



Standard requirements for the submission of programme for eradication, control and monitoring

Annex I.d : Programme for the control and eradication of Bluetongue submitted for obtaining EU cofinancing

Member States seeking a financial contribution from the European Union for national programmes of eradication, control and surveillance shall submit online this application completely filled out.

In case of difficulty, please contact SANTE-VET-PROG@ec.europa.eu, describe the issue and mention the version of this document: 2015 1.06

Your current version of Acrobat is: 11.015

Instructions to complete the form:

- 1) You need to have at least the **Adobe Reader version 8.1.3** or higher to fill and submit this form.
- 2) To verify your data entry while filling your form, you can use the "**verify form**" button at the top of each page.
- 3) When you have finished filling the form, verify that your internet connection is active, save a copy on your computer and then click on the "**submit notification**" button below. If the form is properly filled, the notification will be submitted to the EU server and a submission number will appear in the corresponding field. If you don't succeed to submit your programme following this procedure, check with your IT service that the security settings of your computer are compatible with this online submission procedure.
- 4) All programmes submitted online are kept in a central database. However only the information in the last submission is used when processing the data.
- 5) **IMPORTANT:** Once you have received the submission number, **save the form on your computer** for your records.
- 6) If the form is not properly filled in, an alert box will appear indicating the number of incorrect fields. Please check your form again, complete it and re-submit it according to steps 3). Should you still have difficulties, please contact SANTE-VET-PROG@ec.europa.eu.
- 7) For simplification purposes you are invited to submit **multi-annual programmes**.
- 8) As mentioned during the Plenary Task Force of 28/2/2014, you are invited to submit your programmes in **English**.

Submission Date

Friday, May 29, 2015 12:55:58

Submission Number

1432896960108-4964



Standard requirements for the submission of programme for eradication, control and monitoring

1. Identification of the programme

Member state: ITALIA

Disease: Bluetongue in endemic or high risk areas

Species: Bovines, ovine and caprine animals

This program is multi annual: no

Request of Community co-financing for year :

2016

Standard requirements for the submission of programme for eradication, control and monitoring

1.1 Contact

Name : Dr. Bertani Fabrizio

Phone : 00390659946185

Your job type within the CA : head of Office III - Ministry of Health - General Direction An

Email : emergenza.vet-esotiche@sanita.it

2. Historical data on the epidemiological evolution of the disease

Provide a concise description on the target population (species, number of herds and animals present and under the programme), the main measures (sampling and testing regimes, vaccination schemes) and the main results (incidents, prevalence). The information is given for distinct periods if the measures were substantially modified. The information is documented by relevant summary epidemiological tables (point 6), complemented by graphs or maps (to be attached).

(max. 32000 chars) :

The target species of the programme are all farmed ruminants, in particular cattle, water buffaloes, sheep and goats. The bluetongue (BT) programme is based on the following measures are:

- Serological and entomological surveillance all over the country
- Vaccination of cattle, water buffaloes, sheep and goats in the restricted zones
- Control of animal movements from the restricted zones

BT is a notifiable disease and passive surveillance is in place all over the country: in compliance with article 2 of Commission Regulation (EC) No 1266/2007, a suspected case of bluetongue must be notified to the competent veterinary authority which put in place all diagnostic investigations for BT confirmation. In Italy, an information system for reporting and recording animal disease outbreaks is in place since 2008 (National Information System of Animal Diseases - SIMAN). All suspected and confirmed cases of notifiable animal diseases are registered in SIMAN.

In addition, since 2002, a robust and organized network of sentinel animals has been established in Italy to monitor BT virus (BTV) circulation. It is a system which includes more than 30,000 animals. Currently the national serological programme applied in Italy has been revised. The Italian territory has been divided in 20 x 20 km square grids in free territories and 45 x 45 km in zones under restriction. In each square (of both dimensions), around 58 seronegative animals are selected and used as sentinel animals (sample size able to detect an incidence of 5%, 95% c.I.). Because the sample size is calculated taking into account an infinite population, in the areas where a limited number of animals is present, the number of animal to be selected is proportionally reduced according to the real target animal population in each square. The animals are selected in the herds/flocks to be spatially representative, as much as possible, of the territory of each square.

Two different surveillance pressures have been applied, therefore, in free and restricted territories. In free

Standard requirements for the submission of programme for eradication, control and monitoring

territories the main objective of the serological surveillance system is to early detect the BTV incursions to promptly delimit the areas under movement restriction and subjected to vaccination. In territories under restriction the main objectives of the serological surveillance system are:

- to monitor the level of BTV circulation in order to evaluate the effectiveness of vaccination strategy,
- to collect data for supporting possible requests of amendments of territories under restriction.

A higher sensitivity of the surveillance system is applied, therefore, in free areas to increase the probability of early detection of virus transmission in case of introduction. On the contrary, a lower number of sentinel animals is selected and tested in the areas under restriction, due to the difficulties posed by finding seronegative animals in such areas. The number of sentinels, however, is in fully compliance with the Annex I, point 3 of the Commission Regulation (EC) No 1266/2007 of 26 October 2007 on implementing rules for Council Directive 2000/75/EC as regards the control, monitoring, surveillance and restrictions on movements of certain animals of susceptible species in relation to bluetongue.

NEW PART ADDED

Two different surveillance pressures have been applied in free and restricted territories. In free territories the main objective of the serological surveillance system is to early detect the BTV incursions to promptly delimit the areas under movement restriction and subjected to vaccination. A higher sensitivity of the surveillance system is applied in free areas to increase the probability of early detecting the virus in case of introduction.

The decision of increasing the sensitivity of surveillance system in the current unrestricted zones derives from several considerations:

- The history of BT in Italy clearly demonstrates a great suitability of its territories for BTV transmission, given the favourable climatic conditions and the presence of abundant *Culicoides* populations, belonging to species able to transmit the virus. This is evident not only in the central and southern regions but also in the northern territories, as the circulation of BTV8 in Veneto, Lombardia and Piemonte in 2008 and 2009 demonstrated.
- Given its position in the Mediterranean Basin, Italy is highly exposed to the introduction of BTV serotypes from several origins, without exceptions or areas which can be considered at lower risk of introduction. For example, the recent BTV-4 incursion in the Balkan poses a significant risk for the whole Italian territories overlooking the Adriatic Sea, included the northernmost regions (for example: Veneto, Friuli Venezia Giulia).
- In the current unrestricted territories, less than 10% of the whole Italian sheep population is present. This leads to the consequence that a surveillance approach based on the sole passive recognition of clinical signs of the disease would be not effective in these territories.
- On the contrary, the 65% of cattle population is located in the actual unrestricted zones. The great majority of cattle movements (around 77%) originates from these territories. A priority of the Italian veterinary authority, therefore, will be the preservation of this cattle population from BT infection and the establishment of an effective surveillance system, with the highest possible sensitivity, for detecting the BTV circulation as earliest as possible in case of its introduction. This would allow a prompt application of control measures (based on vaccination and controls on animal movements) in an attempt of reducing, as much as possible, the spread of the infection and the territories involved by virus circulation, thus reducing the economic impact of the infection.
- Furthermore, it should be considered that this increased sensitivity of the Italian surveillance system, applied in the current unrestricted northern regions, is of great benefit for the other neighbouring countries. It should be not forgotten that the northernmost borders of the Italian restricted zone are around 150 km far from France, around 170 km from Switzerland and Slovenia and around 200 km from Austria.

Standard requirements for the submission of programme for eradication, control and monitoring

Given all the considerations above reported, the Italian veterinary authority believe on the inevitability of establishing in the current unrestricted (but highly at risk) territories a surveillance system having the highest possible sensitivity and capable of detecting the virus circulation, in case of introduction, as early as possible, to allow a prompt application of control measures to protect the national, and of neighbouring countries, ruminant populations from the infection.

