EUROPEAN HEALTH AND DIGITAL EXECUTIVE AGENCY (HaDEA)

Department A Health and Food
Unit A2 EU4Health/SMP

Food Programmes for eradication, control and surveillance of animal diseases and zoonoses

submitted for obtaining EU financial contribution

Annex III: Programme for the control and eradication of Transmissible Spongiform Encephalopathies

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Member state : ESPANA

Disease Transmissible Spongiform Encephalopathies

This program is multi annual : no

Request of Union co-financing from beginning : 2023 To end of 2023

1. Contact data

Name Phone

Email Your job type within the CA :

Submission Date **Submission Number**

01/12/2022 15:18:45 **1669904326662-18991**

2. Description of the programme

Please give a short description of the programme (max. 32000 chars) :

n 1994, Spain began to apply measures to prevent, control and eradicate TSEs by monitoring meat meals in feed. Since 1997, in accordance with the criteria of the World Organisation for Animal Health (OIE), and in application of Community regulations, Spain has implemented control and monitoring programmes for transmissible spongiform encephalopathies based on passive monitoring.
As a result of the emergence of the first case of BSE in a bovine animal in Spain in the year 2000, and following publication of Royal Decree 3454/2000 establishing and regulating the Coordinated Integral Programme for the monitoring and control of transmissible spongiform encephalopathies in animals, specific action became necessary, particularly programmes of active monitoring, control of substances used in animal feed, inspection of establishments for the processing of by-products and dead animals and controls on specified risk materials.
At EU level, Regulation (EC) 999/2001 as amended represents the cornerstone of the fight against TSEs, as it is a compilation of all mandatory EU measures in various fields (monitoring, eradication, feedingstuffs, Specified Risk Material, etc.) which hitherto came under various Community Decisions. The strict eradication measures taken to deal with outbreaks of scrapie were based on the theoretical possibility that these animals might be suffering from BSE. The situation has now changed, in that discriminatory diagnostic tests are now available that permit BSE to be distinguished from scrapie. In July 2005 the Commission proposed a new control strategy that was outlined in the 'Road Map' document with the aim of presenting the strategy to combat TSEs in the short, medium and long terms. Owing to a general improvement in the epidemiological situation in the EU and new scientific knowledge, in July 2010 the Commission published the 'New Road Map' aimed at looking into relaxing the measures relating to TSEs, provided that food security is ensured. This document sets out the key points that could change over the coming years. The surveillance and eradication components of this programme comply with Regulation (EC) No 999/2001 as amended, and it would accordingly be re-evaluated and redesigned if necessary to meet any new requirements.
This programme has a double objective:
- to ascertain the epidemiological situation in the population of cattle and small ruminants (sheep and goats) in relation to BSE and scrapie, and
- to detect these diseases and, if necessary, implement the appropriate control and eradication measures.

In 2021 and 2022 the specific objective for the BSE programme is to continue to comply with requirements in order to maintain Spain's classification as a country with negligible BSE risk status, achieved in 2016.
Monitoring scheme for bovine
A.- ACTIVE SURVEILLANCE.
The active surveillance included in the National Program, is adapted to the regulatory changes, both community and national, related to the modifications of the ages of the animals subject to obligatory sampling.
The active monitoring program is aimed at the effective search for the disease, through the control of certain populations of animals for consumption and animals at risk.
In the period 2023, the following animal subpopulations will be monitored by performing rapid diagnostic tests in laboratories authorized by the Autonomous Communities.

A.1. Animals slaughtered for human consumption:
BSE tests will be performed on:
A.1.1.- All animals born in countries included in the Annex to Decision 2009/719/EC and amendments,

authorizing certain Member States to revise their annual BSE monitoring program, of the following age groups:
(a) Over forty-eight months (48) of age provided that they are:
- 1st.-Animals subjected to emergency slaughter.
- 2º.-Animals that during the ante-mortem inspection are suspected of suffering from a disease or being in a state of health that can harm human health, except for animals slaughtered in the framework of an eradication campaign that do not present clinical signs of the disease.
b) All healthy animals slaughtered for human consumption that were born before January 1, 2001, as long as they come from farms in which BSE outbreaks have been diagnosed. This condition will be recorded in the documentation foreseen in article 6 of Royal Decree 728/2007, of June 13, establishing and regulating the General Register of Livestock Movements and the General Register of Individual Animal Identification.

A.1.2.- All animals born in third countries and EEMM not included in the Annex of Decision 2009/719/CE and amendments and therefore are countries not authorized to review their annual BSE monitoring program, of the following age groups:
(a) Over thirty months (30) of age provided that they are:
- 1º.- Animals slaughtered in a normal manner for human consumption. Animals born or not in Great Britain and imported from Great Britain since 01/01/2021 are included; or
- Animals slaughtered within the framework of the execution of Royal Decree 2611/1996, of December 20, 1996, which regulates the national programs for the eradication of animal diseases, as long as in the latter case they do not present clinical signs of the disease.
b) Older than twenty-four months (24) of age if they are:

- 1º.- Animals submitted to emergency slaughter.

- 2º.- Animals that during the ante-mortem inspection are suspected of suffering a disease or being in a state of health that can harm the health of people, except for animals slaughtered within the framework of an eradication campaign that do not present clinical signs of the disease.

The term "emergency slaughter", according to section I, chapter VI, point 1 of Annex III of Regulation (EC) 853/2004, means the slaughter of an animal that, being otherwise healthy, must have suffered an accident that prevented its transport to the slaughterhouse, taking into account its welfare.
"Ante-mortem inspection", according to Regulation (EC) 2017/625, means the verification, prior to slaughtering tasks, of compliance with human health and animal health and welfare requirements, including, where appropriate, the clinical examination of each animal, and the verification of the agri-food chain information referred to in Annex II, Section III, of Regulation (EC) No 853/2004.
Animals without clinical symptoms of the disease, slaughtered in the framework of a disease eradication campaign of those established in Royal Decree 2611/1996, will be exempted from this consideration and will be considered under the corresponding epigraph according to the final destination of those carcasses.
Animals born or not in Great Britain and imported from Great Britain since 01/01/2021 are included.

A.2. Animals dead and not slaughtered for human consumption, older than forty-eight (48) months:
All bovine animals over forty-eight months of age that have died or have been slaughtered, but were not slaughtered as part of an epidemic, as is the case with foot and mouth disease, shall be tested for BSE.
However, in the case of animals born in third countries (Including animals born or not in Great Britain and imported from Great Britain since 01/01/2021) and EEMM not listed in the Annex to Decision 2009/719/EC and amendments, all bovine animals over twenty-four months of age shall be tested for BSE.

The following subpopulations are specifically included:
- Bovine animals which have died on farm or during transport.
- Bovine animals that have been slaughtered, but not for human consumption or in the framework of an epidemic, either on the farm or, exceptionally, in a slaughterhouse until specific establishments or facilities are available, including animals from disease eradication campaigns of those established in Royal Decree 2611/1996, culling or similar not destined for human consumption.
NOTE: Any animal that, having shown symptoms compatible with BSE, dies or is slaughtered on the farm, will be classified within the subpopulation of suspect animal, and therefore will be treated as described in section B explained below.

