negative in a serological test carried out on a sample taken not earlier than 30 days after parturition.

A definition of a suspicion and of a confirmation should be provided, with detailed measures implemented in both situation and how the herd is requalified as free after a positive result.

An establishment keeping bovine or buffalo is suspected of infection with with *B. abortus*, *melitensis* and *suis* without vaccination or with vaccination if:

a) serological testing are not carried out with negative results on samples taken from:

(i) all entire bovine-buffalo over 12 months of age at appropriate intervals of not more than 12 months determined by the competent authority, taking into account the type of production, the situation of the disease and the identified risk factors; or



## Standard requirements for the submission of programme for eradication, control and surveillance

(ii) entire bovine-buffalo over 12 months of age kept in establishments located in a Member State or in a zone free from infection *B. abortus*, *melitensis* and *suis* in accordance with a testing regime set up taking into account the type of production and the identified risk factors.

or

a case of infection with *B. abortus*, *melitensis* and *suis* is suspected in a bovine-buffalo animal kept in the establishment.

or when the following requirements are not fulfilled:

(a) during the past 12 months there has been no confirmed case of infection with *B. abortus*, *melitensis* and *suis* in bovine-buffalo animals kept in the establishment;

(d) animals showing clinical signs consistent with infection with *B. abortus*, *melitensis* and *suis* such as abortions,

have been subjected to investigations with negative results;

(e) since the beginning of the sampling referred bovine-buffalo animals introduced into the establishment originate from establishments free from infection with *B. abortus*, *melitensis* and *suis* without vaccination, or free with vaccination and

(i) originate from a Member State or a zone free from infection with *B. abortus*, *melitensis* and *suis* for the relevant animal population;

(ii) are entire bovine-buffalo over 12 months of age and must have tested negative in a serological test carried out on a sample taken:

— during the 30 days prior to their introduction into the establishment; or

— during the 30 days following their introduction provided they have been kept isolated during this period;

or

(iii) are post-parturient females kept in isolation since their introduction into the establishment until they have tested negative in a serological test carried out on a sample taken not earlier than 30 days after parturition; and

(f) all germinal products of bovine origin introduced into or used in the establishment originate from:

(i) establishments free from infection with *B. abortus*, *melitensis* and *suis* without vaccination; or

(ii) approved germinal product establishments.

g) there are no epidemiological link with an outbreak of *brucella abortus*, *melitensis* and *suis*;

Furthermore, in accordance with the Ministerial Order 28 May 2015, the local veterinary authority in cases of suspected replacement of animals, suspected identification alteration, suspected unauthorized movement, suspected malicious spread of infectious disease or suspected unauthorized vaccination or suspected use of pharmacologically active substances designed to mask the results of diagnostic tests, suspends the status of "establishment free without vaccination or with vaccination" of the holding concerned and any compensation procedures in progress and carries out all the checks deemed necessary.

An animal is confirmed infected with *brucella abortus*, *melitensis* and *suis* when: from his abortion or if slaughtered from his carcass is isolated the *brucella* spp. As well as is considered infected when show clinical sign (abortion) and result positive at RBT test and at CFT test.

An animal is suspected of *brucella abortus* when: show clinical sign (abortion), but give doubtful result: positive at RBT test and negative at CFT test.

Furthermore the bovine-buffalo kept in an outbreak, or in establishment linked with an outbreak are considered infected when result positive only at the RBT test.

In a confirmed outbreak all the positive bovine-buffalo are slaughtered and on their carcasses are done microbiological analysis to try to isolate the *brucella* spp. for genotyping useful for epidemiological

## Standard requirements for the submission of programme for eradication, control and surveillance

enquire purpose. In the Outbreak every 21 days the local veterinary authority perform controls on the rest of animal kept in the establishment with the purpose to remove all the animal positive till when the results of the of the serological tests, on the entire herds, result negative.

The status of free without or with vaccination is regained if the entire bovine-buffalo population over 12 months of age present in the establishment at the time of sampling have tested negative to serological test, on two occasions as follows:

- (i) the first test must be carried out on samples taken not earlier than 3 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 samples taken not earlier than 6 months and not later than 12 months following the date of sampling referred to in point (i);

Detailed information should also be provided as regard the epidemiological investigations done, and the additional laboratory tests foreseen.

