EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Food sustainability, international relations

Unit D4 - Food safety programmes, Emergency funding

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

Member States seeking an EU financial contribution for national programmes of eradication, control and surveillance shall submit online this document completely filled out by the 31 May of the year preceding its implementation (part 2.1 of Annex I to the Single Market Programme Regulation).
Due to the late adoption of the SMP regulation all programmes will be submitted to be approved technically for 2021 and 2022.
Therefore , this document shall also be filled out and submitted after selection of the options:
This programme is multiannual: "YES"
Request for Union cofinancing from beginning 2021 to end of 2022.

If encountering difficulties:
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5) For simplification purposes you are invited to submit multi-annual programmes.
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Member state : ESPANA

Disease Transmissible Spongiform Encephalopathies

This program is multi annual : yes

Type of submission : New multiannual programme or Modification of already approved multiannual programme

Request of Union co-financing from beginning : 2021 To end of 2022

1. Contact data

Name [redacted] Phone [redacted]

Email [redacted] Your job type within the CA : [redacted]

Submission Date

08/10/2021 09:29:36

Submission Number

1633678176375-17569

2. Description of the programme

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

In 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.

3. Description of the epidemiological situation of the disease

Last year's No of cases	Total No	No of classical cases	No of atypical cases	No of undetermined cases
BSE case	1		1	
Scrapie case (ovine)	256	244	12	
Scrapie case (caprine)	32	29	3	
Last case of		date (classical case)	date (atypical case)	date (undetermined case)

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BSE	25/07/2014	21/12/2020	
Scrapie (ovine)	17/12/2020	14/12/2020	
Scrapie (caprine)	29/12/2020	27/09/2020	

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 2020, a total of 799 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 2002-2020 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 2003-2020 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 (2000-2020), 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 2020, 20 outbreaks were declared (index case) (13 in sheep and 7 in goats), of which 7 outbreaks were classical strains and 13 were atypical (see the graph showing the number of outbreaks and the table characterising the outbreaks in Annex I).
In the period 2006-2020 (data shown in the table under point 3 Description of the epidemiological situation of the disease) 367 ovine outbreaks were detected (index cases), of which 148 were classical strains and 219 were atypical; and 106 caprine outbreaks were detected (index cases), of which 52 were classical strains and 54 were atypical.
The last case of classical scrapie in sheep for the 2020 period (last year for which there are definitive data) was detected on 17 December 20120 and in goats on 29 December 2020. As regards atypical strains, the last case in sheep was detected on 14 December 2020 and in goats on 27 September 2020.

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) :

The Programme will be applied throughout Spain. The implementation of the Programme in each Autonomous Community is organised at the following levels:

1. Regional level: the head of the department with responsibilities in the field of animal health in the Autonomous Community is the coordinator of the Programme within the territory of that Community.
2. Provincial level: the provincial coordinator harmonises and monitors the action taken by the various districts of the province.
3. District level: culling of suspect animals and sampling.
This organisational framework may be amended on the basis of changes made by each Autonomous Community, taking into account its own administrative structure.

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.

4.4 System in place for the identification of animals

(max. 32000 chars) :

The 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.

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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.

4.5 Measures in place as regards the notification of the disease

(max. 32000 chars) :

The disease will be officially declared in accordance with Royal Decree 526/2014 establishing the list of notifiable animal diseases and laying down the rules for reporting them.

Furthermore, this notification must be made via the RASVE computer application, as laid down by the RASVE Committees and the specific working groups for the coordination and following-up of the Programme for Surveillance and Control of TSEs.