Sentinels are serologically negative animals, preferably bovines, but in some cases also sheep are selected. They are monthly bled and sera tested for BTV by c-ELISA. Positive results are confirmed by virus neutralization assay against 9 serotypes (BTV-1, BTV-2, BTV-4, BTV-6, BTV-8, BTV-9, BTV-14, BTV-15, BTV-16). From positive animals EDTA blood samples are also tested by RT-PCR. Sentinel animals are sampled all year round with the sole exception of seasonally free territories, where the serological surveillance activities are discontinued during the seasonally free period.

Virus isolation and typing is also performed in all RT-PCR positive sentinels and animals with clinical signs.

Each Istituto Zooprofilattico Sperimentale (IZS) is authorized and capable to screen sentinels by c-ELISA and/or RT-PCR for the presence of BTV antibodies or BTV, respectively. The National Reference Center (CESME – IZS Abruzzo e Molise) has an essential role in confirming the other IZS results and identifying and typing the BTV circulating in Italy.

Results of all laboratory tests are collected and stored in a national database which is updated on weekly basis. With the same frequency an automatic procedure scans these results to identify potential seroconversions. In case of a suspected case of seroconverted sentinel, an alert message is sent to the competent Veterinary Service through SIMAN, which verifies the accuracy of data and makes all investigations in order to confirm the suspected case.

More than 300 Culicoides Onderstepoort black-light suction traps are used for entomological surveillance. The Italian territory has been divided in 40 x 40 km square grids and one or two permanent traps are located in each grid. At least one trap for each Italian province (NUT3 level) is in place. Culicoides catches are performed on weekly basis all over the year in the whole Italy. The insects collected are routinely identified and sorted by species, both by optic microscope and genomic determination (PCR). The results of this surveillance are used:

- to define the seasonal dynamics of main vector species for the annual identification of seasonally free areas and periods, in compliance with the Annex V of Regulation (EC) No 1266/2007,

- to monitor the spatial distribution and abundance of main vector species all over the Italian territory.

The entomological surveillance system in place in Italy is particularly strict and precise to provide the information needed to define the vector dynamics and, therefore, the zones and periods seasonally free (or at lower risk of BTV transmission). Such robust entomological surveillance system is required by the peculiarity of Italian territory, characterized by a high degree of heterogeneity of climates and habitats. In addition, Culicoides trapping activities are performed in herds/flocks where recent BTV circulation has been detected in order to identify the main vector species involved in virus transmission. In these cases, in addition to the identification of Culicoides species, virological tests (RT-PCR and virus isolation assays) are also performed in insect pools.

In the last couple of years, a large BTV-1 outbreak affected, initially, Sardinia, Sicily and some coastal areas of central and southern Italy, and, then, most of the Italian peninsula with the exclusion of its northern regions.

Year 2013: 5,872 BTV-1 outbreaks, with 340,085 BT cases and 107,902 dead animals.

Year 2014: 1,387 BTV-1 outbreaks, with 12,434 BT cases and 6,159 dead animals.

In late autumn 2014, BTV-4 was detected in Apulia region and right now the two serotypes (BTV-1 and BTV-4) are actively co-circulating in this region.

Year 2014: 25 BTV-4 outbreaks, with 19 BT cases and 2 dead animals.

Standard requirements for the submission of programme for eradication, control and monitoring

On 6/5/2015 the Italian national veterinary authority asked the European Commission to re-consider the territories under restrictions in Italy on the basis of the BTV serotypes circulating on 2013 and 2014 and the consideration of vaccine origin for BTV-16 serotype. On the date of writing this programme the request is still under evaluation by the competent services of the European Commission. In case of favorable response, the map of restricted territories in Italy would be significantly simplified, with the presence of three serotypes only: BTV-1 in all territories under restriction, and in addition BTV-4 in Apulia region and BTV-2 limited to Salerno, Cosenza, Catanzaro and Palermo provinces.

Actually only inactivated vaccines are allowed in Italy. In particular a monovalent BTV-1 vaccine for sheep and cattle and a bivalent BTV-2 and BTV-4 vaccine for sheep are commercially available. The use on other species (buffaloes and goats for BTV-1 vaccine and cattle, buffaloes and goats for BTV-2/BTV-4 vaccine) has been authorized by the central veterinary authority in compliance with the article 8 of the Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products, as amended by the Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004.

Movements from the restricted zones are allowed only in compliance with the Regulation (EC) No 1266/2007. In particular conditions of Annex III, letter A, of Regulation (EC) No 1266/2007 are applied for managing the exit of live animals from the restricted areas to free territories or areas with under restriction for different serotypes. The vaccination of animals subjected to movement is considered the main control measure in this framework.

Provisions of article 8, point 4 area also applied for the movements of animals from restricted zones for immediate slaughter. These animals must be slaughtered in designated slaughterhouses, which are approved and recorded in a national list managed by the national veterinary authority and available at the following web page: http://bluetongue.izs.it/pls/izs_bt/BT_REP_021_R.

For more details on BT epidemiological situation in Italy in the last years, please refer to the Annex I document.

3. Description of the submitted programme

Provide a concise description of the programme with its main objective(s) (monitoring, control, eradication, reducing prevalence and incidence), the main measures (sampling and testing regimes, vaccination schemes), the target animal population, the area(s) of implementation and the definition of a positive case taking into account the provisions of Commission Regulation 1266/2007

(max. 32000 chars) :

The present programme has the following objectives:

1. to reduce as much as possible the BTV circulation in the restricted zones through the vaccination of all animals belonging to susceptible species (bovine, buffaloes, sheep, goats), with the aim of regaining the free status in the majority of Italy in 2-3 years, in compliance with the provisions laid down in Annex I, point 3 a) of the Regulation (EC) No 1266/2007,
 2. to control the spread of the disease, through the prompt and strict application of veterinary measures on animal movements from restricted zones,
 3. to early detect any possible BTV incursion in free territories,
 4. to monitor the BTV circulation in the zones already infected, identifying the occurrence of any possible new serotype,
 5. to define the seasonal dynamics of main vector species for the annual identification of seasonally free areas and periods, in compliance with the Annex V of Regulation (EC) No 1266/2007,
 6. to monitor the spatial distribution and abundance of main vector species all over the Italian territory.
- The reduction of BTV circulation in the restricted zones is achieved through the vaccination of all farmed animals belonging to the susceptible species (cattle, buffaloes, sheep, goats) with inactivated vaccines.

Standard requirements for the submission of programme for eradication, control and monitoring

To date a monovalent BTV-1 vaccine for sheep and cattle and a bivalent BTV-2 and BTV-4 vaccine for sheep are commercially available. The use on other species (buffaloes and goats for BTV-1 vaccine and cattle, buffaloes and goats for BTV-2/BTV-4 vaccine) has been authorized by the central veterinary authority in compliance with the article 8 of the Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products, as amended by the Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004. The vaccine inoculation is performed by official veterinarians or private practitioners specifically appointed by the official veterinary local authority. The vaccination activities are recorded by the official veterinarians into the national information system, strictly linked to the national animal database. Starting from 2015 vaccination data is registered for each bovine animal and buffalo, and for each flock in the case of ovine and caprine animals.

The spread of the disease by animal movements is avoided through the strict application of provisions laid down in Annex III, letter A, of Regulation (EC) No 1266/2007. The vaccination of animals subjected to movement is considered the main control measure in this framework.

Provisions of article 8, point 4 area also applied for the movements of animals from restricted zones for immediate slaughter. These animals must be slaughtered in designated slaughterhouses, which are approved and recorded in a national list managed by the national veterinary authority and available at the following web page: http://bluetongue.izs.it/pls/izs_bt/BT_REP_021_R.