Already at the suspicious the prorogation of a Ministerial Order 28 May 2015, provide for that within 2 days from the suspicious or positivity confirmation, the local Veterinary Service in collaboration with the regional Veterinary Service or the Local Laboratory (Istituto Zooprofilattico Sperimentale) have to carry out an epidemiological investigation with the objective of confirm, manage and close the outbreak as soon as possible, investigating the origin of the infection and verifying the possibility of any contact with other farms.

In the herds epidemiologically linked with the outbreak all, the susceptible animals are tested. The epidemiological investigation is register in the appropriate Information Systems (SIMAN) and according to the prorogation, of the Ministerial Order 28 May 2015 the person in charge of the Animal Health Veterinary Service verifies, at least every 4 months, the compliance of epidemiological investigations execution timing with the regulations in force. A special dashboard is in available on VETINFO to perform automatically the extraction of the data from the SIMAN System and perform analysis of the application of the programme.

### Identification of genetic clusters

Some research conducted at the National Center of Reference for Brucellosis has allowed the identification of genetic clusters with specific geographic spreads. It is important to note that some genetic clusters are exclusively present in some geographic areas as in some Sicilian and Calabrian provinces. In conclusion, the molecular epidemiology methodologies implemented by the National Reference Center allow to analyze the Brucella strains by determining their genetic variants and to report them to the global and local epidemiological context. This helps to support epidemiological investigations in order to determine the dynamics of outbreaks by monitoring their temporal evolution.

### 4.4.10 Compensation scheme for owners of slaughtered and killed animals

(max. 32000 chars) :

The value of the compensation is set and update annually, by the Ministry of Health, in agreement with the Ministry of Agricultural and the Financial Ministry, after market values have been determined (Article 6 of Law No 296/81).

In the decree, specific tables for bovine and buffalo, indicate the compensation to be paid to the different categories of animals subject to compensation (bull, cow, calf, etc.), considering their genetic value (whether registered or not in a genealogical book) and for adult animals taking into account their productive age at the time of slaughter (above or below 8 years of age). The value of the carcass that the farmer obtains from the slaughter of the animal does not affect the compensation, which remains

## Standard requirements for the submission of programme for eradication, control and surveillance

unchanged, however in case of destruction of the carcass it is considered to pay a higher compensation as indicated in the table of the decree for these cases. In any case the sum of compensation more carcass value, not pass the market value.

Furthermore, Law No 218/88 provides for increases (up to a maximum of 40% of the compensation due) if a high percentage of the stock has to be slaughtered.

The regions and the ASLs must take all the necessary measures to ensure compliance with the deadlines laid down in the art.8 of the Ministerial Order 28 May 2015, for paying compensation to farmers.

### 4.4.11 Control on the implementation of the programme and reporting including detailed reference to relevant Union legislation and its implementation in the Member State for this disease

*Please indicate also when the last FVO audit has taken place and provide a table listing the recommendations and the actions taken by the national authorities to this regard.*

*Please mention if a Task Force subgroup visit has taken place and the state of play as regards the implementation of the recommendations suggested if any.*

(max. 32000 chars) :

Commission Implementing Regulation (EU) 2002/2020 provides for the deadlines for Member States to submit eradication programmes and Union surveillance programmes.

At national level the Central Authority, the Regional Authority and the Local Authority monitor the implementation of the eradication programme.

The Ministerial Order 28 May 2015 provided all the measures for a correct monitoring of the plan: Programming, inserting of data, verification of the controls performed, using the veterinary informatics system (VETINFO). This system is composed from sub-systems that have different functionality:

-BDN, is the system where the veterinary services charge all the data for the identification of the establishments and for the identification of the animals. The animals are identified individually and electronically.

-SANAN, is the management system of the local veterinary Authority. In this system is inserted the programming of the activities at the beginning of the year and all the controls performed day by day during the year.

-SIMAN, is the system where the local veterinary Authority charge all the information regarding outbreaks and elaborate electronically the epidemiological enquire;

- SISTEMA CONTROLLI is the system where the local veterinary authority charge the data of the check list of the controls performed on dealers.

All the data inside these above mentioned, system are elaborated every week by a statistic program that give, to the local veterinary authority, the regional authority, laboratories (Istituti Zooprofilattici Sperimentali) and the Central Authority by a DASHBOARD, an analysis of the controls performed showing by specific indicators (prevalence, incidence, controls performed, dealers, movement checks, outbreaks, epidemiological enquires done, etc.).