The owners or persons in charge of the animals and the veterinary official who attends the farm must, on the emergence of any of the clinical symptoms consistent with BSE, notify the Autonomous Community in order to implement the measures detailed in the section below on 'suspicion of disease'.
For each confirmed primary case (outbreak), the competent authority for animal health responsible for notification of the outbreak will send MAPA as soon as possible, and in any event within one month of confirmation of the outbreak, the following additional epidemiological information:
- Clinical symptoms (if any, and if it is a suspected case), e.g. decline in milk production, ataxia, weight loss, changes in behaviour, etc. ;
- vaccine type (meat/milk);
- indicate whether the positive case was confirmed on the farm or herd of birth (yes/no);
- herd type (meat/milk/mixed production purpose);
- Feed system during the first year of life, e.g. feed concentrate, mixed, grass, etc.;
- If the cohort ate the same feed as the positive case: indicate whether or not samples were taken, the number of samples and the number of positive and negative results.
- If there was an age cohort: indicate whether or not samples were taken, the number of samples and the number of positive and negative results.
- If there was offspring: indicate whether or not samples were taken, the number of samples and the number of positive and negative results.
- Father data (if available): indicate whether or not samples were taken, the number of samples and the number of positive and negative results.
- Mother data (if available): indicate whether or not samples were taken, the number of samples and the number of positive and negative results.
This information is sent in accordance with Chapter B of Annex III to Regulation 999/2001, since each

year the EFSA asks Member States that have declared positive BSE cases for this information, so that it can be included in the summary report on TSE trends and sources in the EU.

4.6 Testing

4.6.1 Rapid tests in bovine animals

Targets for year **2021**

	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	200	200
Risk animals born in MS listed in Annex to CD 2009/719/EC	48	69 500	69 500
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

Targets for year **2022**

	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	200	200
Risk animals born in MS listed in Annex to CD 2009/719/EC	48	67 000	67 000
Healthy slaughtered bovine animals NOT born in MS liisted in Annex to CD 2009/719/EC	30	25	25
Risk animals NOT born in MS listed in Annex to CD 2009/719/EC	24	7	7
Suspect animals (as referred to in Art 12.2 of Regulation (EC) No 999/2001)		10	10

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. 12 535 816

Targets for year **2021**

	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	700
Ovine animals from holdings affected by BSE	0
Suspect animals (c)	10

Total number of tests	30 710

Targets for year **2022**

	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	14 000
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	34 005

(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 .	2 151 156

Targets for year **2021**

	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	2 000
Caprine animals from holdins affected by atypical scrapie	500
Caprine animals from holdings affected by BSE	0
Suspect animals (c)	10
Total number of tests	**22 510**

Targets for year **2022**

	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	1 500
Caprine animals from holdins affected by atypical scrapie	0
Caprine animals from holdings affected by BSE	0
Suspect animals (c)	5
Total number of tests	**21 505**

(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 **2021**

	Estimated number of tests
Confirmatory tests in Bovine animals	4
Confirmatory tests in Ovine an Caprine animals	800

Targets for year **2022**

	Estimated number of tests
Confirmatory tests in Bovine animals	4
Confirmatory tests in Ovine an Caprine animals	700

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 **2021**

	Estimated number of tests
Primary molecular testing on bovine animals	2
Primary molecular testing on ovine and caprine animals	350
Total	**352**

Targets for year **2022**

	Estimated number of tests
Primary molecular testing on bovine animals	2

Primary molecular testing on ovine and caprine animals	300
Total	**302**

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 **2021**

	Estimated number
Genotyping of TSE cases	300
Random genotyping	0

Targets for year **2022**

	Estimated number
Genotyping of TSE cases	275
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 **2021**

	Estimated number
Bovine animals culled and destroyed	20

Targets for year **2022**

	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
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 **2021**

	Estimated number
Ovine and caprine animals culled and destroyed (due to classical scrapie)	40
Ovine and caprine animals compulsory slaughter (due to classical scrapie)	4 000
Genotyping tests - monitoring and eradication measures	22 500

Targets for year **2022**

	Estimated number
Ovine and caprine animals culled and destroyed (due to classical scrapie)	30
Ovine and caprine animals compulsory slaughter (due to classical scrapie)	3 500
Genotyping tests - monitoring and eradication measures	20 000

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) :

In 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 **2021**

	Estimated number
Ewes to be genotyped under the framework of a breeding programme referred to in Article 6a of Regulation (EC) No 999/2001	90 000
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	110 000

Targets for year **2022**

	Estimated number
Ewes to be genotyped under the framework of a breeding programme referred to in Article 6a of Regulation (EC) No 999/2001	90 000
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	110 000