Bovine animals slaughtered as an application of the eradication measures of a BSE outbreak, and belonging to the population at risk (offspring and age cohort) will all be sampled based on the epidemiological investigation carried out in that outbreak.
In case the result of the rapid tests performed is positive or doubtful, the sample will be referred for analysis by confirmatory testing to the National Reference Laboratory for TSEs (LCV).
B.- PASSIVE SURVEILLANCE.
The passive surveillance of the disease consists, basically, in the detection of positive animals due to the communication by veterinarians or farmers/animal handlers or the appearance of animals with clinical symptomatology compatible with TSEs.
All animals suspected by symptomatology (defined in section 4.6.B of this program) will be submitted to control, independently of their age, by means of confirmatory tests established in the OIE Manual, in the National Reference Laboratory for TSEs (LCV).
They shall be submitted to control by means of confirmatory tests established in the OIE Manual, at the National Reference Laboratory:

B.1.- All animals suspected by symptomatology (any live, slaughtered or dead animal that presents or has presented neurological or behavioral abnormalities or CNS disorder, for which no other diagnosis can be established on the basis of clinical examination, response to treatment, post-mortem examination or following ante or post-mortem laboratory analysis).

B.2.- All animals of groups A1 and A2 specified above, whose sample has been positive or doubtful to rapid tests in authorized laboratories.
At all times, the animals described as TSE suspects will be submitted to control by means of methods and protocols of confirmation, established in the OIE Manual, in the National Reference Laboratory for TSEs (LCV).

Monitoring in sheep and goats

A. Active surveillance:

Aimed at actively searching for the disease, by means of random and representative sampling of a certain number of animals, classified into different groups called "subpopulations".

The selection of the sample will be made in such a way as to avoid over-representation of any group in terms of origin, age, breed, type of production or any other characteristic. The sample shall be representative of each region and season, avoiding, whenever possible, multiple sampling in the same herd. Whenever possible, efforts should be made to test for TSEs in subsequent years on all officially registered farms with more than 100 head on which TSEs have never been detected.

The subpopulations to be sampled presented below have been adapted to the provisions of Decision 2014/288/EU and to those requested by the European Commission in Annex III, the model through

which the program is sent for approval and subsequent co-financing.

A.1.- Animals intended for human consumption older than 18 months, or whose gums have erupted two permanent incisors.
This includes 10,000 sheep and 10,000 goats. In this subpopulation, animals slaughtered within the framework of a livestock sanitation campaign, as contemplated in Royal Decree 2611/1996, may be included, without this group exceeding 10% of the minimum total established, as established in Annex I of this program.
In addition, a maximum of 50 % of its minimum sample of sheep or goats slaughtered for human consumption established, can be substituted by the analysis of dead sheep or goats older than eighteen months, at a ratio of 1:1.

A.2.- Animals not slaughtered for human consumption, older than 18 months, or whose gums have erupted two permanent incisors.
10,000 sheep and 10,000 goats are included, which in turn are divided into the following groups:
- dead on the farm.
- slaughtered, but not for human consumption or as part of a disease eradication campaign, regulated by Royal Decree 2611/1996.

A.3 Animals from holdings subject to control and eradication measures of Regulation 999/2001 (monitoring in holdings subject to control and eradication measures for TSEs).
In this point, the animals referred to in points 2.2.2 b and 2.2.2.c of Chapter B of Annex VII will be sampled.
This includes animals that are slaughtered for destruction or for human consumption in application of the eradication measures: option 1 (slaughter and destruction/human consumption of all animals) and option 2 (slaughter and destruction/human consumption of all susceptible animals).

A.3.a. - In the case that slaughter and destruction is chosen, sampling will be as follows:
In this case, an established minimum quantity6 (animals > 18 months) will be sampled according to the census in the herd in which the positive is detected, as detailed in the following table6.

Number of animals older than 18 months, or with a dentition of more than two permanent incisors, slaughtered for destruction in the herd. Minimum sample size
70 or less All eligible animals
80 68
90 73
100 78
120 86
140 92
160 97
180 101
200 105
250 112
300 117
350 121
400 124
450 127
500 or more 150

A.3.b.- In the case that slaughter and destination for human consumption is chosen, all the premises

established in Order PRE/1642/2013 must be fulfilled. All animals > 18 months destined for human consumption will be sampled.
Animals from holdings under control and eradication measures of Regulation 999/2001 (monitoring in holdings under control and eradication measures for TSEs).
In this point, the animals referred to in points 2.2.1 shall be sampled when the presence of BSE in the farm cannot be ruled out.
In this case, a minimum established quantity6 (animals > 18 months) will be sampled according to the census in the herd in which the positive is detected, as detailed in the table above (A.3.a).

A.4 Animals from holdings subjected to monitoring (analysis of sheep, for 2 years, after the application of the measures (animals referred to in Annex VII, chapter B, point 3.1: after applying options 1 and 2 and when BSE is not excluded).
After the application of the different eradication measures in the case of classical scrapie (point 4.7 of this program) the animals must undergo monitoring Animals from holdings under control and eradication measures of Regulation 999/2001 (monitoring in holdings under control and eradication measures for TSEs).
At this point, the animals referred to in points 2.2.1 shall be sampled when the presence of BSE in the farm cannot be ruled out.
In this case, a minimum established quantity (animals > 18 months) will be sampled according to the census in the herd in which the positive is detected, as detailed in the table above (A.3.a).

A.5 Animals from flocks subjected to monitoring (analysis of sheep, for 2 years, after the application of the measures (animals referred to in Annex VII, chapter B, point 3.1: after applying options 1 and 2 and when BSE is not excluded).
After the application of the different eradication measures in the case of classical scrapie (point 4.7 of this program) the animals must be subjected to an intensified surveillance (point 3, Chapter B Annex VII) of at least two years consisting of the analysis of:
- all animals > 18 months dead or slaughtered not for consumption;
- all animals > 18 months slaughtered for human consumption that were present on the farm when the case of classical scrapie was confirmed.

A.6.- Animals from infected flocks (option 3 or the exceptions contemplated in option 2), subjected to follow-up (ovine analysis, for 2 years and applying the measures of point 4.1.
Chapter B Annex VII).
The following must be sampled
- all animals > 18 months dead or slaughtered not for consumption;
- all animals > 18 months slaughtered for human consumption.
A.7.- All holdings that carry out intra-community trade must comply with the conditions established in Annex VIII, Chapter A, Section A of Regulation 999/2001.
The sampling will depend on the classification of the farms against classical scrapie (Controlled Risk or Insignificant Risk) and will focus on the analysis of all dead animals > 18 months in the qualified farms.
B. Passive surveillance.
Any animal that presents clinical symptoms compatible with scrapie will be sacrificed. The tissue will be sent to the LNR, as established in the "Manual for taking samples and sending them to the LNR".

3. *Description of the epidemiological situation of the disease*

Annex III: Programme for the control and eradication of Transmissible Spongiform Encephalopathies

Last year's No of cases	Total No	No of classical cases	No of atypical cases	No of undetermined cases
BSE case	2	0	2	0
Scrapie case (ovine)	190	184	6	0
Scrapie case (caprine)	45	43	2	0
Last case of		date (classical case)	date (atypical case)	date (undetermined case)
BSE		25/07/2014	17/08/2021	
Scrapie (ovine)		11/01/2022	18/01/2022	
Scrapie (caprine)		01/09/2021		

Comments (if any)

The epidemiological monitoring conducted in Spain, provided for in Royal Decree 3454/2000 establishing and regulating the Coordinated Integral Programme for the monitoring and control of transmissible spongiform encephalopathies in animals, has been changing on several occasions to adapt it to new scientific knowledge on the subject and to Community rules.
This approach of gradual changes to the monitoring programme has made it possible to steadily raise the age of cattle for compulsory sampling. This explains the slight but continuous reduction in the number of BSE tests carried out, which was particularly marked in 2014, following the decision to stop sampling healthy cattle slaughtered for human consumption.
The main changes to relax the rules on BSE monitoring in Spain were introduced on 4 June 2009, following publication of the amendment to the Spanish Royal Decree to bring it into line with Decision 2008/908/EU (repealed by Decision 2009/719/EC) authorising certain Member States to revise their annual BSE monitoring programmes, including Spain.
Since then, the successive amendments to Decision 2009/719/EC have been transposed into Spanish law to continue raising the age of cattle for compulsory sampling.
The most recent amendment was adopted by the Commission Implementing Decision of 4 February 2013 (Decision 2013/76/EC), authorising certain Member States to stop active BSE monitoring in healthy animals slaughtered in slaughterhouses. This and other measures to relax the rules are set out in Order PRE/1550/2013, which has been in force in Spain since 14 August 2013.