The Ministerial Order 28 May 2015 provided for at the art, 12 that the local veterinary Authority perform every 4 months a check on the DASHBOARD, for the verification of the efficacy of the controls related at the application of the programme of eradication for brucella abortus.

Furthermore for the monitoring of the application of the program are performed Audits and inspections of the Ministry of Health on the Regional Authorities and by these, on the Local veterinary Authorities.

AUDIT FVO and actions taken to respond at the recommendations.

During the GENERAL FOLLOW-UP AUDIT held in Italy in March 2021 - ref 2021-7155 all the Recommendations regarding the Audit FVO on brucellosis program and TB program (2013-6979) have

## Standard requirements for the submission of programme for eradication, control and surveillance

been closed.

Commission Implementing Regulation (EU) 2002/2020 provides for the deadlines for Member States to submit eradication programmes and Union surveillance programmes.

At national level the Central Authority, the Regional Authority and the Local Authority monitor the implementation of the eradication programme.

The Ministerial Order 28 May 2015 provided all the measures for a correct monitoring of the plan: Programming, inserting of data, verification of the controls performed, using the veterinary informatics system (VETINFO). This system is composed from sub-systems that have different functionality:

-BDN, is the system where the veterinary services charge all the data for the identification of the establishments and for the identification of the animals. The animals are identified individually and electronically.

-SANAN, is the management system of the local veterinary Authority. In this system is inserted the programming of the activities at the beginning of the year and all the controls performed day by day during the year.

-SIMAN, is the system where the local veterinary Authority charge all the information regarding outbreaks and elaborate electronically the epidemiological enquire;

- SISTEMA CONTROLLI is the system where the local veterinary authority charge the data of the check list of the controls performed on dealers.

All the data inside these above mentioned, systems are elaborated every week by a statistic program that give, to the local veterinary authority, the regional authority, laboratories (Istituti Zooprofilattici Sperimentali) and the Central Authority by a DASHBOARD, an analysis of the controls performed showing by specific indicators (prevalence, incidence, controls performed, dealers, movement checks, outbreaks, epidemiological enquires done, etc.).

The Ministerial Order 28 May 2015 provided for at the art. 12 that the local veterinary Authority perform every 4 months a check on the DASHBOARD, for the verification of the efficacy of the controls related at the application of the programme of eradication for brucella abortus.

Furthermore for the monitoring of the application of the program are performed Audits and inspections of the Ministry of Health on the Regional Authorities and by these, on the Local veterinary Authorities.

AUDIT FVO and actions taken to respond at the recommendations.

During the GENERAL FOLLOW-UP AUDIT held in Italy in March 2021 - ref 2021-7155 all the Recommendations regarding the Audit FVO on brucellosis program and TB program (2013-6979) have been closed.

### 5. Benefits of the programme

*A description is provided of the benefits of the programme on the economical and animal and public health points of view. Describe*

- progress expected compared to the situation of the disease in the previous years, in line with the objectives and expected results
- cost efficiency of the programme including management costs

*(max. 32000 chars):*

The eradication programme makes provision for specific costs of the services of self-employed veterinarians, reimbursement of the Laboratories (IIZZSS) that carry out the serological tests, the disinfection of premises on infected holdings and compensation to farmers for animals slaughtered during the eradication operations.



## Standard requirements for the submission of programme for eradication, control and surveillance

Progress are register in the application of the program. Further territories have been assess as free by the EU Commission and in particular some provinces of the center and south of Italy: Teramo in Abruzzo Region and Vibo Valentia in Calabria Region. This are waiting to be list in the Delegate Regulation 620/2021.

The declaration of OBF of the new italian territories will bring a large numbers of benefit at the Country in terms of: trade of the animal products that will increase; movements of animals and animal products that will be facilitated; veterinary resource that may be addressed to eradicate the disease in the hot spot. All this benefits will anyway bring at the principal target of the eradication of the disease that means the availability of higher quality, safer foodstuffs, which will eliminate the negative impact of this zoonosis on human health.

# Standard requirements for the submission of programme for eradication, control and surveillance

## 7. Targets

The blocks 7.1.1, 7.1.2.1, 7.1.2.2, 7.2, 7.3.1 and 7.3.2 are repeated multiple times in case of first year submission of multiple program.