A surveillance system is in place to early detect any possible BTV incursion in free territories, and to monitor the BTV circulation in the zones already infected, identifying the occurrence of any possible new serotype. This surveillance includes a passive surveillance of all possible BT cases, suspected on the basis of the clinical signs. All suspected and confirmed cases of notifiable animal diseases are registered in the National Information System of Animal Diseases (SIMAN).

In addition, a serological programme is applied. The Italian territory has been divided in 20 x 20 km square grids in free territories and 45 x 45 km in zones under restriction. In each square (of both dimensions), around 58 seronegative animals are selected and used as sentinel animals (sample size able to detect an incidence of 5%, 95% c.i.). Because the sample size is calculated taking into account an infinite population, in the areas where a limited number of animals is present, the number of animal to be selected is proportionally reduced according to the real target animal population in each square. The animals are selected in the herds/flocks to be spatially representative, as much as possible, of the territory of each square. Sentinels are serologically negative animals, preferably bovines, which are monthly bled and sera tested for BTV by c-ELISA. Positive results are confirmed by virus neutralization assay against 9 serotypes (BTV-1, BTV-2, BTV-4, BTV-6, BTV-8, BTV-9, BTV-14, BTV-15, BTV-16). From positive animals EDTA blood samples are also tested by RT-PCR. Sentinel animals are sampled all year round with the sole exception of seasonally free territories, where the serological surveillance activities are discontinued during the seasonally free period. Virus isolation and typing is also performed in all RT-PCR positive sentinels and animals with clinical signs.

Results of all laboratory tests are collected and stored in a national database which is updated on weekly basis. With the same frequency an automatic procedure scans these results to identify potential seroconversions. In case of a suspected case of seroconverted sentinel, an alert message is sent to the competent Veterinary Service through SIMAN, which verifies the accuracy of data and makes all investigations in order to confirm the suspected case.

Case definition in force in Italy perfectly meets that laid down in the article 2 of the Regulation (EC) No 1266/2007.

The surveillance based on sentinel animals is coupled by the entomological surveillance based on more than 300 Culicoides Onderstepoort black-light suction traps. For this purpose, the Italian territory has been divided in 40 x 40 km square grids and one or two permanent traps are located in each grid. At least one trap for each Italian province (NUT3 level) is in place. Culicoides catches are performed on weekly basis all over the year in the whole Italy. The insects collected are routinely identified and sorted

Standard requirements for the submission of programme for eradication, control and monitoring

by species, both by optic microscope and genomic determination (PCR). The results of this surveillance are used:

- to define the seasonal dynamics of main vector species for the annual identification of seasonally free areas and periods, in compliance with the Annex V of Regulation (EC) No 1266/2007,

- to monitor the spatial distribution and abundance of main vector species all over the Italian territory.

In addition, Culicoides trapping activities are performed in herds/flocks where recent BTV circulation has been detected in order to identify the main vector species involved in virus transmission. In these cases, in addition to the identification of Culicoides species, virological tests (RT-PCR and virus isolation assays) are also performed in insect pools.

4. Measures of the submitted programme

4.1 Summary of measures under the programme

Duration of the programme: 2016

First year :

Control

Testing

Slaughter of animals tested positive

Killing of animals tested positive

Vaccination

Eradication, control or monitoring

Standard requirements for the submission of programme for eradication, control and monitoring

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

Describe the authorities in charge of supervising and coordinating the departments responsible for implementing the programme and the different operators involved. Describe the responsibilities of all involved.

(max. 32000 chars):

The General Direction of Animal Health and Veterinary Medicines (GDAH) of the Ministry of Health is the national competent authority for the definition and implementation of the programme. It provides guidelines on and coordinates the activities performed by the Regional Veterinary Offices and the Local Veterinary Offices (placed in the Local Health Units - LHU).

In particular, the Regional Veterinary Offices organize and coordinate the activities performed by the veterinary offices of the LHU, verifying the objectives achievement according to the guidelines and provisions given in the national programme.

The veterinary offices of LHU perform the activities and the provisions given in the national programme. The laboratory tests are performed in the 10 Istituti Zooprofilattici Sperimentali (IZS), which are authorized to tests blood samples collected in the regions of competence and performing c-ELISA and RT-PCR for BTV genome detection (not serotype specific). They are authorized to perform also the entomological identifications and RT-PCR for BTV detection in insect pools. The National Reference Center (CESME – IZS Abruzzo e Molise) performs also confirmatory tests for the whole Italy: serum neutralization on c-ELISA positive sera, serotype-specific RT-PCR on BTV RT-PCR positive specimens (blood, insect pools, organs).

Ring tests are regularly performed by the CESME and the other IZS to assure the reliability of laboratory results and the quality of tests performed.

In addition, the National Reference Centre for Veterinary Epidemiology, Programming, Information and Risk Analysis (COVEPI – IZS Abruzzo e Molise), developed and constantly manage the national information system on bluetongue (http://bluetongue.izs.it/pls/izs_bt/bt_gestmenu.bt_index), which collects data on the surveillance activities performed, which are weekly analysed to update the epidemiological situation. The COVEPI, in collaboration with the CESME, also supports the GDAH on the definition of surveillance and control measures, providing the GDAH with the requested scientific opinions and risk assessment studies.

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

Describe the name and denomination, the administrative boundaries, and the surface of the administrative and geographical areas in which the programme is to be applied. Illustrate with maps.

(max. 32000 chars):

The whole Italian territory is included in the programme for the control and surveillance of bluetongue. The serological and entomological surveillance programmes are applied all over the country. In relation to the serological programme, the Italian territory has been divided in 20 x 20 km square grids in free territories and 45 x 45 km in zones under restriction. In each square (of both dimensions), around 58 seronegative animals are selected and used as sentinel animals (sample size able to detect an incidence of 5%, 95% c.i.). The surveillance based on sentinel animals is coupled by the entomological surveillance based on more than 300 Culicoides Onderstepoort black-light suction traps. For this purpose, the Italian territory has been divided in 40 x 40 km square grids and one or two permanent traps are located in

Standard requirements for the submission of programme for eradication, control and monitoring

each grid. At least one trap for each Italian province (NUT3 level) is in place. (See Annex I). The vaccination activities are carried out in the restricted zones, where also the provisions for the control of animal movements are applied. On the basis of surveillance results the seasonally free areas and periods are annually defined in compliance with the Annex V of Regulation (EC) No 1266/2007. In particular, the following criteria are used to define the areas and periods seasonally free:

- maximum daily temperature less than 10 °C (calculated on the basis of the temperatures of the last 5 years, source: Land Surface Temperature Day, MODIS) , and
- absence of *C. imicola* in the catches of the last 5 years, and
- less than five individuals for other *Culicoides* species in the catches of the last 5 years, and
- absence of evidence of BTV circulation in the last 5 years.

NEW PART ADDED

The last updated situation on bluetongue virus (BTV) circulation and the related map of restricted zones is presented below (Figure 1, Table 1 - Annex II). For some of the latest changes in the list restricted areas occurred in August 2015, the decision of the Standing Committee on Plants, Animals, Food and Feed is still pending. The request for changes will be submitted and presented by the Italian veterinary authority at the earliest available meeting.

Programme for bluetongue (BT) control will be implemented both in the restricted zones and in the rest of Italy, according to the following specifications.

The target species of the programme are all farmed ruminants, in particular cattle, water buffaloes, sheep and goats. The BT programme is based on the following measures:

- Serological and entomological surveillance all over the country
- Vaccination of cattle, water buffaloes, sheep and goats in the restricted zones
- Control of animal movements from the restricted zones

For the serological surveillance plan, the Italian territory has been divided in 20 x 20 km squares grid in free territories and 45 x 45 km in zones under restriction. In each square (of both dimensions), around 58 seronegative animals are selected and used as sentinel animals (sample size able to detect an incidence of 5%, 95% c.i.) (Figure 2 - Annex II). Sentinels are serologically negative animals, preferably bovines, but in some cases also sheep are selected. They are monthly bled and sera tested for BTV by c-ELISA. Positive results are confirmed by virus neutralization assay against 9 serotypes (BTV-1, BTV-2, BTV-4, BTV-6, BTV-8, BTV-9, BTV-14, BTV-15, BTV-16). From positive animals EDTA blood samples are also tested by RT-PCR. Sentinel animals are sampled all year round with the sole exception of seasonally free territories, where the serological surveillance activities are discontinued during the seasonally free period.

