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 : ITALIA

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 15:31:24

Submission Number

1633700057968-17579

[redacted]

2. Description of the programme

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

The Ministry of Health (MoH) – Directorate General for animal health and veterinary medicinal products – Unit III is the central authority in charge of supervising and coordinating the departments responsible for implementing the programme.
It manages the relations with the European Commission and other European Institutions, provides information and indication to the regional/local authorities on the measures to be implemented for the surveillance and eradication of the TSEs, it carries out audits and inspections to verify the level of implementation of the Regulation.
MoH guarantees, in cooperation with NRL for TSEs (Centro Nazionale di Riferimento per le Encefalopatie Spongiformi Animali - CEA) and 'Istituto Superiore di Sanità' (ISS - reference laboratory for strain typing and genetic of animal TSEs), the management and control of scrapie and BSE, and mainly with CEA, all the activities concerning diagnostic examination, ring tests, risk evaluation, epidemiological analysis and audit performed on the territorial laboratories.

Directorate-General for animal health and veterinary medicinal products – Unit 3, on the basis of the scientific opinion of NRL for TSE (epidemiological center: Biostatistics, Epidemiology and Risk Analysis - BEAR -in CEA), authorizes derogations to point 2.2.2.d) of in Annex VII of Regulation (EC) 999/2001 and carries out checks accordingly.
The regional and local vet authorities (LVUs) are responsible for the proper implementation on the field of the preventive activities and control measures of that regulation CE 999/2001. In some cases, referred to in Annex VII of Regulation 999/2001, the reference center (BEAR) carries out a health assessment to apply the most correct measure.
In order to ensure uniform conditions for the implementation of the Union disease TSE notification and reporting rules, Regulation UE 2016/429 and national law (applying the regulation UE) for cattle, sheep and goats, are immediately applicable.

First year the implementation of the programme described in this document is 2021
Second year the implementation of the programme described in this document will be 2022

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	0	0	0	0
Scrapie case (ovine)	121	104	6	11
Scrapie case (caprine)	16	13	3	0
Last case of		date (classical case)	date (atypical case)	date (undetermined case)
BSE		29/11/2009	10/01/2011	00/00/0000
Scrapie (ovine)		28/12/2020	03/11/2020	30/10/2020
Scrapie (caprine)		21/11/2020	06/11/2020	00/00/0000

Comments (if any)

Out of the 121 positive sheep samples detected in 2020, 6 were atypical scrapie, 11 were inconclusive at discriminatory WB due to their very low PrPSc content in the available brain tissues. These 11 sheep were all secondary cases from flocks where the presence of BSE had been excluded based on the discriminatory
WB results: the index case and other secondary cases from the same affected flocks were confirmed as classical scrapie cases.
One sheep index case resulted "BSE not excluded" at primary molecular testing with discriminatory WB. This case was referred to the EURL and was definitively considered as "non BSE" after secondary molecular testing (indicated as CH1641-like in this report)". The outbreak was managed as a classical scrapie incompliance with the indications of the European Commission. Among the 16 positive caprine samples detected in 2020, 13 resulted in classical cases and 3 were atypical scrapie.

Below information on the latest outbreaks of classical and atypical scrapie in ovine and caprine animals, specified in the table above:
Classical Scrapie in ovine: sampling date is 28.12.2020, confirmation date is 01.02.2021 , Primary Molecular Test date is 08.03.2021.
Atypical Scrapie in ovine: sampling date is 03.11.2020, confirmation date is 23.11.2020, Primary Molecular Test date is 04.02.2021.
Undetermined Scrapie in ovine: sampling date is 30.10.2020, confirmation date is 11.12.2020, Primary Molecular Test date is 08.03.2021.
Classical Scrapie in caprine: sampling date is 21.11.2020, confirmation date is 17.12.2020 , Primary Molecular Test date is 08.03.2021.
Atypical scrapie in caprine: sampling date is 6.11.2020, confirmation date is 26.11.2020, primary molecular test date is 04.02.2021.