### 7.1 Targets related to testing (one table for each year of implementation)

#### 7.1.1 Targets on diagnostic tests for year : **2023**

Region	Type of the test	Target population	Type of sample	Objective	Number of planned tests	
ABRUZZO	Rose Bengal test	Bovines and buffalo	blood	qualification	38 891	<b>X</b>
BASILICATA	Rose Bengal test	Bovines and buffalo	blood	qualification	106 000	<b>X</b>
CALABRIA	Rose Bengal test	Bovines and buffalo	blood	qualification	157 451	<b>X</b>
CAMPANIA	Rose Bengal test	Bovines	blood	qualification	141 600	<b>X</b>
CAMPANIA	Rose Bengal test	Buffalo	blood	qualification	627 442	<b>X</b>
MOLISE	Rose Bengal test	Bovines and buffalo	blood	qualification	22 772	<b>X</b>
PUGLIA	Rose Bengal test	Bovines and buffalo	blood	qualification	190 000	<b>X</b>
SICILIA	Rose Bengal test	Bovines and buffalo	blood	qualification	482 172	<b>X</b>
ABRUZZO	complement fixation test	Bovines and buffalo	blood	qualification	28	<b>X</b>
BASILICATA	complement fixation test	Bovines and buffalo	blood	qualification	600	<b>X</b>
CALABRIA	complement fixation test	Bovines and buffalo	blood	qualification	1 660	<b>X</b>
CAMPANIA	complement fixation test	Bovines	blood	qualification	13 300	<b>X</b>

## Standard requirements for the submission of programme for eradication, control and surveillance

CAMPANIA	complement fixation test	Buffalo	blood	qualification	170 000	X
MOLISE	complement fixation test	Bovines and buffalo	blood	qualification	430	X
PUGLIA	complement fixation test	Bovines and buffalo	blood	qualification	400	X
SICILIA	complement fixation test	Bovines and buffalo	blood	qualification	109 538	X
CAMPANIA	Elisa test	Bovines	milk	qualification	30	X
CAMPANIA	Elisa test	Buffalo	milk	qualification	545	X
SICILIA	Elisa test	Bovines and buffalo	milk	qualification	135	X
CAMPANIA	bacteriological test	Bovines	milk, organs, foetus	qualification	130	X
CAMPANIA	bacteriological test	Buffalo	milk, organs, foetus	qualification	5 033	X
SICILIA	bacteriological test	Bovines and buffalo	milk, organs, foetus	qualification	475	X
SICILIA	PCR	Bovines and buffalo	milk, organs, foetus	qualification	235	X
MOLISE	PCR	Bovines and buffalo	milk, organs, foetus	qualification	20	X
<b>Total</b>					2 068 887	
<b>Add a new row</b>						

## Standard requirements for the submission of programme for eradication, control and surveillance

	Total number of tests
Total number of tests	2 068 887
Rose Bengal test	1 766 328
complement fixation test	295 956
Elisa test	710
bacteriological test	5 638
PCR	255

### 7.1.2 Targets on testing herds and animals

#### 7.1.2.1 Targets on the testing of herds for year: **2023**

										Target indicators		
Region	Animal species	Total number of herds	Total number of herds under the programme	Number of herds expected to be checked	Number of expected positive herds	Number of expected new positive herds	Number of herds expected to be depopulated	% positive herds expected to be depopulated	Expected % herd coverage	% positive herds Expected period herd prevalence	% new positive herds Expected herd incidence	
ABRUZZO	Bovines	3 701	2 005	2 005	0	0	0	0,000	100,000	0,000	0,000	X



## Standard requirements for the submission of programme for eradication, control and surveillance

BASILICATA	Bovines	2 665	2 318	2 318	0	0	0	0,000	100,000	0,000	0,000	X
CALABRIA	Bovines	8 292	5 280	5 280	0	0	0	0,000	100,000	0,000	0,000	X
CAMPANIA	Bovines	5 000	3 005	3 005	12	7	0	0,000	100,000	0,399	0,233	X
CAMPANIA	Buffalo	1 134	1 049	1 049	103	16	20	19,417	100,000	9,819	1,525	X
MOLISE	Bovines	761	432	432	0	0	0	0,000	100,000	0,000	0,000	X
PUGLIA	Bovines	1 717	1 614	1 614	30	20	5	16,667	100,000	1,859	1,239	X
SICILIA	Bovines	9 946	8 277	8 277	87	50	6	6,897	100,000	1,051	0,604	X
<b>Total</b>		33 216	23 980	23 980	232	93	31	13,362	100,000	0,967	0,388	
									<b>Add a new row</b>			