For the entomological surveillance plan, the Italian territory has been divided in 40 x 40 km squares grid and one or two permanent traps (*Culicoides* Onderstepoort black-light suction traps) are located in each square. At least one trap for each Italian province (NUT3 level) is in place. *Culicoides* catches are performed on weekly basis all over the year in the whole Italy. The insects collected are routinely identified and sorted by species, both by optic microscope and genomic determination (PCR) (Figure 3 - Annex II).

4.4 Description of the measures of the programme

Standard requirements for the submission of programme for eradication, control and monitoring

A comprehensive description needs to be provided of all measures implemented taking into account the provisions of Directive 2000/75/EC and Regulation 1266/2007. The national legislation in which the measures are laid down is mentioned

4.4.1 Notification of the disease

(max. 32000 chars) :

The notification of animal diseases is regulated by the following legislations:

- Council Directive 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community,
- Decision No 2119/98/EC of the European Parliament and of the Council of 24 September 1998 setting up a network for the epidemiological surveillance and control of communicable diseases in the Community,
- Decree of the President of Italian Republic of 8 February 1954 No 320 on "Regulation of Veterinary Police",
- Circular letter No 13691 of the Ministry of Labour, Health and social Politics of 24 July 2009 on the notification of animals diseases and related information systems.

Specifically related to bluetongue:

- Council Directive 2000/75/EC of 20 November 2000 laying down specific provisions for the control and eradication of bluetongue,
- Commission Regulation (EC) No 1266/2007 of 26 October 2007 on implementing rules for Council Directive 2000/75/EC as regards the control, monitoring, surveillance and restrictions on movements of certain animals of susceptible species in relation to bluetongue,
- Legislative decree No 225/2003 of adoption of Directive 200/75/EC laying down specific provisions for the control and eradication of bluetongue.

BT is a notifiable disease and any suspected case of bluetongue must be notified to the competent veterinary authority which put in place all diagnostic investigations for BT confirmation. All veterinarians (official or private) as well as animal owners and keepers are subjected to the obligation of notifying to the competent authority any suspicion of notifiable animal disease.

Case definition in force in Italy for BT perfectly meets that laid down in the article 2 of the Regulation (EC) No 1266/2007.

In Italy, an information system for reporting and recording animal disease outbreaks is in place since 2008 (National Information System of Animal Diseases - SIMAN). All suspected and confirmed cases of notifiable animal diseases are registered in SIMAN by the official veterinarians.

SIMAN is accessed by veterinary services of the local and Regional levels, National Reference Laboratories, GDAH and IZS. SIMAN is able to collect data produced at local level, using uniform procedures and templates for data input and output, and can display data in table format or as thematic maps. An automatic email alert system informs the competent authorities of suspects and confirmations of disease outbreaks. Data and information collected by SIMAN were set up according to those required by the European Commission animal disease notification systems (ADNS) and OIE WAHIS.

4.4.2 Target animals and animal population

(max. 32000 chars) :

All animals belonging to the susceptible species (cattle, buffaloes, sheep, goats) farmed in restricted zones are subjected to vaccination and measures for movement controls.

Sentinels used for serological surveillance are serologically negative animals, preferably bovines, but in some cases also sheep are selected, when the requested number of bovine sentinel animals is not

Standard requirements for the submission of programme for eradication, control and monitoring

available.

Ruminants belonging to wild species (e.g. deer, roe deer, chamois) are not included in the programme, although in case of man-made movements, for examples for repopulation purposes, the movements restrictions foreseen by the legislation are applied to these animal species too. Restrictions to the movements are applied also for animals of susceptible ruminant species hosted in circuses.

4.4.3 Identification of animals and registration of holdings

(max. 32000 chars) :

BOVINE ANIMALS AND WATER BUFFALOES

The identification and registration (I&R) system for bovine animals and water buffaloes is in place in Italy since 1996 and it has been recognised fully operative by the European Commission on February 2006. The legal basis of the I&R system is constituted by the following acts:

- Regulation (EC) No 1760/2000 of the European Parliament and of the Council of 17 July 2000 establishing a system for the identification and registration of bovine animals and regarding the labelling of beef and beef products and repealing Council Regulation (EC) No 820/97, and following amendments,
- Inter-ministerial Decree of 31 of January 2002 on the cattle national database, as modified by the Decree of Ministry of Health of 13 October 2004.

All bovine animals and buffaloes reared in Italian holdings are registered in the cattle I&R system, with the data of all their movements on the Italian territory. Starting from 1st of May 2015, for new born animals the individual passport will be no longer issued. For that reason, starting from that date, the data on BT vaccination (date of vaccination, type of vaccine, BTV serotypes) will be recorder for each individual bovine animal and buffalo in the national veterinary information system. The registration of this information will substitute the previous obligations of reporting the BT vaccination status in the individual cattle passport and will be useful for health certifications by official veterinarians.

Before the 2015 the data on BT vaccinations were registered by official veterinarians in the national information system for bluetongue.

Cattle and buffaloes subjected to movements must be accompanied by a movement form (model IV), which contains the identification of holdings of departure and arrival, the identification code of animals, the certification of their health status in relation to diseases subjected to national control (such as brucellosis, tuberculosis, and the vaccination status for BT), data on dealer and transport vehicle, and the information required by the Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97.

Model IV can be also printed by the official veterinarians directly through the specific on-line services provided by the national veterinary information system.

OVINE AND CAPRINE ANIMALS

The legal basis of the I&R system for sheep and goats is constituted by the following acts:

- Council Regulation (EC) No 21/2004 of 17 December 2003 establishing a system for the identification and registration of ovine and caprine animals and amending Regulation (EC) No 1782/2003 and Directives 92/102/EEC and 64/432/EEC, and following amendments,
- Circular of the Ministry of Health of 28 July 2005 providing indications for the application of Regulation (EC) No 21/2004.

All holdings rearing ovine or caprine animals are registered in a national database. All animals must be identified within 6 months of age and in any case before they leave the holding of birth. The animals must be identified by the apposition of an ear-tag and an additional electronic identifier bearing a

Standard requirements for the submission of programme for eradication, control and monitoring

unique individual code. As a derogation of the identification rules above, animals destined to direct slaughter before the 12 months of ages may be identified by an ear-tag bearing the sole code of holding of origin.

For each holding an annual census of animals kept is registered. Although there is no obligation to register the single individual animals in the national database, in several Regions the electronically identified animals are recorded.

Since 2015 BT vaccination data is recorded by the official veterinarians in the national veterinary information system for each flock. Voluntarily the registration for each single animal can be made. Before the 2015 the data on BT vaccinations were registered by official veterinarians in the national information system for bluetongue.

Sheep and goats subjected to movements must be accompanied by a movement form (model IV), which contains the identification of holdings of departure and arrival, the identification code of animals, the certification of their health status in relation to diseases subjected to national control (such as brucellosis, tuberculosis, and the vaccination status for BT), data on dealer and transport vehicle, and the information required by the Council Regulation (EC) No 1/2005 of 22 December 2004 on the protection of animals during transport and related operations and amending Directives 64/432/EEC and 93/119/EC and Regulation (EC) No 1255/97.