With regard to BSE, between confirmation of the first case of BSE in Spain in 2000 and 31 December 2021, a total of 801 outbreaks (index case) were detected (see the map in Annex I). The graph showing the annual number of outbreaks in Spain in this period shows a peak in 2003 followed by a constant reduction, typical of a pattern of eradication of the disease (Annex I). Thus, the trend analysis for the time series 2002-2020 shows that the decline is significant for the whole series (Mantel test for trend $p< 0.001$ (Abramson J.H. WINPEPI (PEPI-for-Windows): computer programs for epidemiologists. Epidemiologic Perspectives & Innovations 2004, 1: 6).

For a better understanding of the distribution of BSE in recent years it is necessary to analyse the age of the animals, grouping the cases by the year of birth of the positive animals. The pattern of distribution of the cases grouped using this criterion is similar to that of its appearance (a peak followed by a gradual reduction). (See Annex I). The greatest proportion of the cases detected corresponds to animals born during the period 1995-1998, and the maximum number of positive animals were born in 1997.
We thus detect a period of seven years between the maximum births of cases testing positive for BSE (1997) and the year when the greatest number of cases of BSE were detected (2003).
Analysis of the average age of the cases detected shows that this has risen since surveillance began, from an average of 6.4 years of age to 15.9 years of age (the average in 2016) with a peak average age of 18.66 years in 2014 (see Annex I). The most recent cases detected in 2011 and 2012 in animals born in 2005

were cases of atypical BSE, which should not be taken into account in the joint assessment of the average age of positive animals since their condition is not linked to the consumption of contaminated feed. In the risk analysis conducted to demonstrate the efficacy of the control measures, entering data that are not linked to those measures might skew the results obtained. However, given that the emergence of these cases in the EU is relatively recent and the European Commission has not set out guidelines for the independent notification of atypical strains, in Spain these positives are included in the assessment of the evolution of the disease until all the Member States reach a consensus on how they should be notified.
The last case of classical BSE was detected on 25 July 2014 (date of sampling) and the last case of atypical BSE was detected on 23 December 2020.
Conclusions from the epidemiological evolution of BSE:
• A constant decline in the number of BSE cases has been observed in Spain, with the peak decline of 46% recorded in 2007.
• The trend analysis for the time series 2002-2021 shows that the decline is significant for the whole series.
• The increase in the average age indicates progress in eradicating BSE.
• The reduction in the number of cases and the increase in the average age of the animals detected demonstrate the effectiveness of the control measures adopted and the progress made in eradicating this disease.
• It may be concluded from the results of the retrospective discriminatory study that the prevalence of the atypical strains during the 2003-2021 period remained low and constant and was concentrated in animals of advanced years. Bearing in mind that these results are similar in the other Member States studied, the data obtained reinforce the hypothesis that atypical BSE is a spontaneous, sporadic disease.
• In light of the favourable development of the epidemiological indicators, Spain asked the World Organisation for Animal Health (OIE) to recognise it as a country with negligible BSE risk status. Our request was granted in May 2016 and that status will be maintained provided that the requirements giving rise to the request continue to be met.

As regards scrapie, there is no clear pattern in the development of the disease. The trend analysis shows a decline, but it is not significant for the whole period (2000-2021), only for the period 2008-2016. The software used to analyse time trends was WINPEPI software (Abramson, J.H. WINPEPI (PEPI-for-Windows): computer programs for epidemiologists. Epidemiologic Perspectives & Innovations 2004, 1: 6).
In 2021, 18 outbreaks were declared (index case) (11 in sheep and 7 in goats), of which 10 outbreaks were classical strains and 8 were atypical (see the graph showing the number of outbreaks and the table characterising the outbreaks in Annex I).
In the period 2006-2021 (data shown in the table under point 3 Description of the epidemiological situation of the disease) 11 ovine outbreaks were detected (index cases), of which 5 were classical strains and 6 were atypical; and 7 caprine outbreaks were detected (index cases), of which 5 were classical strains and 2 were atypical.

4. Measures included in the programme

4.1 Designation of the central authority in charge of supervising and coordinating the departements responsible for implementing the programme

(max. 32000 chars) :

• The central authority responsible for the coordination and follow-up of the departments responsible for carrying out the programme: the Subdirectorate-General for Animal Health and Hygiene and Traceability

(Ministry of Agriculture, Fisheries and Food – MAPA) is responsible for coordinating the programme and for informing the Commission concerning the development of this disease.
The 'National Committee for the Veterinary Health Alert System', set up under Royal Decree 1440/2001 of 21 December 2001 establishing the veterinary health alert system, is responsible for studying and proposing measures to eradicate diseases and monitoring the development of the epidemiological situation for diseases subject to eradication programmes. The committee is a collegiate body on which all the authorities responsible for coordinating and executing the measures planned in this Programme are represented.
• Competent authorities at regional level: the Veterinary Services for Animal Health and Production, and for Public Health and Quality Control of Food and Agriculture in the Autonomous Communities, are responsible for implementing the Programme and compiling, evaluating and computerising the data obtained in their territory and sending it to the central authorities.
• National Reference Laboratories: the following are recognised as National Reference Laboratories:
a) the Algete (Madrid) Central Veterinary Laboratory of the Ministry of Agriculture, Fisheries and Food is the National Reference Laboratory for the diagnosis of Bovine Spongiform Encephalopathy (BSE).
b) The Food and Agriculture Arbitration Laboratory of the Ministry of Agriculture, Fisheries and Food is the National Reference Laboratory for testing for the presence of animal products or remains, including meat and bone meal, in substances intended for feeding to production animals.
• Authorised or recognised laboratories: the competent bodies in the Autonomous Communities will designate laboratories located within their areas of jurisdiction to be responsible for the analytical monitoring of encephalopathies, including rapid post-mortem tests and the diagnostic techniques defined in the OIE's Diagnostics Manual and checks on the substances intended to feed production livestock. These laboratories may be public or private.
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4.2 Description and delimitation of the geographical and administrative areas in which the programme is to be applied

(max. 32000 chars) :

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• Authorised or recognised laboratories: the competent bodies in the Autonomous Communities will designate laboratories located within their areas of jurisdiction to be responsible for the analytical monitoring of encephalopathies, including rapid post-mortem tests and the diagnostic techniques defined in the OIE's Diagnostics Manual and checks on the substances intended to feed production livestock. These laboratories may be public or private.

4.3 System in place for the registration of holdings

(max. 32000 chars) :

Article 38(1) of Law 8/2003 of 24 April 2003 on animal health states that all livestock holdings must be registered in the Autonomous Community where they are located and that the basic information on those holdings is to be included in a national information register.
On that basis, Royal Decree 479/2004 of 26 March 2004 setting up and regulating the General Register of Livestock Holdings (REGA) was approved. It is a multi-species register containing data provided by each of the Autonomous Communities on all farms in Spain.

REGA is part of the Integrated Animal Traceability System (SITRAN) together with the Movements Register (REMO) and the Individual Animal Identification Register (RIIA), the legal basis for which is Royal Decree 728/2007 of 13 June 2007 setting up and regulating the General Register of Livestock Movements and the General Individual Animal Identification Register.