### 7.1.2.2 *Targets on the testing of animals for year :* **2023**

Region	Species	Total number of animals	Number of animals under the programme	Number of animals expected to be tested	Number of animals to be tested individually	Number of expected positive animals	Slaughtering		Target indicators		
							Number of animals with positive result expected to be slaughtered or culled	Total number of animals expected to be slaughtered	Expected % coverage at animal level	% positive animals (Expected animal prevalence)	
ABRUZZO	Bovine	43 009	38 891	38 891	38 891	0	0	0	100,000	0,000	X
BASILICATA	Bovine	99 013	77 000	77 000	77 000	0	0	0	100,000	0,000	X
CALABRIA	Bovine	109 682	97 963	97 963	97 963	0	0	0	100,000	0,000	X

## Standard requirements for the submission of programme for eradication, control and surveillance

CAMPANIA	Bovine	86 000	74 000	74 000	74 000	90	90	90	100,000	0,122	<b>X</b>
CAMPANIA	Buffalo	297 038	283 721	283 721	283 721	6 017	6 017	7 017	100,000	2,121	<b>X</b>
MOLISE	Bovine	16 943	11 886	11 886	11 886	0	0	0	100,000	0,000	<b>X</b>
PUGLIA	Bovine	87 892	86 072	86 072	86 072	350	350	450	100,000	0,407	<b>X</b>
SICILIA	Bovine	331 292	287 996	287 996	287 996	950	950	1 150	100,000	0,330	<b>X</b>
<b>Total</b>		1 070 869	957 529	957 529	957 529	7 407	7 407	8 707	100,000	0,774	
									<b>Add a new row</b>		
Total number of animals expected to be slaughtered or culled : BOVINES									1 690		
Total number of animals expected to be slaughtered or culled : BUFFALO									7 017		
Total number of animals expected to be tested									957 529		

### 7.2 *Targets on qualification of herds and animals*

### 7.2 *Targets on qualification of herds and animals for year :* **2023**

Targets on the status of herds and animals under the programme									
		Expected not free or not free from disease							
	Total number of herds and animals under the programme	Expected unknown	Last check positive	Last check negative	Expected free or officially free from disease status suspended	Expected free from disease	Expected officially free from disease		

## Standard requirements for the submission of programme for eradication, control and surveillance

Region	Animal species	Herds	Animals	Herds	Animals	Herds	Animals	Herds	Animals	Herds	Animals	Herds	Animals	Herds	Animals	
ABRUZZO	Bovines	2 005	38 891	0	0	0	0	0	0	0	0	0	0	2 005	38 891	X
BASILICATA	Bovines	2 318	77 000	0	0	0	0	0	0	0	0	0	0	2 318	77 000	X
CALABRIA	Bovines	5 328	98 931	11	85	0	0	53	429	9	54	0	0	5 264	98 417	X
CAMPANIA	Bovines	3 004	73 900	0	0	5	400	14	512	6	12	0	0	2 985	72 988	X
CAMPANIA	Buffalo	1 049	283 721	0	0	34	10 000	31	9 500	6	3 200	2	1 230	984	264 221	X
MOLISE	Bovines	432	11 886	0	0	0	0	0	0	0	0	0	0	432	11 886	X
PUGLIA	Bovines	1 614	86 072	0	0	10	100	0	0	5	100	0	0	1 604	85 972	X
SICILIA	Bovines	8 868	278 427	0	0	31	1 667	44	1 520	35	1 311	0	0	8 793	275 240	X
<b>Total</b>		24 618	948 828	11	85	80	12 167	142	11 961	61	4 677	2	1 230	24 385	924 615	
												<b>Add a new row</b>				

### 7.3 Targets on vaccination or treatment

#### 7.3.1 Targets on vaccination or treatment for year : **2023**

Region	Animal species	Total number of herds in vaccination or treatment programme	Total number of animals in vaccination or treatment programme	Targets on vaccination or treatment programme												
				Number of herds in vaccination or treatment programme	Number of herds expected to be vaccinated or treated	Number of animals expected to be vaccinated or treated	Number of doses of vaccine or treatment expected to be administered	Number of adults expected to be vaccinated	Number of young animals expected to be vaccinated							