4.4.4 Rules for the movement of animals

A description is provided taking into account the provisions of the EU legislation on bluetongue

(max. 32000 chars):

Movements of animals belonging to BT susceptible species from the restricted zone to the rest of Italian territory are prohibited. As derogation to this ban, movements may be allowed under the provisions laid down in Annex III, letter A, of Regulation (EC) No 1266/2007. The vaccination of animals subjected to movement is considered the main control measure in this framework.

Provisions of article 8, point 4 of Regulation (EC) No 1266/2007 are also applied for the movements of animals from restricted zones for immediate slaughter. These animals must be slaughtered in designated slaughterhouses, which are approved and recorded in a national list managed by the national veterinary authority and available at the following web page: http://bluetongue.izs.it/pls/izs_bt/BT_REP_021_R.

The provisions for the control of movements from restricted zones to free areas are applied also in case of restricted zones for different BTV serotypes.

Provisions of article 8, point 1 b) of Regulation (EC) No 1266/2007 have been used for allowing movements of specific limited animals, which cannot be vaccinated for any reason. In these cases a channelling procedure has been put in place and the animals have been moved further to their first destination at least for 60 days after the arrival and excluded by the intra-community trade.

4.4.5 Tests used and sampling schemes

(max. 32000 chars):

The laboratory tests are performed in the 10 Istituti Zooprofilattici Sperimentali (IZS), which are authorized to tests blood samples collected in the regions of competence and performing c-ELISA and RT-PCR for BTV genome detection (not serotype specific). They are authorized to perform also the entomological identifications and RT-PCR for BTV detection in insect pools. The National Reference Center (CESME – IZS Abruzzo e Molise) performs also confirmatory tests for the whole Italy: serum neutralization on c-ELISA positive sera, serotype-specific RT-PCR on BTV RT-PCR positive specimens

Standard requirements for the submission of programme for eradication, control and monitoring

(blood, insect pools, organs).

Ring tests are regularly performed by the CESME and the other IZS to assure the reliability of laboratory results and the quality of tests performed.

Sentinel animals are monthly bled and sera tested for BTV by c-ELISA by the competent IZS. Positive samples are sent to CESME for confirmation by virus neutralization assay, which is routinely performed against 9 serotypes (BTV-1, BTV-2, BTV-4, BTV-6, BTV-8, BTV-9, BTV-14, BTV-15, BTV-16). From positive animals EDTA blood samples are also tested by RT-PCR.

Virus isolation and typing is routinely attempted on RT-PCR positive blood samples taken from sentinel animals and in blood and organ samples taken from animals with clinical signs.

Results of all laboratory tests are collected and stored in a national database which is updated on weekly basis. With the same frequency an automatic procedure scans these results to identify potential seroconversions. In case of a suspected case of seroconverted sentinel, an alert message is sent to the competent Veterinary Service through SIMAN, which verifies the accuracy of data and makes all investigations in order to confirm the suspected case.

The competent IZS test the insects collected on weekly basis by the permanent traps network, performing the identification of Culicoides species, both by optic microscope and genomic determination (PCR). In addition, Culicoides trapping activities are performed in herds/flocks where recent BTV circulation has been detected in order to identify the main vector species involved in virus transmission. In these cases, in addition to the identification of Culicoides species, virological tests (RT-PCR and virus isolation assays) are also performed in insect pools.

4.4.6 Vaccines used and vaccination schemes

(max. 32000 chars):

The reduction of BTV circulation in the restricted zones is achieved through the vaccination of all farmed animals belonging to the susceptible species (cattle, buffaloes, sheep, goats) with inactivated vaccines. To date a monovalent BTV-1 vaccine for sheep and cattle and a bivalent BTV-2 and BTV-4 vaccine for sheep are commercially available. The use on other species (buffaloes and goats for BTV-1 vaccine and cattle, buffaloes and goats for BTV-2/BTV-4 vaccine) has been authorized by the central veterinary authority in compliance with the article 8 of the Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products, as amended by the Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004. The vaccine inoculation is performed by official veterinarians or private practitioners specifically appointed by the official veterinary local authority, in compliance with the vaccination schemes suggested by the vaccine manufacturers.

Before the 2015 the data on BT vaccinations were registered by official veterinarians in the national information system for bluetongue.

Starting from 2015 vaccination data is registered for each bovine animal and buffalo, and for each flock in the case of ovine and caprine animals into the national information system, strictly linked to the national animal database.

NEW PART ADDED

Actually only inactivated vaccines are allowed in Italy. In particular, a monovalent BTV-1 vaccine for sheep and cattle and a bivalent BTV-2 and BTV-4 vaccine for sheep are currently commercially available in Italy.

The use of these vaccines in other species (buffaloes and goats for BTV-1 vaccine and cattle, buffaloes and goats for BTV-2/BTV-4 vaccine) is authorized by the central veterinary authority in compliance with

Standard requirements for the submission of programme for eradication, control and monitoring

the article 8 of the Directive 2001/82/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to veterinary medicinal products, as amended by the Directive 2004/28/EC of the European Parliament and of the Council of 31 March 2004.

To date no monovalent BTV-2 and monovalent BTV-4 inactivated vaccines are available in Italy. Vaccination against BTV-16 is not performed.

Vaccination will be performed in all restricted areas according to the serotypes combination for which they are under restriction (Table 1). Given the current vaccines availability, a bivalent BTV-2/BTV-4 vaccine will be used in Puglia region and in Salerno province.

In table 2 the number of animals (comprising all farmed cattle, sheep, goats and water buffaloes) to be vaccinated in the restricted zones and the relative number of doses are reported.

The vaccine inoculation is performed by official veterinarians or private practitioners specifically appointed by the official veterinary local authority. The vaccination activities are recorded by the official veterinarians into the national information system, strictly linked to the national animal database. Starting from 2015 vaccination data is registered for each bovine animal and buffalo, and for each flock in the case of ovine and caprine animals.

Adult animals, regardless the species, are expected to be inoculated once (annual re-vaccination), while young animals will be inoculated twice (initial and booster dose).

4.4.7 Information on bio-security measures implemented in the holdings and their assessment by official services.

(max. 32000 chars) :

In case of BT confirmation the following measures are applied in the herd/flock:

- whenever is possible the confinement of animals within the stables during the hours of major vector activity,
- application of authorised repellents on the animals, with respect of the prescribed withdrawal periods for meat and milk,
- treatments of stables and surrounding areas with authorised insecticides.

4.4.8 Measures in case of a positive result

A short description is provided of the measures as regards positive herds taking into account the provisions of the EU legislation.

(max. 32000 chars) :

Any suspected case of BT is immediately notified to the competent local veterinary authority of the LHU, which will register the suspected case into the SIMAN, after a preliminary assessment of the legitimacy of the suspicion. The competent local veterinary authority put in place also the following measures:

- herd / flock embargo with confinement of animals within the stables during the hours of major vector activity whenever is possible,
- application of movement animal restrictions,
- repellents and insecticides application,

Standard requirements for the submission of programme for eradication, control and monitoring

- animal sampling from animals with suspected clinical cases (blood and organs from euthanized animals) and from a representative number of animals within the same herd / flock.

After BT case confirmation, when a new territory (Municipality) is involved (by the infection or following the introduction of a new BTV serotype), the competent local veterinary authority will also perform:

- epidemiological inquiry to identify the possible source of BTV introduction and any chance of further spread from the infected holding,
- entomological catches for vector identification,
- clinical visits in sheep flocks located within 4 km of radius from the infect holding,
- blood sampling in a representative number of animals located within 4 km of radius from the infect holding.

In compliance with article 6 of the Directive 2000/75/EC, slaughtering or stamping policy is not applied in BT confirmed outbreaks. The official veterinarians may decide to euthanize for animal welfare purposes those sick animals showing severe signs of disease.

Application of stamping out measures may be considered only in case the epidemiological and laboratory findings are reasonably suggesting a very recent BTV introduction in a free zone, following the approval of the national veterinary authority (DGAH) and with the favourable scientific opinion of the national reference laboratory (CESME).