SITRAN is a heterogeneous and distributed database that feeds the records in the various Autonomous Communities into a centralised register, through specifically developed information exchange mechanisms.
Apart from Spanish legislation (in force) to mention EU legislation that supports it:

• Regulation (EU) 2016/429: PART IV REGISTRATION, AUTHORIZATION, TRACEABILITY AND DISPLACEMENT

• Commission Delegated Regulation (EU) 2019/2035 of 28 June 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for establishments keeping terrestrial animals and hatcheries, and the traceability of certain kept terrestrial animals and hatching eggs

4.4 System in place for the identification of animals

(max. 32000 chars) :

he identification system for bovine animals is regulated at EU level by Regulation 1760/2000 of 17 July 2000 establishing a system of identification and registration of bovine animals and at domestic level by Royal Decree 1980/1998 of 18 September 1998 establishing a system for identifying and registering bovine animals.
The identification system consists of the following elements:
- Ear tags: consisting of two plastic tags that are fixed to each of the ears and bear the same unique identification code that can identify each individual animal and the holding on which it was born.
- Computerised database: in Spain it is called SITRAN and it incorporates the General Register of

Livestock Holdings (REGA), the Individual Animal Identification Register (RIAA) and the Movements Register (REMO).
- Bovine Identification Document (DIB) which accompanies the animal on any movement.
- Holding logbook which may be manual or computerised and must be accessible to the competent authority for at least three years.

Royal Decree 685/2013 of 16 September 2013, repealing the provisions laid down for ovine and caprine species in Royal Decree 947/2005, establishes an identification and registration system for animals of ovine and caprine species pursuant to Regulation (EC) No 21/2004.
The identification system consists of the following elements:
- Means of identification: animals shall generally be identified by means of a yellow plastic tag placed in the animal's right ear and the introduction of a ruminal bolus. As an alternative, the competent authority may nevertheless authorise the replacement of the ruminal bolus:
---in ovine animals, with an electronic eartag;
---in caprine animals, with one of the following alternatives: an electronic eartag, an electronic tag in the pastern of the right hind leg or an injectable tag in the right metatarsal.
Both the eartag and the electronic identifier must bear the same identification code.
- Computerised database: in Spain it is called SITRAN and it incorporates the General Register of Livestock Holdings (REGA), the Individual Animal Identification Register (RIAA) and the Movements Register (REMO).
- Movement or transfer documents that contain data on the holding of origin, the destination holding and the movement.
- A holding register, which may be kept manually or electronically and must be accessible to the competent authority for a minimum of three years following the last entry
Apart from Spanish legislation (in force) to mention EU legislation that supports it:

• Regulation (EU) 2016/429: PART IV REGISTRATION, AUTHORIZATION, TRACEABILITY AND DISPLACEMENT

• Commission Delegated Regulation (EU) 2019/2035 of 28 June 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for establishments keeping terrestrial animals and hatcheries, and the traceability of certain kept terrestrial animals and hatching eggs

• Commission Implementing Regulation (EU) 2021/520 of 24 March 2021 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to the traceability of certain kept terrestrial animals

4.5 Measures in place as regards the notification of the disease

(max. 32000 chars) :

Apart from Spanish legislation (in force) to mention EU legislation that supports it:

• Regulation (EU) 2016/429: PART IV REGISTRATION, AUTHORIZATION, TRACEABILITY AND DISPLACEMENT

• Commission Delegated Regulation (EU) 2019/2035 of 28 June 2019 supplementing Regulation (EU) 2016/429 of the European Parliament and of the Council as regards rules for establishments keeping terrestrial animals and hatcheries, and the traceability of certain kept terrestrial animals and hatching

eggs

• Commission Implementing Regulation (EU) 2021/520 of 24 March 2021 laying down rules for the application of Regulation (EU) 2016/429 of the European Parliament and of the Council with regard to the traceability of certain kept terrestrial animals

4.6 Testing

4.6.1 Rapid tests in bovine animals

Targets for year **2023**

	Age (in months) above which animals are tested	Estimated number of animals to be tested	Estimated number of rapid tests, including rapid tests used for confirmation
Healthy slaughtered bovine animals born in Ms listed in Annex to CD2009/719/EC	72	5	5
Risk animals born in MS listed in Annex to CD 2009/719/EC	48	64 000	64 000
Healthy slaughtered bovine animals NOT born in MS liisted in Annex to CD 2009/719/EC	30	20	20
Risk animals NOT born in MS listed in Annex to CD 2009/719/EC	24	10	10
Suspect animals (as referred to in Art 12.2 of Regulation (EC) No 999/2001)		7	7

4.6.2 Rapid tests on small ruminants

The sampling rules applicable for the monitoring of ovine and caprine animals slaughtered or not for human consumption (described below as healthy slaughtered/dead animals) are in compliance with provisions of Annex III, II, 4 of Regulation (EC) No 999/2001, in particular:

- *Animals are over 18 months of age or have more than two permanent incisors,*
- *No over-representation of any group (origin, age, breed, production type, etc),*
- *Sampling representative of each region and season,*
- *Multiple sampling in the same flock avoided whenever possible,*
- *A system is in place to ensure that in successive sampling years, all officially registered holdings with more than 100 animals where TSE cases have never been detected are subject to TSE testing,*
- *A system is in place to check that animals are not being diverted from sampling (except derogation communicated to the Commission):*

☒ *yes* ☐ *no*

If no please explain.

4.6.2.1 Rapid tests on ovine animals

Estimated population of adult ewes and ewe lambs put to the ram.	12 277 962

Targets for year **2023**

	Estimated number of animals to be tested
Healthy slaughtered ovine animals (a)	10 000
Dead ovine animals (b)	10 000
In the context of measures of control/eradication on holdings affected by TSE as described in Annexes III and VII of the TSE regulation	
Ovine animals from holdings affected by classical scrapie	10 000
Ovine animals from holdins affected by atypical scrapie	0
Ovine animals from holdings affected by BSE	0
Suspect animals (c)	5
Total number of tests	30 005

(a) Annex III, A, II, 2 of the TSE regulation
(b) Annex III, A, II, 3 of the TSE regulation
(c) Art 12 of the TSE regulation

4.6.2.2 Rapid tests on caprine animals

Estimated population of female goats and female kids mated .	2 130 342

Targets for year **2023**

	Estimated number of animals to be tested
Healthy slaughtered caprine animals (a)	10 000
Dead caprine animals (b)	10 000
In the context of measures of control/eradication on holdings affected by TSE as described in Annexes III and VII of the TSE regulation	
Caprine animals from holdings affected by classical scrapie	1 600

Caprine animals from holdins affected by atypical scrapie	
Caprine animals from holdings affected by BSE	0
Suspect animals (c)	5
Total number of tests	**21 605**

(a) Annex III, A, II, 2 of the TSE regulation
(b) Annex III, A, II, 3 of the TSE regulation
(c) Art 12 of the TSE regulation

4.6.3 Confirmatory tests ***other than rapid tests*** as referred to in Annex X Chapter C of Regulation (EC) No 999/2001

Targets for year **2023**

	Estimated number of tests
Confirmatory tests in Bovine animals	4
Confirmatory tests in Ovine an Caprine animals	650

4.6.4 Discriminatory tests (Annex X.C point 3.1 (c) and 3.2 (c)(i) of Regulation (EC) No 999(2001)

Targets for year **2023**

	Estimated number of tests
Primary molecular testing on bovine animals	4
Primary molecular testing on ovine and caprine animals	280
Total	**284**

4.6.5 Genotyping of positive and randomly selected animals

Adult sheep population

☒ *More than 750,000 animals*
☐ *Less than or equal to 750,000 animals*

Targets for year **2023**

	Estimated number
Genotyping of TSE cases	300
Random genotyping	0

4.7 Eradication

4.7.1 Measures following confirmation of a TSE case in bovine animals

4.7.1.1 Description

(max. 32000 chars) :

If a TSE is confirmed, or in the event of a suspected case where the presence of a TSE cannot be ruled out after carrying out the relevant clinical, laboratory and/or ante-post mortem analyses, total or selective culling of the stocks identified below will be carried out:

a) all the other bovines on the holding on which the animal in which the disease has been confirmed is located.

b) when the disease was confirmed in a female animal, its progeny born within two years prior to, or after, clinical onset of the disease.

c) all animals of the cohort of the animal in which the disease was confirmed.