In the Epidemiological reports are contained more details:
Annex I: BSE's Epidemiological Report
Annex II: Scrapie's Epidemiological Report
Annex III: Breeding Programme Report

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) :

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It manages the relations with the European Commission and other European Institutions, provides information and indication to the regional/local authorities on the measures to be implemented for the surveillance and eradication of the TSEs, it carries out audits and inspections to verify the level of implementation of the Regulation.
MoH guarantees, in cooperation with NRL for TSEs (Centro Nazionale di Riferimento per le Encefalopatie Spongiformi Animali - CEA) and 'Istituto Superiore di Sanità' (ISS - reference laboratory for strain typing

and genetic of animal TSEs), the management and control of scrapie and BSE, and mainly with CEA, all the activities concerning diagnostic examination, ring tests, risk evaluation, epidemiological analysis and audit performed on the territorial laboratories.
Directorate-General for animal health and veterinary medicinal products – Unit 3, carries out checks of the application of regulation (CE) 999/2001
The regional and local vet authorities (LVUs) are responsible for the proper implementation on the field of the preventive activities and control measures. The Ministry of Health - Unit3 - has provided guidelines to properly manage farms in the event of an scrapie outbreak.
In order to ensure uniform conditions for the implementation of the Union disease TSE notification and reporting rules, Regulation UE 2016/429 delegated and execution acts and national law (applying the regulation UE) for cattle, sheep and goats, are immediately applicable.

4.2 Description and delimitation of the geographical and administrative areas in which the programme is to be applied

(max. 32000 chars) :

The programme for the control of transmissible spongiform encephalopathies (TSEs) is applied to all the territories of Italy, islands included.

4.3 System in place for the registration of holdings

(max. 32000 chars) :

Until 21 April 2021 (before application of regulation UE 2016/429 delegated and execution acts) Bovine, ovine, and caprine holdings, according to national legislation DPR n. 317 of 30.04.1996, transposition of Directive 92/102/EEC, are registered to in national database by LVUs, responsible to approve the holding code regarding the place where the animals are kept as one single epidemiological unit.
The holding code is composed by the following alphanumeric sequence (000XX000): first three numbers refer to the ISTAT code of the Municipality, two capital letters in the middle refer to the Province and the last number is progressive reference of the holding registered in the territory of that Municipality.
The owner of any holding has to inform the LVU when starting the breeding activity and the granting of the code.
In the section for cattle of the national database, 'Banca Dati Nazionale' (BDN) are registered all the holdings, farms, owners, keepers, bovine animals and their movements included to the slaughterhouse, as well as all the information on the animals slaughtered, dead and killed.
Furthermore, to in the national database are also registered all the slaughterhouses, and their owners responsible to register animals slaughtered.
In the section for ovine and caprine animals have registered all the holdings , owners, keepers .
All the holdings included in the national breeding programme (genotyping) shall register in BDN the individual identification of ovine and caprine animals kept as well as their genotype.

As of April 21, 2021, the system for registering establishments and identifying and registering animals including traciability of movements shall be implemented in compliance with with Regulation UE 429/2016 and its Delegated acts / Implementing acts: the delegated act (EU) 2019/2035 for registration in computerized databases and Implementing Act (EU) 2021/520 regarding the traceability of kept terrestrial animals.

4.4 System in place for the identification of animals

(max. 32000 chars) :