# Standard requirements for the submission of programme for eradication, control and surveillance

CAMPANIA	Buffalo	740	190 000	394	394	18 771	112 626	0	18 771	X
CAMPANIA	Bovines	1 542	36 143	152	152	489	489	0	489	X
<b>Total</b>		2 282	226 143	546	546	19 260	113 115	0	19 260	
							<b>Add a new row</b>			



# Standard requirements for the submission of programme for eradication, control and surveillance

## 8.2. Financial informaton

### 1. Identification of the implementing entities - financial circuits/flows

Identify and describe the entities which will be in charge of implementing the eligible measures planned in this programme which costs will constitute the reimbursement/payment claim to the EU. Describe the financial flows/circuits followed.

Each of the following paragraphs (from a to e) shall be filled out if EU cofinancing is requested for the related measure.

a) Implementing entities - **sampling**: who performs the official sampling? Who pays?

(e.g. authorised private vets perform the sampling and are paid by the regional veterinary services (state budget); sampling equipment is provided by the private laboratory testing the samples which includes the price in the invoice which is paid by the local state veterinary services (state budget))

*(max. 32000 chars):*

In Italy the sampling is performed from state veterinarians that work in a local veterinarian unit called ASL or ASP. In some Regions, private veterinarians are called to support the state veterinarians in their work. These veterinarians have private contracts calculated in hours per week of work. They are paid, as well as the state veterinarians, from the Regions using their sanitary fund.

For state prevention operations relating to brucellosis in cattle and buffaloes the regions use the resources allocated by the Treasury to the National Health Fund.

Under the legal and economic framework governing the National Health Service, all such expenses incurred are paid out of the National Health Fund's appropriations.

The share of that fund due to the individual regions is credited to them from year to year as a lump sum; that is to say, the total amount is used to run the

## Standard requirements for the submission of programme for eradication, control and surveillance

entire regional health service (the region in turn distributes the amount to the individual ASLs), of which the veterinary service constitutes only a very small part.

b) Implementing entities - **testing**: who performs the testing of the official samples? Who pays?  
(e.g. regional public laboratories perform the testing of official samples and costs related to this testing are entirely paid by the state budget)

*(max. 32000 chars):*

In Italy the testing are performed from public Laboratories called IZS (Istituti Zooprofilattici Sperimentali). Also these Institutes are financed from the Regions using their sanitary fund.

c) Implementing entities - **compensation**: who performs the compensation? Who pays?  
(e.g. compensation is paid by the central level of the state veterinary services,  
or compensation is paid by an insurance fund fed by compulsory farmers contribution)

*(max. 32000 chars):*

The compensation of the animals positive a the tests for brucellosis, are paid from the Local veterinary Public Service Called ASL or ASP. They use regionals fund that are resources allocated by the Treasury to the National Health Fund.

d) Implementing entities - **vaccination**: who provides the vaccine and who performs the vaccination? Who pays the vaccine? Who pays the vaccinator?  
(e.g. farmers buy their vaccine to the private vets, send the paid invoices to the local state veterinary services which reimburse the farmers of the full amount and the vaccinator is paid by the regional state veterinary services)

## Standard requirements for the submission of programme for eradication, control and surveillance

(max. 32000 chars):

(who provides the vaccine = CZ vaccines – distributor Fatro  
(who performs the vaccination = The local Veterinary Authority  
(Who pays the vaccine = Regione Campania  
(Who pays the vaccinator = The local Veterinary Authority

e) Implementing entities - **other essential measures**: who implements this measure? Who provide the equipment/service? Who pays?

(max. 32000 chars):

For all the operations related to state prevention relating to bovine buffalo brucellosis the regions use the resources allocated by the Treasury to the National Health Fund.

### 2. Source of funding of eligible measures

All eligible measures for which cofinancing is requested and reimbursement will be claimed are financed by public funds.

*yes*

*no*

## Standard requirements for the submission of programme for eradication, control and surveillance

### 3. Additional measures in exceptional and justified cases

In the "*Guidelines for the Union co-funded veterinary programmes*", it is indicated that in exceptional and duly justified cases, additional necessary measures can be proposed by the Member States in their application.

*If you introduced these type of measures in this programme, for each of them, please provide detailed technical justification and also justification of their cost:*

Cofinancing proposal, for a plan for disposal of endoruminal boluses.