However, where the culling of all the other bovines on the holding on which the animal in which the disease has been confirmed is concerned, the competent authority may exempt the following animals from slaughter:

- all animals brought onto the holding in question over the 12 months prior to the emergence of the case, provided that they came from another holding, as well as any of their progeny during that period.
- On those holdings which the affected animal entered in the previous twelve months, not all the bovine livestock on the holding will be culled. In this situation, the animals specified in paragraphs (b) and (c) of point 1 (total eradication culling) must be culled and completely destroyed, as well as any animals for which there is incomplete traceability and which cannot therefore be ruled out as belonging to these groups.

The competent authority may exempt from slaughter all the other bovines on the holding on which the animal in which the disease has been confirmed is located and proceed with eradication by selective slaughter.

In this case, provided identification and traceability are guaranteed by means of computer systems or birth records, the at-risk stocks defined by the World Organisation for Animal Health (the animals born on the holding during the twelve months before or after the birth of the affected animal and all descendants born in the last two years) will be slaughtered. Likewise, all those bovines whose identification and perfect traceability cannot be guaranteed by means of computer systems or birth records will be slaughtered.

Animals will be re-introduced onto the holding following authorisation from the competent bodies of the Autonomous Communities.

As an exception to the immediate total or selective slaughter of the cohort of positive animals, the Commission Implementing Decision of 15 March 2013 authorises the use of at-risk bovines in Spain until the end of their productive lives following confirmation of the presence of BSE. That exception may apply subject to prior authorisation from the Ministry of Agriculture, Food and Environment following analysis of whether the requirements set out in the Decision are met.

4.7.1.2 Summary table

Targets for year **2023**

	Estimated number
Bovine animals culled and destroyed	20

4.7.2 Measures following confirmation of a TSE case in ovine and caprine animals

4.7.2.1 Description

(max. 32000 chars) :

When a case of scrapie is confirmed different measures are taken (Annex VII to Regulation (EC) No 999/2001 as subsequently amended) according to the kind of scrapie diagnosed and the species concerned:
1 -Epidemiological survey;
2 –Eradication options
b.1) Classical scrapie:
Option 1: immediate culling and complete destruction (or immediate culling and human consumption).
Option 2: selective culling: immediate or deferred culling and destruction of susceptible animals (or immediate or deferred culling and human consumption of susceptible animals).
Option 3: No slaughter.
b.2) Atypical scrapie : no additional measures
3- Breeding programme for TSE resistance in ovines.

4.7.1 Inquiry to identify all animals at risk: the corresponding epidemiological survey is carried out to identify all the animals that are at risk. The aspects to be covered in such a survey are summarised in Annex III to this Programme and a model for carrying it out is attached.

This survey must identify:

a) all the ruminants other than sheep and goats from the holding on which the disease was confirmed;

b) the parents, when these can be identified and, in the case of females, the embryos, ova and progeny of the last generation;

c) all ovines and caprines from the holding on which the disease has been confirmed;

d) the possible origin of the disease and the identification of other holdings on which there are animals, embryos or ova which may have become infected by the TSE agent or exposed to the same feed or contamination source;

e) the movement of feedingstuffs or other potentially contaminated materials or any other means of transmission of the TSE agent;

4.7.2 Measures for the eradication of all the animals at risk (identified in accordance with point 4.7.1) and their products: as provided for in Regulation (EC) Nos 142/2011 and 1069/2009.

In cases of both typical and atypical scrapie it is mandatory to rule out BSE (primary molecular discriminatory tests carried out by the NRL in all cases that test positive for scrapie).

a) If the laboratory results provided for in Annex X, Chapter C, point 3.2 of Regulation (EC) No 999/2001 do not permit BSE to be ruled out: the animals, embryos and ova identified in the epidemiological survey (4.7.1 from b) to e)) will be immediately slaughtered and completely destroyed.

All the animals > 18 months of age slaughtered for destruction will be tested for TSEs. The milk and milk products derived from the animals to be destroyed and that were present on the holding from the date of confirmation that BSE cannot be ruled out will also be destroyed until all the animals have been destroyed.

After the slaughter and complete destruction, the holding will be subject to intensified surveillance for two years (see point b.1.4)

b) If BSE is ruled out in accordance with Annex X, Chapter C, point 3.2 of Regulation No 999/2001, the legislation allows for different options, depending on various factors such as the type of TSE, the animals' genotype, difficulties in restocking, etc.
b.1) CLASSICAL SCRAPIE:

When BSE and atypical scrapie are ruled out, there are three options for eradication (see diagram in Annex III).

Milk and milk products from the animals which have to be eliminated (culled for destruction or slaughtered for human consumption) present on the holding since the case of classic scrapie was confirmed and until the eradication measures have been fully implemented (until the case is closed) may not be used for feeding to ruminants other than those on this holding. The placing of these products on the market for feeding non-ruminants is to be limited to the national market, in line with the specific legislation and the conditions on labelling and transport from point 2.2.2(a) of Annex VII to Regulation (EC) No 999/2001.

b.1.1) OPTION 1: Culling and complete destruction of all animals (point 2.2.2(b) of Annex VII to Regulation (EC) No 999/2001).

Option applicable to both sheep and goats with classical scrapie.

Culling and complete destruction, without delay, of all animals, embryos and ova identified by the inquiry and referred to in points b) and c) of point 4.7.1 above.

Measures applicable:
a) Animals > 18 months of age that are slaughtered for destruction will be analysed in accordance with paragraph 5, Part II, Chapter A of Annex III to Regulation (EC) No 999/2001 point 4.6.1) (A.3 of this programme).

b) For ovines the prion protein genotype of at least 50 animals has to be determined.

c) Derogation from culling and complete destruction: pursuant to point 2.2.2.b.i of Annex VII to Regulation (EC) No 999/2001 and Order PRE 1642/2013, culling and complete destruction may be replaced by immediate slaughter for human consumption subject to the following conditions:
- the competent authority authorises the animals to leave the holding and the transfer document for the

animals indicates that they come from a holding on which a case of scrapie has been diagnosed.
- the animals are slaughtered in a slaughterhouse located on Spanish territory.
- all animals which are over 18 months of age or in which more than two permanent incisors have erupted through the gum are analysed to detect the presence of TSE.

d) Until the culling and complete destruction or total slaughter for human consumption are complete, the following measures are applicable on the holding:
- Milk and milk products from the animals which have to be eliminated (culled for destruction or slaughtered for human consumption) present on the holding since the case of classic scrapie was confirmed and until the eradication measures have been fully implemented (until the case is closed) may not be used for feeding to ruminants other than those on this holding.
- The placing of these products on the market for feeding non-ruminants is to be limited to the national market, in line with the specific legislation and the conditions on labelling and transport from point 2.2.2 (a) of Annex VII to Regulation (EC) No 999/2001.
- Animals may only be moved for slaughter and destruction or slaughter for human consumption.

e) Once this option has been completed (the outbreak has been declared closed), the holding must be subject to intensified surveillance under the measures provided for at point b.1.4) (point 3 of Chapter 2 of Annex VII to Regulation (EC) No 999/2001).

b.1.2) OPTION 2: Culling and complete destruction of susceptible animals (selective slaughter by genotyping). (point 2.2.2(c) of Annex VIII to Regulation (EC) No 999/2001). Option applicable to both sheep and goats with classical scrapie.