4.4.9 Control of the implementation of the programme by the Competent Authority - Documentation of the official controls

(max. 32000 chars) :

The national veterinary information system collects all data related to BT surveillance and suspected/confirmed BT outbreaks. A constant monitoring is therefore applied to surveillance activities.

An automatic procedure weekly scans these laboratory results to identify potential seroconversions. In case of a suspected case of seroconverted sentinel, an alert message is sent to the competent Veterinary Service through SIMAN, which verifies the accuracy of data and makes all investigations in order to confirm the suspected case.

In addition every month an evaluation of the amount of surveillance activities performed in each Province is made. Whenever the level of performed activities are less than 50% of planned, the Province is declared as "territory epidemiologically unknown" and the same restrictions of the restricted zones are applied for the following 30 days.

A national crisis unit is activated at the national level and periodical meetings are performed.

5. Benefits of the programme

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

(max. 32000 chars) :

BTV infection causes direct losses due to animal deaths and in consequence of clinical disease. Severe direct losses, however, have been experienced mainly in sheep bred in Sardinia island. In the rest of Italy the main impact of BTV infection is related to the application of animal movements ban with severe economic detriment of the national live animal trading system, with particular reference to the within the country cattle trade system.

The vaccination of animals against BTV is, therefore, the main tool for reducing the direct losses in sheep (mainly in Sardinia) and to allow controlled animals movements, decreasing the economic impacts on cattle trade.

Standard requirements for the submission of programme for eradication, control and monitoring

The financial balance between vaccination costs and economic benefits (even only calculated as avoided losses) is advantageous for the application of a mass-vaccination strategy.

Standard requirements for the submission of programme for eradication, control and monitoring

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:

2016

| Region | Type of the test | Target population | Type of sample | Objective | Number of planned tests |
|-----------------------|------------------|---------------------|----------------|--------------|-------------------------|
| abruzzo | ELISA | susceptible species | serum | surveillance | 3 828 |
| basilicata | ELISA | susceptible species | serum | surveillance | 3 936 |
| calabria | ELISA | susceptible species | serum | surveillance | 6 324 |
| campania | ELISA | susceptible species | serum | surveillance | 4 896 |
| emilia romagna | ELISA | susceptible species | serum | surveillance | 16 731 |
| friuli venezia giulia | ELISA | susceptible species | serum | surveillance | 4 939 |
| lazio | ELISA | susceptible species | serum | surveillance | 7 416 |
| liguria | ELISA | susceptible species | serum | surveillance | 3 564 |

Standard requirements for the submission of programme for eradication, control and monitoring

| | | | | | | |
|--------------------------|-------|---------------------|-------|--------------|--------|----------|
| lombardia | ELISA | susceptible species | serum | surveillance | 27 049 | X |
| marche | ELISA | susceptible species | serum | surveillance | 3 888 | X |
| molise | ELISA | susceptible species | serum | surveillance | 1 464 | X |
| piemonte | ELISA | susceptible species | serum | surveillance | 20 185 | X |
| puglia | ELISA | susceptible species | serum | surveillance | 7 644 | X |
| sardegna | ELISA | susceptible species | serum | surveillance | 10 440 | X |
| sicilia | ELISA | susceptible species | serum | surveillance | 10 440 | X |
| toscana | ELISA | susceptible species | serum | surveillance | 9 588 | X |
| trentino alto adige (bz) | ELISA | susceptible species | serum | surveillance | 792 | X |
| trentino alto adige (tn) | ELISA | susceptible species | serum | surveillance | 275 | X |
| umbria | ELISA | susceptible species | serum | surveillance | 2 928 | X |
| valle d'aosta | ELISA | susceptible species | serum | surveillance | 880 | X |
| veneto | ELISA | susceptible species | serum | surveillance | 3 267 | X |
| abruzzo | PCR | susceptible species | blood | surveillance | 0 | X |
| basilicata | PCR | susceptible species | blood | surveillance | 66 | X |
| calabria | PCR | susceptible species | blood | surveillance | 105 | X |
| campania | PCR | susceptible species | blood | surveillance | 82 | X |

Standard requirements for the submission of programme for eradication, control and monitoring

| | | | | | | |
|--------------------------|-----|---------------------|-------|--------------|-----|---|
| emilia romagna | PCR | susceptible species | blood | surveillance | 0 | X |
| friuli venezia giulia | PCR | susceptible species | blood | surveillance | 0 | X |
| lazio | PCR | susceptible species | blood | surveillance | 124 | X |
| liguria | PCR | susceptible species | blood | surveillance | 0 | X |
| lombardia | PCR | susceptible species | blood | surveillance | 0 | X |
| marche | PCR | susceptible species | blood | surveillance | 0 | X |
| molise | PCR | susceptible species | blood | surveillance | 24 | X |
| piemonte | PCR | susceptible species | blood | surveillance | 0 | X |
| puglia | PCR | susceptible species | blood | surveillance | 127 | X |
| sardegna | PCR | susceptible species | blood | surveillance | 0 | X |
| sicilia | PCR | susceptible species | blood | surveillance | 174 | X |
| toscana | PCR | susceptible species | blood | surveillance | 160 | X |
| trentino alto adige (bz) | PCR | susceptible species | blood | surveillance | 0 | X |
| trentino alto adige (tn) | PCR | susceptible species | blood | surveillance | 0 | X |
| umbria | PCR | susceptible species | blood | surveillance | 0 | X |
| valle d'aosta | PCR | susceptible species | blood | surveillance | 0 | X |
| veneto | PCR | susceptible species | blood | surveillance | 0 | X |

Standard requirements for the submission of programme for eradication, control and monitoring

| | | | | | | |
|--------------------------|----------------------|---------------------|-------|--------------|-------|---|
| abruzzo | serum neutralization | susceptible species | serum | surveillance | 0 | X |
| basilicata | serum neutralization | susceptible species | serum | surveillance | 594 | X |
| calabria | serum neutralization | susceptible species | serum | surveillance | 945 | X |
| campania | serum neutralization | susceptible species | serum | surveillance | 738 | X |
| emilia romagna | serum neutralization | susceptible species | serum | surveillance | 0 | X |
| friuli venezia giulia | serum neutralization | susceptible species | serum | surveillance | 0 | X |
| lazio | serum neutralization | susceptible species | serum | surveillance | 1 116 | X |
| liguria | serum neutralization | susceptible species | serum | surveillance | 0 | X |
| lombardia | serum neutralization | susceptible species | serum | surveillance | 0 | X |
| marche | serum neutralization | susceptible species | serum | surveillance | 0 | X |
| molise | serum neutralization | susceptible species | serum | surveillance | 216 | X |
| piemonte | serum neutralization | susceptible species | serum | surveillance | 0 | X |
| puglia | serum neutralization | susceptible species | serum | surveillance | 1 143 | X |
| sardegna | serum neutralization | susceptible species | serum | surveillance | 0 | X |
| sicilia | serum neutralization | susceptible species | serum | surveillance | 1 566 | X |
| toscana | serum neutralization | susceptible species | serum | surveillance | 1 440 | X |
| trentino alto adige (bz) | serum neutralization | susceptible species | serum | surveillance | 0 | X |