Italy has used the electronic identification for bovine / buffalo, since 2006, year of enactment of the Ordinance of the Ministry of Health "Extraordinary Measures veterinary police regarding tuberculosis, brucellosis and bovine buffalo, sheep and goat brucellosis, enzootic in Calabria, Campania, Puglia and Sicily", by adopting specifically the rumen bolus ceramic as containing an electronic device able to guarantee the certainty of the identification of animals especially in herds at pasture.

That position was later confirmed in the ordinances issued August 9, 2012 and May 28, 2015.

The massive use of this device, that after death / killing / slaughter of the animals must be recovered and kept by the competent veterinary service, resulted in an accumulation of about 165,000 ceramic bolus (approximately 10 tons) at the slaughterhouse and the veterinary services waiting for directives about the correct way of disposal of them.

Till now the disposal of such endoruminal boluses has taken in some regions an emergency character, primarily from the point of view of safety of their custody (possible theft and re-use for the identification of animals not declared), thus making it urgent to find a solution for the disposal of the same.

In Italy the Ordinance of the Ministry of Health have introduced the mandate of using endoruminal boluses on the basis of the recommendations of the European Commission, in order to improve animals identification and therefore enhance the plans for the eradication of Brucellosis.

In this respect it would therefore helpful if the European Commission may consider: the disposal endoruminal boluses, their recover, kept and distruction; an indispensable voice of cost of the program, and consider the possibility to co-financy the use of it, in the next the Guidelines for co-financed programs for the eradication, control and monitoring of animal diseases and zoonoses.

+++Furthermore, we would like to underline that Italy has invested a big amount of resource to develop informatics veterinary systems with the aim of better monitor the program. This investment has been at central, Regional and local levels and has asked a lot of energy in terms of economic as well as of human resource. The veterinary informatics systems are implemented by the veterinarians of the local veterinary unit that are not only in duty for sampling the animals but are also responsible of the implementation, quality control and analysis of the data charged in the systems. To do this work they utilize a large amount of time that is not calculate at the aim of co-financing. Also at regional and central level the implementation and the analysis of the data charged in the systems request a big amount of time for their correct use. The veterinarian work, to implement an eradication program is

## Standard requirements for the submission of programme for eradication, control and surveillance

changed and is not only done of samplings and analysis of the flocks but is composed from these elements more the informatics needs for the constant control of the program. We wish that the Commission will take in consideration the evolution of the veterinarian work in relation of the development of the informatics need and start to consider a way to co-financing these measures."

---



# Standard requirements for the submission of programme for eradication, control and surveillance

## Attachments

### IMPORTANT :

- 1) The more files you attach, the longer it takes to upload them .
- 2) This attachment files should have one of the format listed here : [jpg](#), [jpeg](#), [tiff](#), [tif](#), [xls](#), [xlsx](#), [doc](#), [docx](#), [ppt](#), [pptx](#), [bmp](#), [pna](#), [pdf](#).
- 3) The total file size of the attached files should not exceed 2 500Kb (+- 2.5 Mb). You will receive a message while attaching when you try to load too much.
- 4) IT CAN TAKE **SEVERAL MINUTES TO UPLOAD** ALL THE ATTACHED FILES. Don't interrupt the uploading by closing the pdf and wait until you have received a Submission Number!
- 5) Only use letters from a-z and numbers from 1-10 in the attachment names, otherwise the submission of the data will not work.

## List of all attachments

	Attachment name	File will be saved as (only a-z and 0-9 and -_):	File size
	19167_14891.pdf	19167_14891.pdf	183 kb
	19167_14892.pdf	19167_14892.pdf	185 kb
	19167_14893.pdf	19167_14893.pdf	297 kb
	19167_14894.pdf	19167_14894.pdf	690 kb
	19167_14895.pdf	19167_14895.pdf	142 kb
	19167_14896.pdf	19167_14896.pdf	186 kb
	19167_14897.pdf	19167_14897.pdf	185 kb

# Standard requirements for the submission of programme for eradication, control and surveillance

	19167_14898.pdf	19167_14898.pdf	29 kb
	19167_14899.pdf	19167_14899.pdf	182 kb
	ERAFUNDSPESTFUNDS_PPD.pdf	ERAFUNDSPESTFUNDS_PPD.pdf	288 kb
		Total size of attachments :	2368 kb