Genetic resistance to classic scrapie has been demonstrated in sheep, and goats, so this option is applicable to both.

On mixed holdings, the slaughter of goats cohabiting with sheep or sheep cohabiting with goats (depending which specie is the index case) may be deferred, as detailed at d) and explained below.

Genotyping and identification of all animals on the holding must be undertaken prior to selective culling.

If it is decided to send animals for destruction or for human consumption it is not necessary to genotype them.

Animals with sensitive genotypes are subsequently culled, thus all animals, embryos and ova identified by the inquiry and referred to in points b) and c) of point 4.7.1 above are culled and destroyed, except:
- male ovines intended for breeding of the ARR/ARR genotype,
- breeding female ovines having at least one ARR allele and not having the VRQ allele and, when these are pregnant at the time of the survey, the lambs, if their genotype meets the above requirements.
- ovines with one ARR allele which are intended for slaughter.

Measures applicable:

a) Animals > 18 months of age that are slaughtered for destruction will be analysed in accordance with paragraph 5, Part II, Chapter A of Annex III to Regulation (EC) No 999/2001 (point 4.6.1, A.3 of this programme).

b) Exceptions to the immediate slaughter and complete destruction of susceptible animals:
- Pursuant to point 2.2.2.c.i of Annex VII to Regulation (EC) No 999/2001 and Order PRE 1642/2013 culling

and complete destruction may be replaced by immediate slaughter for human consumption subject to the following conditions:
- the competent authority authorises the animals to leave the holding and the transfer document for the animals indicates that they come from a holding on which a case of scrapie has been diagnosed.
- the animals are slaughtered in a slaughterhouse located on Spanish territory.
- all animals which are over 18 months of age or in which more than two permanent incisors have erupted through the gum are analysed to detect the presence of TSE.

c) Until the culling and complete destruction or total slaughter for human consumption are complete, the following measures are applicable on the holding:

Milk and milk products from the animals which have to be eliminated (culled for destruction or slaughtered for human consumption) present on the holding since the case of classic scrapie was confirmed and until the eradication measures have been fully implemented (until the case is closed) may not be used for feeding to ruminants other than those on this holding. The placing of these products on the market for feeding non-ruminants is to be limited to the national market, in line with the specific legislation and the conditions on labelling and transport from point 2.2.2(a) of Annex VII to Regulation (EC) No 999/2001.

- The following animals > 18 months of age (except ARR/ARR males) will be tested for TSEs):
-animals intended for human consumption which were present on the holding at the time when the index case was confirmed,
- animals that died or were slaughtered other than for human consumption except animals slaughtered in culling campaigns.
- Only ARR/ARR males and females with at least one ARR and no VRQ may be re-introduced onto the holding.
- Only the following may be used for breeding: rams of the ARR/ARR genotype, semen from ARR/ARR males and embryos containing at least one ARR and no VRQ.
- The movement of animals is permitted only under the following conditions:
slaughter and destruction, goats with at least one ARR may be sent to the slaughterhouse for human consumption, females with at least one ARR and no VRQ may travel to holdings under restrictions (when taking option 1 or option 2);
to the slaughterhouse for human consumption subject to the conditions set out above;
without prejudice to the previous paragraph, lambs and kids may be moved to another holding solely for the purposes of fattening prior to slaughter, provided that the holding of destination does not contain any ovine or caprine animals other than those being fattened prior to slaughter. At the end of the fattening period, and at the age of 12 months at the latest, they should go directly to a Spanish slaughterhouse.

d) Pursuant to point 2.2.2.c.ii and iii of Annex VII to Regulation (EC) No 999/2001, the obligatory immediate slaughter and destruction or slaughter for consumption of susceptible animals may be deferred:

d.1) by no more than three months when the date of confirmation of the index case (primary case) coincides or is close to the time of parturition provided that the sheep and goats and their young do not have contact with sheep and goats from other holdings (point 2.2.2.c.ii).

d.2) by no more than three years from the date of confirmation of the index case, in ovine and mixed flocks (ovines-caprines). The objective of this exception is to create a herd with resistant genotypes as it replaces itself, and the ultimate objective is therefore the slaughter of sensitive animals, increasing the frequency of ARR alleles and eliminating VRQ alleles (point 2.2.2.c.iii of Regulation (EC) No 999/2001).

The conditions for applying this exemption are the following:
---The frequency of resistant alleles in the herd is low and external restocking poses difficulties, including for economic reasons;
---immediate slaughter or castration of male animals that are not ARR/ARR;
---culling of females with VRQ;
---culling as soon as possible of females that do not have at least one ARR;
---The Competent Authority must guarantee that the number of animals slaughtered after these three years is not greater than the number of susceptible animals present on the holding when the index case was confirmed.
---If a holding applies this derogation it will be subject to the arrangements set out in point b.1.3 (a) to (h) until a decision is reached on the slaughter and destruction or slaughter for human consumption of susceptible animals.

e) Once this option 2 has been completed, whether by immediate or deferred application (the outbreak has been declared closed), the holding will be subject to intensified surveillance in the form of the measures set out at point b.1.4.

b.1.3) OPTION 3: No mandatory culling and complete destruction (point 2.2.2 (d) of Annex VIII to Regulation (EC) No 99/2001).

The competent authority may decide not to kill or destroy animals identified in an epidemiological survey (point 4.7.1 (b) and (c) above) when it is difficult to replace sheep of a given genotype (male ARR/ARR, female ARR/no VRQ), when the frequency of the ARR allele within the breed or holding is low, when it is deemed necessary in order to avoid inbreeding or based on reasoned consideration of all the epidemiological factors.

The prion protein genotype of at least 50 animals is to be determined within three months of the confirmation of the index case.

If the Member State permits this option to be applied to manage outbreaks of classical scrapie, the competent authority must keep a record, with reasons and criteria, of each case in which this option is invoked. If the Competent Authority decides to apply this option, this decision must be communicated to MAPA.

If further cases of classical scrapie occur on a holding on which this option was taken, the Competent Authority must re-evaluate the choice of this option. If this reassessment shows that Option 3 does not ensure proper control of the disease on that holding, the decision may be taken to apply options 1 or 2.

When it is decided to apply option 3 (no mandatory culling and complete destruction) or exception d.2 under option 2 (deferral of slaughter and destruction or slaughter for human consumption by no more than 3 years), the following intensified surveillance measures shall be applied immediately (pursuant to point 4, chapter B of Annex VII to Regulation (EC) No 999/2001):
- In the case of option 3: the measures described below shall be applied for two years from the date of confirmation of the last case of classical scrapie on the holding.

If an atypical scrapie case is diagnosed during this period of intensified surveillance, the outbreak must be declared but restrictions on movement will not apply. Neither aditional monitoring.

- In the event of exception d.2 of option 2: these measures shall apply until all the susceptible animals have been destroyed or all the susceptible animals have been slaughtered for human consumption

(within three years of the appearance of the index case).

a) Milk and milk products from the animals which have to be eliminated (culled for destruction or slaughtered for human consumption) present on the holding since the case of classic scrapie was confirmed and until the eradication measures have been fully implemented (until the case is closed) may not be used for feeding to ruminants other than those on this holding.

The placing of these products on the market for feeding non-ruminants is to be limited to the national market, in line with the specific legislation and the conditions on labelling and transport from point 2.2.2 (a) of Annex VII to Regulation (EC) No 999/2001.

b) The following animals > 18 months of age (except ARR/ARR males) will be tested for TSEs:

- animals intended for human consumption

- animals that died or were slaughtered other than for human consumption except animals slaughtered in culling campaigns.

c) Only ARR/ARR males and females with at least one ARR and no VRQ may be re-introduced onto the holding.