Standard requirements for the submission of programme for eradication, control and monitoring

| Region | Species | Total number of animals | Number of animals under the programme | Number of animals expected to be tested | Number of animals to be individually tested | Number of expected positive animals | 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 | susceptible speci | 269 301 | 319 | 319 | 319 | 0 | 0 | 0 | 100 | 0 |
| basilicata | susceptible speci | 418 044 | 328 | 328 | 328 | 66 | 0 | 0 | 100 | 20,12 |
| calabria | susceptible speci | 530 354 | 527 | 527 | 527 | 105 | 0 | 0 | 100 | 19,92 |
| campania | susceptible speci | 407 545 | 408 | 408 | 408 | 82 | 0 | 0 | 100 | 20,1 |
| emilia romagna | susceptible speci | 643 834 | 1 521 | 1 521 | 1 521 | 0 | 0 | 0 | 100 | 0 |
| friuli venezia giulia | susceptible speci | 106 911 | 449 | 449 | 449 | 0 | 0 | 0 | 100 | 0 |
| lazio | susceptible speci | 989 135 | 618 | 618 | 618 | 124 | 0 | 0 | 100 | 20,06 |
| liguria | susceptible speci | 38 957 | 297 | 297 | 297 | 0 | 0 | 0 | 100 | 0 |
| lombardia | susceptible speci | 1 703 061 | 2 459 | 2 459 | 2 459 | 0 | 0 | 0 | 100 | 0 |
| marche | susceptible speci | 207 800 | 324 | 324 | 324 | 0 | 0 | 0 | 100 | 0 |
| molise | susceptible speci | 126 678 | 122 | 122 | 122 | 24 | 0 | 0 | 100 | 19,67 |
| piemonte | susceptible speci | 985 623 | 1 835 | 1 835 | 1 835 | 0 | 0 | 0 | 100 | 0 |
| puglia | susceptible speci | 498 795 | 637 | 637 | 637 | 127 | 0 | 0 | 100 | 19,94 |
| sardegna | susceptible speci | 3 667 355 | 870 | 870 | 870 | 0 | 0 | 0 | 100 | 0 |
| sicilia | susceptible speci | 1 330 876 | 870 | 870 | 870 | 174 | 0 | 0 | 100 | 20 |
| toscana | susceptible speci | 537 897 | 799 | 799 | 799 | 160 | 0 | 0 | 100 | 20,03 |
| trentino alto adige (bz) | susceptible speci | 194 483 | 72 | 72 | 72 | 0 | 0 | 0 | 100 | 0 |

Standard requirements for the submission of programme for eradication, control and monitoring

| Region | Species | Total number of animals | Number of animals under the programme | Number of animals expected to be tested | Number of animals to be individually tested | Number of expected positive animals | 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) |
|--------------------------|-------------------|-------------------------|---------------------------------------|---|---|-------------------------------------|---|--|-------------------------------------|---|
| trentino alto adige (tn) | susceptible speci | 86 885 | 25 | 25 | 25 | 0 | 0 | 0 | 100 | 0 |
| umbria | susceptible speci | 175 884 | 244 | 244 | 244 | 0 | 0 | 0 | 100 | 0 |
| valle d'aosta | susceptible speci | 41 252 | 80 | 80 | 80 | 0 | 0 | 0 | 100 | 0 |
| veneto | susceptible speci | 831 589 | 297 | 297 | 297 | 0 | 0 | 0 | 100 | 0 |
| Total | | 13 792 259 | 13 101 | 13 101 | 13 101 | 862 | 0 | 0 | 100 | 6,58 |
| Total | | 13 792 259 | 13 101 | 13 101 | 13 101 | 862 | 0 | 0 | 100 | 6,58 |
| Total | | 13 792 259 | 13 101 | 13 101 | 13 101 | 862 | 0 | 0 | 100 | 6,58 |
| Total | | 13 792 259 | 13 101 | 13 101 | 13 101 | 862 | 0 | 0 | 100 | 6,58 |
| Total | | 13 792 259 | 13 101 | 13 101 | 13 101 | 862 | 0 | 0 | 100 | 6,58 |
| Total | | 13 792 259 | 13 101 | 13 101 | 13 101 | 862 | 0 | 0 | 100 | 6,58 |
| Add a new row | | | | | | | | | | |

7.1.2.2 Targets on sampling herds

Targets on the sampling of herds for year: **2016**

Standard requirements for the submission of programme for eradication, control and monitoring

| 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 | Target indicators | | |
|-----------------------|---------------------|-----------------------|---|--|-----------------------------------|---------------------------------------|--|---|--------------------------|--|--|---|
| | | | | | | | | | | % positive herds Expected period herd prevalence | % new positive herds Expected herd incidence | |
| abruzzo | susceptible species | 11 976 | 46 | 46 | 0 | 0 | 0 | 0 | 100 | 0 | 0 | X |
| basilicata | susceptible species | 10 814 | 47 | 47 | 2 | 2 | 0 | 0 | 100 | 4,26 | 4,26 | X |
| calabria | susceptible species | 18 154 | 75 | 75 | 4 | 4 | 0 | 0 | 100 | 5,33 | 5,33 | X |
| campania | susceptible species | 21 920 | 58 | 58 | 3 | 3 | 0 | 0 | 100 | 5,17 | 5,17 | X |
| emilia romagna | susceptible species | 11 198 | 217 | 217 | 0 | 0 | 0 | 0 | 100 | 0 | 0 | X |
| friuli venezia giulia | susceptible species | 3 347 | 64 | 64 | 0 | 0 | 0 | 0 | 100 | 0 | 0 | X |
| lazio | susceptible species | 21 910 | 88 | 88 | 4 | 4 | 0 | 0 | 100 | 4,55 | 4,55 | X |
| liguria | susceptible species | 4 112 | 42 | 42 | 0 | 0 | 0 | 0 | 100 | 0 | 0 | X |
| lombardia | susceptible species | 15 258 | 351 | 351 | 0 | 0 | 0 | 0 | 100 | 0 | 0 | X |
| marche | susceptible species | 8 178 | 46 | 46 | 0 | 0 | 0 | 0 | 100 | 0 | 0 | X |
| molise | susceptible species | 5 691 | 17 | 17 | 1 | 1 | 0 | 0 | 100 | 5,88 | 5,88 | X |
| piemonte | susceptible species | 24 424 | 262 | 262 | 0 | 0 | 0 | 0 | 100 | 0 | 0 | X |
| puglia | susceptible species | 9 037 | 91 | 91 | 5 | 5 | 0 | 0 | 100 | 5,49 | 5,49 | X |
| sardegna | susceptible species | 29 947 | 124 | 124 | 0 | 0 | 0 | 0 | 100 | 0 | 0 | X |
| sicilia | susceptible species | 21 857 | 124 | 124 | 6 | 6 | 0 | 0 | 100 | 4,84 | 4,84 | X |

Standard requirements for the submission of programme for eradication, control and monitoring

| | | | | | | | | | | | | |
|--------------------------|---------------------|---------|-------|-------|----|----|---|---|----------------------|------|------|----------|
| toscana | susceptible species | 10 719 | 114 | 114 | 6 | 6 | 0 | 0 | 100 | 5,26 | 5,26 | X |
| trentino alto adige (bz) | susceptible species | 12 985 | 10 | 10 | 0 | 0 | 0 | 0 | 100 | 0 | 0 | X |
| trentino alto adige (tn) | susceptible species | 3 162 | 4 | 4 | 0 | 0 | 0 | 0 | 100 | 0 | 0 | X |
| umbria | susceptible species | 6 628 | 35 | 35 | 0 | 0 | 0 | 0 | 100 | 0 | 0 | X |
| valle d'aosta | susceptible species | 2 199 | 11 | 11 | 0 | 0 | 0 | 0 | 100 | 0 | 0 | X |
| veneto | susceptible species | 17 591 | 42 | 42 | 0 | 0 | 0 | 0 | 100 | 0 | 0 | X |
| Total | | 271 107 | 1 868 | 1 868 | 31 | 31 | 0 | 0 | 100 | 1,66 | 1,66 | |
| | | | | | | | | | Add a new row | | | |

7.2 Targets on vaccination

Targets on vaccination for year :