5. Costs

5.1 Detailed analysis of the costs

(max. 32000 chars) :

The economic forecast for the 2020-2022 Programme was prepared in accordance with European Commission documents: WORKING DOCUMENT SANTE/2017/10186 REV. Guidelines for the Union co-funded programmes of eradication, control and surveillance of animal diseases and zoonoses for the years 2018-2020 (updates for 2019 and 2020) and SANTE/12250/2015 rev 4, Financial Guidelines for Member States for EU funding of veterinary programmes (update for 2019 and 2020 programmes). The possible updating of unit and eligible costs, the expected number of tests and slaughtered animals for 2020 may 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 2020, 2021 and 2022 is calculated according to the Autonomous Communities' forecasts and the certified costs from 2020. 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, different from the rapid tests. The real eligible cost is € 436.00 for each year (€ 109.00/ confirmatory test 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 €112.36/test;

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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 2021 and 2022:

- the certified costs from the Autonomous Communities for 2020;

- 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 2021 and 2022, it is estimated that between 0 and 40 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 40 animals will be slaughtered and destroyed in 2021 and 20 in 2022. 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.

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• 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.

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 WORKING DOCUMENT SANTE/2017/10186 REV , Guidelines for the Union co-funded programmes of eradication, control and surveillance of animal diseases and zoonoses for the years 2018-2020 (updates for 2019 and 2020) y SANTE/12250/2015 rev 4, Financial Guidelines for Member States for EU funding of veterinary programmes (update for 2019 and 2020 programmes).

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 WORKING DOCUMENT SANTE/2017/10186 REV and SANTE/12250/2015 rev 4 and according to the certified sums from 2018.

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 2018 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 2021: 4000 categorised as slaughtered and intended for consumption and 40 as slaughtered and destroyed.

For 2022: 3500 categorised as slaughtered and intended for consumption and 30 as slaughtered and destroyed.

SCRAPIE TOTAL COSTS:
The total cost calculated for the expenditure that is eligible for co-financing for the three lines of action : surveillance, eradication and genotyping.

5.2 Detailed analysis of the cost of the programme

Costs of the planned activities for year : 2021

1. Rapid tests in bovine animals (as referred to in point 4.6.1)

Cost related to	Specification	Number of tests	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Testing	Rapid tests on bovine animals born in MSs listed in CD 2009/719 | Healthy slaughtered animals	200	12.77	2554	no	30	0	X
Testing	Rapid tests on bovine animals born in MSs listed in CD 2009/719 | Risk animals	69 500	12.77	887,515	yes	30	266 254,5	X
Testing	Rapid tests on bovine animals not born in MSs listed in CD 2009/719 | Healthy slaughtered animals	20	12.77	255.4	yes	30	76,62	X
Testing	Rapid tests on bovine animals not born in MSs listed in CD 2009/719 | Risk animals	10	12.77	127.7	yes	30	38,31	X
Testing	Rapid tests on suspect bovine animals	7	12.77	89.39	yes	30	26,82	X

2. Rapid tests in ovine and caprine animals (as referred to in point 4.6.2 and 4.6.3)

Cost related to	Specification	Total number of tests	Cost per test	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Testing	Rapid Tests - ovine	30 710	12.77	392,166.7	yes	30	117 650,01	X
Testing	Rapid Tests - caprine	22 510	12.77	287,452.7	yes	30	86 235,81	X

3. Confirmatory testing (as referred to in point 4.6.4)

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Cost related to	Compensation of	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Testing	Confirmatory Tests in Bovines	4	77.99	311.96	yes	30	93,59	X
Testing	Confirmatory Tests in Ovines and Caprines	800	77.99	62392	yes	30	18 717,6	X

4. Discriminatory testing (as referred to in point 4.6.5)

Cost related to	Specification	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Testing	Primary molecular tests	352	145.87	51346.24	yes	30	15 403,87	X

5. Genotyping

Cost related to	Specification	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Testing	Genotyping test (standard) - monitoring and eradication measures	22 500	29.33	659,925	yes	30	197 977,5	X
Testing	Genotyping test (standard) - breeding programme	110 000	29.33	3,226,300	yes	30	967 890	X
Testing	Genotyping test - TSE cases	300	110.07	33021	yes	30	9 906,3	X
Testing	Genotyping test (standard) - random sample	0	29.33	0	no	30	0	X