However, in the case of the indigenous breeds at risk of extinction listed in Annex IV to Regulation 1974/2006, and when the frequency of the ARR allele is low on the holdings, the entry of males with at least one ARR and no VRQ and females with no VRQ allele may be authorised.

d) Only the following may be used for breeding: rams of the ARR/ARR genotype, semen from ARR/ARR males and embryos containing at least one ARR and no VRQ may be used.

However, in the case of the indigenous breeds at risk of extinction listed in Annex IV to Regulation 1974/2006 and when the frequency of the ARR allele is low on the holdings, breeding rams with at least one ARR and no VRQ, semen from males with at least one ARR and no VRQ and embryos with no VRQ allele may be authorised.

e) The movement of animals is permitted only under the following conditions:
- slaughter and destruction;
- ARR/ARR animals may leave the holding for all purposes, including breeding, provided that the holding of destination is subject to the measures applicable in option 2 or option 3 (points B.1.2 and B.1.3) of this programme and points 2.2.2.c and 2.2.2.d of Regulation (EC) No 999/2001
- directly to slaughter in the slaughterhouse for human consumption:
- animals with at least 1 ARR,
- lambs and kids under 3 months of age and
- the animals listed in Section D.2 of option 2 (point b.1.2 of this programme and 2.2.2.c.iii of Regulation (EC) No 999/2001) and option 3 (point b.1.3 of this programme and 2.2.2.d of the Regulation) with the established sampling criteria.

f) Lambs and kids may be moved to another holding solely for the purposes of fattening prior to slaughter, provided that the holding of destination does not contain any ovine or caprine animals other than those being fattened prior to slaughter. At the end of the fattening period, and at the age of 12 months at the latest, they should go directly to a Spanish slaughterhouse.

g) The Competent Authority shall ensure that the semen, embryos and ova do not leave the holding.

h) All ovine and caprine animals from the holding shall be denied access to common pasture during the period of parturition and rearing of young.

Access to common pasture outside the period of parturition and rearing of young shall be subject to the conditions set by the competent authority.

b.1.4) Intensified surveillance

This generally applies when any of the eradication options set out above apply, i.e. once:

- all the animals on the holding have been slaughtered and destroyed (point a: BSE cannot be ruled out in goats or sheep).
- all the animals have been culled and destroyed (option1) or all the animals previously testing negative for TSEs have been slaughtered for human consumption (exception of option 1).
- all the animals have been immediately culled and destroyed (option 2) or all the animals previously testing negative for TSEs have been slaughtered immediately for human consumption (exception of option 2).

If it is decided to implement these selective eradication measures deferred by a maximum of three years, this point will first be applied once this period is over and the eradication measures have been taken.

The measures described below will be applied until the ARR/ARR genotype is obtained in all ovine animals on the holding or for 2 years since the eradication measures of option 1 or option 2 were applied completely and providing no other case of classic scrapie has been diagnosed on the holding.

If an atypical scrapie case is diagnosed during this period of intensified surveillance, the outbreak must be declared but restrictions on movement will not apply. Neither aditional monitoring.

Intensified surveillance measures (in accordance with point 3, Chapter B, Annex VII of Regulation (EC) No 999/2001):

a) The holding must be subject to a protocol of intensified surveillance including the testing of all animals > 18 months (except ARR/ARR sheep):

- animals intended for human consumption which were present in the holding at the time when the index case was confirmed;

- animals that died or were slaughtered other than for human consumption except animals slaughtered in culling campaigns.

b) Entry of animals to the holding: only males with the ARR/ARR genotype, females with ARR and no VRQ and caprine animals may be reintroduced onto the holding after cleansing and disinfection of the accommodation.

c) For breeding: only rams of the ARR/ARR genotype, semen from ARR/ARR males and embryos containing at least one ARR and no VRQ may be used.

d) The movement of animals from the holding will be subject to the following conditions: -- for destruction;

-- the following may be moved for any purpose, including breeding:

- ARR/ARR ovines,

- females with at least one ARR and no VRQ may be moved to other holdings subject to restrictions (holdings that are applying options 2 or 3)

- caprines may be moved to other holdings with restrictions (holdings on which options 2 or 3 are being applied).

-- the following may be moved directly for slaughter for human consumption:

- ovines with at least one ARR allele;

- caprines;

- lambs and kids under 3 months of age; -

all animals subject to the exceptions provided for at points b.1.1, (c) and b.1.2(b) of this programme

b.2) ATYPICAL SCRAPIE

When atypical scrapie is diagnosed in sheep or goats on a holding, the outbreak must be declared but restrictions on movement will not apply. Neither aditional monitoring.

When applying any of the eradication measures set out in this point 4.7.2, compliance with the requirements on the protection of animals, in accordance with Regulation (EC) No 1099/2009 of 24 September 2009 and Royal Decree 37/2014 of 24 January 2014 on the protection of animals at the time of slaughter, is mandatory.

With effect from 1 January 2013 Council Regulation (EC) No 1099/2009 of 24 September 2009 on the protection of animals at the time of slaughter applies.

This Regulation provides that, in the event of depopulation, the competent authorities should act to safeguard the welfare of the animals involved and inform the European Commission and the public ex post of the measures taken.

By depopulation the above-mentioned legislation means not only action in the event of outbreaks of animal diseases, but also action when animals have to be killed for reasons such as public health, animal welfare or environmental reasons, always under the supervision of the competent authority.

When depopulation is to be undertaken for reasons of animal health and in accordance with this Manual, the document entitled 'Protection of animals at slaughter for depopulation for health reasons in accordance with Regulation (EC) No 1099/2009 of 24 September 2009' should be used in a complementary manner and at the same time. This can be found at:

https://www.mapa.gob.es/es/ganaderia/temas/produccion-y-mercadosganaderos/bienestanimal/en-la-granja/default.aspx1

The competent authorities of the Autonomous Communities will supplement the document on the

protection of animals with such information as is necessary. The document 'Protection of animals during slaughter for depopulation for health reasons in line with Regulation (EC) No 1099/2009 of 24 September 2009' forms part of this Manual, along with the standardised working procedures in the annexes thereto. Furthermore, it will be updated when there are changes in the rules that apply, when required by acquired experience or when it is necessary to update the information included therein (such as the procedures referring to the enterprises involved in the supply of material or the competent authority's relationship with the same).

4.7.2.2 Summary table

Targets for year **2023**

	Estimated number
Ovine and caprine animals culled and destroyed (due to classical scrapie)	30
Ovine and caprine animals compulsory slaughter (due to classical scrapie)	4 000
Genotyping tests - monitoring and eradication measures	22 000

4.7.3 Breeding programme for resistance to TSEs in sheep

4.7.3.1 General description

Description of the programme according to the minimum requirements set out in Annex VII, Chapter B of Regulation (EC) No 999/2001

(max. 32000 chars) :

n the wake of the latest scientific opinions concerning the disease, various amendments to Regulation (EC) No 999/2001 of 22 May 2001 have been published. Accordingly, the decision to continue with ovine breeding programmes to select for resistance to TSEs is left to the Member States. Those programmes shall include a framework to recognise the TSE-resistant status of certain flocks.