2016

| Region | Animal species | Total number of herds | Total number of animals | Targets on vaccination | | | | | Number of young animals expected to be vaccinated | |
|------------|---------------------|-----------------------|-------------------------|--------------------------------|---|---|--|--|---|----------|
| | | | | Number of herds in vaccination | Number of herds expected to be vaccinated | Number of animals expected to be vaccinated | Number of doses of vaccine expected to be administered | Number of adults expected to be vaccinated | | |
| abruzzo | susceptible species | 11 976 | 269 301 | 11 976 | 11 976 | 323 161 | 377 021 | 269 301 | 53 860 | X |
| basilicata | susceptible species | 10 814 | 418 044 | 10 814 | 10 814 | 501 653 | 585 262 | 418 044 | 83 609 | X |

Standard requirements for the submission of programme for eradication, control and monitoring

| | | | | | | | | | | |
|--------------------------|---------------------|--------|-----------|--------|--------|-----------|-----------|-----------|---------|----------|
| calabria | susceptible species | 18 154 | 530 354 | 18 154 | 18 154 | 636 425 | 742 496 | 530 354 | 106 071 | X |
| campania | susceptible species | 21 920 | 407 545 | 21 920 | 21 920 | 489 054 | 570 563 | 407 545 | 81 509 | X |
| emilia romagna | susceptible species | 11 198 | 643 834 | 2 276 | 2 276 | 72 992 | 85 157 | 60 827 | 12 165 | X |
| friluli venezia giulia | susceptible species | 3 347 | 106 911 | 0 | 0 | 0 | 0 | 0 | 0 | X |
| lazio | susceptible species | 21 910 | 989 135 | 21 910 | 21 910 | 1 186 962 | 1 384 789 | 989 135 | 197 827 | X |
| liguria | susceptible species | 4 112 | 38 957 | 953 | 953 | 9 838 | 11 478 | 8 198 | 1 640 | X |
| lombardia | susceptible species | 15 258 | 1 703 061 | 0 | 0 | 0 | 0 | 0 | 0 | X |
| marche | susceptible species | 8 178 | 207 800 | 8 178 | 8 178 | 249 360 | 290 920 | 207 800 | 41 560 | X |
| molise | susceptible species | 5 691 | 126 678 | 5 691 | 5 691 | 152 014 | 177 350 | 126 678 | 25 336 | X |
| piemonte | susceptible species | 24 424 | 985 623 | 0 | 0 | 0 | 0 | 0 | 0 | X |
| puglia | susceptible species | 9 037 | 498 795 | 9 037 | 9 037 | 598 554 | 1 396 626 | 498 795 | 99 759 | X |
| sardegna | susceptible species | 29 947 | 3 667 355 | 29 947 | 29 947 | 4 400 826 | 5 134 297 | 3 667 355 | 733 471 | X |
| sicilia | susceptible species | 21 857 | 1 330 876 | 21 857 | 21 857 | 1 597 051 | 1 863 226 | 1 330 876 | 266 175 | X |
| toscana | susceptible species | 10 719 | 537 897 | 10 719 | 10 719 | 645 476 | 753 055 | 537 897 | 107 579 | X |
| trentino alto adige (BZ) | susceptible species | 12 985 | 194 483 | 0 | 0 | 0 | 0 | 0 | 0 | X |
| trentino alto adige (TN) | susceptible species | 3 162 | 86 885 | 0 | 0 | 0 | 0 | 0 | 0 | X |
| umbria | susceptible species | 6 628 | 175 884 | 6 628 | 6 628 | 211 061 | 246 238 | 175 884 | 35 177 | X |
| valle d'aosta | susceptible species | 2 199 | 41 252 | 0 | 0 | 0 | 0 | 0 | 0 | X |
| veneto | susceptible species | 17 591 | 831 589 | 0 | 0 | 0 | 0 | 0 | 0 | X |

Standard requirements for the submission of programme for eradication, control and monitoring

| | | | | | | | | | |
|--------------|---------|------------|---------|---------|------------|-------------------|----------------------|-----------|--|
| Total | 271 107 | 13 792 259 | 180 060 | 180 060 | 11 074 427 | 13 618 478 | 9 228 689 | 1 845 738 | |
| | | | | | | | Add a new row | | |

Standard requirements for the submission of programme for eradication, control and monitoring

8. Detailed analysis of the cost of the programme

8.1 Costs of the planned activities for year: **2016**

The blocks are repeated multiple times in case of first year submission of multiple program.

To facilitate the handling of your cost data, you are kindly requested to:

1. Fill-in the text fields IN ENGLISH
2. Limit as much as possible the entries to the pre-loaded options where available.
3. If you need to further specify a pre-loaded option, please keep the pre-loaded text and add your clarification to it in the same box.

| 1. Testing | | | | | | | |
|------------------|---------------------------|-------------------------------|-----------------|---------------------|---------------------|-------------------------|----------|
| Cost related to | Specification | Unit | Number of units | Unitary cost in EUR | Total amount in EUR | Union funding requested | |
| Cost of analysis | ELISA | Individual animal sample/test | 150 474 | 1.69 | 254 301,06 | yes | X |
| Cost of analysis | PCR | Individual animal sample/test | 862 | 25.08 | 21618,96 | yes | X |
| Cost of analysis | Other | Individual animal sample/test | 7 758 | 10 | 77580 | yes | X |
| Cost of sampling | Domestic animals | Individual animal sampled | 13 101 | 2.12 | 27774,12 | yes | X |
| 2. Vaccines | | | | | | | |
| Cost related to | Specification | Unit | Number of units | Unitary cost in EUR | Total amount in EUR | Union funding requested | |
| Vaccine doses | BTV 1 and Bivalent BTV2-4 | Vaccine dose | 13 618 478 | 0.3 | 4,085,543.4 | yes | X |

Standard requirements for the submission of programme for eradication, control and monitoring

| | | Add a new row | |
|---|---------------------------------|--------------------|----------------------------------|
| Total number of Vaccine doses (see at the right) corresponds to the total nr of vaccines in table 7.2.1 | Total number of Vaccine doses : | 13 618 478 | Amount (funding requested = yes) |
| | Total number of Others : | 0 | Amount (funding requested = yes) |
| | | Grand Total | Grand Total |
| | | | 4 085 543,4 |
| | | | 0 |
| | | | 4 466 817,54 € |

8.2. Financial information

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 perform 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) :

The official veterinarians of the ASLs and contracted veterinarians will perform the sampling. They are paid by the ASLs with national/regional budget.

Standard requirements for the submission of programme for eradication, control and monitoring

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) :

The Istituti Zooprofilattici Sperimentali perform the testing and the confirm is performed by NRL. The costs related to this testing are entirely paid by national budget.

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) :

Compensation is paid by the Ministry of Health (national budget).

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 monitoring

(max. 32000 chars) :

Vaccination costs (both costs of doses and vaccination costs) are paid in advance by Regional authorities and after the Ministry of Health reimburse up for a maximum of 2/3 of the medium vaccines (per doses) cost. The amount is based on the regional data referred to the total number of doses factually employed in the vaccination campaign.

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

(max. 32000 chars) :

Other measures will be implemented by the regional veterinary authorities. Equipment and services will be provided by regional veterinary authorities, local veterinary services and local Istituti Zooprofilattici Sperimentali. All measures are charged on national budget.

2 Co-financing rate (see provisions of applicable Work Programme)

The maximum co-financing rate is in general fixed at 50%. However based on provisions of Article 5.2 and 5.3 of the Regulation (EU) No 652/2014, we request that the co-financing rate for the reimbursement of the eligible costs would be increased:

Up to 75% for the measures detailed below

Up to 100% for the measures detailed below

Standard requirements for the submission of programme for eradication, control and monitoring

3. 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 monitoring

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, .png, .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 |
|--|-----------------------|--|-----------|
| | Annex I _ BT 2016.pdf | AnnexI_BT2016.pdf | 431 kb |
| | annex II.docx | annexII.docx | 433 kb |
| | | Total size of attachments : | 864 kb |