6. Compulsory culling/slaughter

Cost related to	Specification	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Compensation	Bovine animals culled and destroyed	20	408.97	8179.4	yes	30	2 453,82	X
Compensation	Ovine and caprine animals culled and destroyed	40	67.33	2693.2	yes	30	807,96	X
Compensation	Ovine and caprine animals - compulsory slaughter	4 000	67.33	269,320	yes	30	80 796	X

7. Chronic Wasting Disease

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Cost related to	Specification	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
				0	yes		0	X

Total with Union funding request (€):	5,881,095.69	including	1,764,328.71
Total without Union funding request (€):	2554		= requested EU contribution in €

Costs of the planned activities for year : **2022**

1. Rapid tests in bovine animals (as referred to in point 4.6.1)

Cost related to	Specification	Number of tests	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Testing	Rapid tests on bovine animals born in MSs listed in CD 2009/719 | Healthy slaughtered animals	200	12.77	2554	no	30	0	X
Testing	Rapid tests on bovine animals born in MSs listed in CD 2009/719 | Risk animals	67 000	12.77	855,590	yes	30	256 677	X
Testing	Rapid tests on bovine animals not born in MSs listed in CD 2009/719 | Healthy slaughtered animals	25	12.77	319.25	yes	30	95,78	X
Testing	Rapid tests on bovine animals not born in MSs listed in CD 2009/719 | Risk animals	7	12.77	89.39	yes	30	26,82	X
Testing	Rapid tests on suspect bovine animals	10	12.77	127.7	yes	30	38,31	X

2. Rapid tests in ovine and caprine animals (as referred to in point 4.6.2 and 4.6.3)

Cost related to	Specification	Total number of tests	Cost per test	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Testing	Rapid Tests - ovine	34 005	12.77	434,243.85	yes	30	130 273,15	X
Testing	Rapid Tests - caprine	21 505	12.77	274,618.85	yes	30	82 385,65	X

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3. Confirmatory testing (as referred to in point 4.6.4)

Cost related to	Compensation of	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Testing	Confirmatory Tests in Bovines	4	77.99	311.96	yes	30	93,59	X
Testing	Confirmatory Tests in Ovines and Caprines	700	77.99	54593	yes	30	16 377,9	X

4. Discriminatory testing (as referred to in point 4.6.5)

Cost related to	Specification	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Testing	Primary molecular tests	302	145.87	44052.74	yes	30	13 215,82	X

5. Genotyping

Cost related to	Specification	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Testing	Genotyping test (standard) - monitoring and eradication measures	20 000	29.33	586,600	yes	30	175 980	X
Testing	Genotyping test (standard) - breeding programme	110 000	29.33	3,226,300	yes	30	967 890	X
Testing	Genotyping test - TSE cases	275	110.07	30269.25	yes	30	9 080,77	X
Testing	Genotyping test (standard) - random sample	0	29.33	0	yes	30	0	X

6. Compulsory culling/slaughter

Cost related to	Specification	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
Compensation	Bovine animals culled and destroyed	20	408.97	8179.4	yes	30	2 453,82	X
Compensation	Ovine and caprine animals culled and destroyed	30	67.33	2019.9	yes	30	605,97	X
Compensation	Ovine and caprine animals - compulsory slaughter	3 500	67.33	235,655	yes	30	70 696,5	X

7. Chronic Wasting Disease

Cost related to	Specification	Number of units	Unitary cost in EUR	Total amount in EUR	Union funding requested	Cofinancing rate	Requested Union contribution in EUR	
				0			0	X

Total with Union funding request (€):	5,752,970.29	including	1,725,891.08
Total without Union funding request (€):	2554		= requested EU contribution in €

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).

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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 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) :

N/A

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

(max. 32000 chars) :

N/A

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

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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*

4. 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:

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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
		17569_12957.docx	17569_12957.doc	613 kb
			Total size of attachments :	613 kb