In Spain, the Ministry of Agriculture, Fisheries and Food (MAPA), in cooperation with the Autonomous Communities and the breeders' associations, has decided to continue running the 'National Programme for Genetic Selection for Resistance to Transmissible Spongiform Encephalopathies (TSEs) in Sheep' (see description in Annex IV), while certain amendments have been made in light of the above-mentioned scientific opinions, the most relevant being the voluntary participation by the breeders' associations in the Genetic Selection Programme. Those amendments are reflected in Royal Decree 21/2013 of 18 January 2013, the current basis for the programme. Nevertheless, the main lines of action of this programme are still the following:

-- individual identification and study of genotypes for the PNRP gene,

-- information system for identifying and genotyping sheep (ARIES),

-- dissemination of improvements and level of resistance,

-- Algete Molecular Genetics Reference Laboratory,

-- selection programmes for resistance to TSEs.

In general, since 2003, a continuing trend has been observed of a rise in ARR at the expense of a decline in ARQ, which has resulted in ARR/ARR replacing ARR/ARQ as the most common genotype, which previously had replaced ARQ/ARQ. The intensity of selection seems to be accelerating somewhat, although the period considered does not meet the criteria previously used for mean generation interval, and significantly fewer samples were tested than in the two periods studied previously, so this trend needs to be confirmed later.

4.7.3.2 Summary table

Targets for year **2023**

	Estimated number
Ewes to be genotyped under the framework of a breeding programme referred to in Article 6a of Regulation (EC) No 999/2001	80 000
Rams to be genotyped under the framework of a breeding programme referred to in Article 6a of Regulation (EC) No 999/2001	20 000
Total	100 000

5. Costs

5.1 Detailed analysis of the costs

(max. 32000 chars) :

The economic forecast for the 2023 Programme was prepared in accordance with European Commission documents: Grant Agreement VP/2021-2022/ES/SI2.869406 . The possible updating of unit and eligible costs, the expected number of tests and slaughtered animals for 20203may be updated according to the changes made to this WG and in line with the disease's epidemiological situation in Spain.

BSE COSTS:

• Cost of diagnosis for the surveillance and control programme: cost of conducting rapid, confirmatory and discriminatory tests for detecting BSE per animal investigated.

• Costs of compensating livestock farmers for the compulsory culling of animals which test positive and animals subjected to preventive culling on the farm, or animals which the competent authority, in view of the epidemiological survey results, considers should be culled.

5.1.1.- Costs of implementing the follow-up programme.

The estimated number of rapid tests for the rapid detection of BSE for 2023 is calculated according to the Autonomous Communities' forecasts and the certified costs from 2021. The confirmatory tests carried out by the NRL are also included when confirmation is carried out using rapid tests.

☐ It is planned that the NRL will carry out confirmatory tests(€ 77.99), different from rapid tests.

☐ The spontaneous appearance of atypical strains means it is necessary to plan for the following: discriminatory tests for BSE carried out by the NRL, representing expenditure eligible for co-financing of unit cost €145.87/test; The estimated real expenditure eligible for co-financing for monitoring under the Monitoring Programme for BSE includes: rapid tests + confirmatory tests + discriminatory tests for BSE

5.1.2 - Costs of compensating livestock farmers for the compulsory culling of animals.

Several factors have to be taken into account to forecast the number of animals that are eligible in 2023:

- the certified costs from the Autonomous Communities for 2021;

- the epidemiological evolution of the disease along with the number of animals that have to be slaughtered as provided for in point 2(a) of Annex VII to Regulation (EC) No 999/2001;

- the trend towards the eradication of classical BSE at the same time as new atypical forms are discovered;

- the possibility open to Spain of deferring the slaughter of the cohorts of a positive animal until the end of their productive lives.

For 2023, it is estimated that between 0 and 20 animals will be slaughtered each year, given that no outbreaks of classical BSE are expected to be diagnosed. However, as a result of the appearance of atypical strains together with the application of Decision 2013/137/EU, it is estimated that 20 animals will be slaughtered and destroyed in 2023. The average compensation per slaughtered animal is estimated at €408,97, calculated by the average rate of compensation of 2017 (last available rate certified by the Autonmomous Communities) on the basis of the Royal Decree establishing the scales for compensation for animals under the national programmes for combating, controlling or eradicating bovine tuberculosis, bovine brucellosis, ovine and caprine brucellosis, bluetongue and transmissible spongiform encephalopathies.

BSE TOTAL COSTS:
The total cost calculated for the expenditure that is eligible for co-financing for the two lines of action :surveillance and eradication.

SCRAPIE COSTS:
Estimations have been calculated taking into account that there are several big holdings under TSE eradication measures and under intensified monitoring protocol.

The cost of the programme derives from three lines of action:

• Cost of diagnosis for the surveillance and control programme: cost of conducting rapid, confirmatory and discriminatory tests for detecting TSE in animals investigated and the cost of confirmatory and discrimination tests on scrapie positives.

• Cost of analysing the genotype of the PNRP gene: cost of conducting tests for analysing the genotype of the PNRP gene per animal investigated.

• Costs of compensating livestock farmers for the compulsory culling of animals which test positive and animals subjected to preventive culling on the farm, or animals which the competent authority, in view of the epidemiological survey results, considers should be culled.

Annex III: Programme for the control and eradication of Transmissible Spongiform Encephalopathies

1.- Diagnostic costs.

Estimations for rapid tests, confirmatory tests and discriminatory tests for the detection of TSE in small ruminants:

The estimated expenditure eligible for co-financing for surveillance, have been taking into account unit costs and eligible costs according to Grant Agreement VP/2021-2022/ES/SI2.869406.

The estimated real expenditure eligible for co-financing for monitoring under the Monitoring Programme for Scrapie contain rapid tests + confirmatory tests + discriminatory tests

2. Costs of analysing genotypes.
The estimated expenditure eligible for co-financing in line with Grant Agreement VP/2021-2022/ES/SI2.869406.

According to Commission Regulation (EU) 2017/894 of 24 May 2017 amending Annexes III and VII to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the genotyping of ovine animals, Spain remains exempt from the obligation to genotype a minimum sample (random genotyping), since the Spanish Breeding Programme does not meet the criteria laid down in Point 8, Part 1, Chapter C of Annex VII, which lays down the minimum requirements of a breeding programme for sheep resistant to TSEs.

The estimated real cost of genotyping includes positive animals, eradication measures and breeding programme).

3.- Costs of compensating livestock farmers for culling.

As mentioned above, based on the number of animals slaughtered as an eradication measure in 2021 and the average size of flock per outbreak, the number of animals to be slaughtered pursuant to point 2(b) in Annex VII to Regulation (EC) No 999/2001, i.e. in applying measures to eradicate scrapie, is estimated to be for 2023: 4000 categorised as slaughtered and intended for consumption and 40 as slaughtered and destroyed.

5.2 Detailed analysis of the cost of the programme

5.3. 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 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) :

TSE sampling is carried out by official or authorised veterinarians. The cost is borne by the Autonomous Community, which subsequently receives financial support from the State (MAPA).

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) :

Samples are analysed (rapid tests) by the authorised regional laboratories in the different Autonomous Communities. Confirmation of suspect samples and strain discrimination is carried out in the National Reference Laboratory (Algete Central Veterinary Laboratory). The laboratory personnel is made up of official or authorised veterinarians and the costs are borne by the Autonomous Community or MAPA.

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 slaughter of animals for the purpose of eradication is carried out in authorised slaughterhouses by slaughterhouse staff under the supervision of official veterinarians. The Autonomous Community pays the compensation for compulsory culling of animals to the farmers and subsequently receives financial support from the State (MAPA).

d) Implementing entities - **vaccination (if applicable)** : 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)

(max. 32000 chars) :

NA

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

(max. 32000 chars) :

NA

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*

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:

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
		a_Anexo I TSE FINAL REPORT 2021.pdf	a_AnexoITSEFINALREPORT2021.pdf	1210 kb
		ERAFUNDSPESTFUNDS_PPD.pdf	ERAFUNDSPESTFUNDS_PPD.pdf	288 kb
			Total size of attachments :	1497 kb