In Italy until April 21, 2021, the animal identification and registration (I & R) of bovine animals was based on these elements (ex Article 3 of Regulation (EC) 1760/2000):
1) individual identification with ear tag, 2 ear tags are applied to all bovine animals born in Italy or imported from Third Countries.
Since 1.1.1998 ear tags are in compliance with the requirements referred to in Regulation (EC) 911/2004. The identification code printed on each ear tag, issued by 'Centro Servizi Nazionale per l'anagrafe zootecnica', is checked by the veterinary authority and the animal owner/keeper shall apply it within 20 days from birth and before the animals leave the holding of origin.
2) Individual identification document (passport): veterinary authorities issue a passport for each bovine accompanying the animals during each movement. All the information reported in the passport are in compliance with Regulation (EC) 911/2004.
3) Holding register: animal owner/keeper must have a paper register at farm level or electronic in BDN, regularly updated concerning birth, introduction, death and movement of each animal.
4) National database (BDN) correspond to the system for the registration of all holdings/farms and bovine animals, owners and keepers as well as identification data of each animal, movements, included to the slaughterhouse, and containing all the information of animals slaughtered, killed/depopulated and dead.
I & R of ovine and caprine animals is in accordance to Regulation (EC) 21/2004. All the animals born since 9 July 2005 shall be identified with an alphanumeric code (IT+12 characters) within 6 months of age and before the animals leave the holding of origin.
As identification system may be applied 2 plastic ear tags or 1 plastic ear tag and a tattoo. According to Regulation (EC) 1560/2007, amending of Regulation (EC) 21/2004, all new born since 31 December 2009 shall be identified with an electronic system associated to a visible identifier as required by Regulation (EC) 933/2008, with exception of animals younger than 12 months and to be slaughtered, to which is possible to apply only one ear tag with the code of the holding of birth. The holding register shall be updated by animal owner/keeper, as paper register at farm level or electronic in BDN, concerning identification, introduction, birth, death, total number of ewes older than 12 months or having lambs (every 90 days) and the number of animals present on 15 March each year.

According to article 3 paragraph 1 of Regulation UE 2016/429, its delegated and implementing acts, the maximum time of registration in the national database (BDN) of all the information of article 112, letter d) and 113, paragraph 1, letter c) (Regulation UE 2016/429) for cattle, sheep and goats, are immediately applicable.
The ovine and caprine population in Italy during 2020 is estimated as follows: 6.525.161 ovine animals, 1.058.431 caprine animals.
Individually registered male sheep: 6.160.359 female sheep 222.106 male sheep. Male goats individually registered: 73.240 females 984.051 (as of May 2021).

4.5 Measures in place as regards the notification of the disease

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(max. 32000 chars) :

In Italy BSE and scrapie are compulsorily notifiable diseases since 10 May 1991, when they have been included in the list of notifiable diseases with an Ordinance of the Minister of Health.
The LVU at the reception of the official confirmation, to a rapid test carried out by the CEA for BSE and scrapie and to a discriminatory test by ISS for scrapie, notifies it at the Ministry of Health – DG for animal health – Unit 3 and put in place all the control measures.
Since July 2009, a national IT system is in place for the official notification of animal diseases SIMAN (Sistema informativo malattie animali Nazionale), which is now still mandatory and largely used.
In application of the new EU Regulation 429/2016 and Italian laws that implement it, the notification system of the disease from suspicion to confirmation is entrusted to the local veterinary officer.

According to Regulation EC 999/2001 suspect animals are live, slaughtered or dead animal, which show or have shown neurological or behavioural disorders or a progressive deterioration of the general condition linked to impairment of the central nervous system and for which the information gathered on the basis of a clinical examination, response to treatment, a post-mortem examination or an ante or post-mortem laboratory analysis do not allow an alternative diagnosis to be established.
In this case (suspect TSE animals), the whole head is collected and dispatched to the Reference TSE Centre in Turin (CEA) without performing a rapid test. At the CEA, the confirmatory tests, as reported in the Annex X of Reg 999, will be carried out on the brainstem.
After a first confirmation test (test carried out at the NRL in Turin), the discriminatory test is carried out at the ISS based in Rome.

For active surveillance in both, bovine and small ruminants (laid down Annex III to Regulation No 999/2001 i.e.), the rapid test is carried out at the national public laboratories (IIZZSS: experimental zooprophylactic institutes dependent on the Ministry of Health - MoH), the national reference laboratory in Turin (CEA / NRL) carries out the confirmatory test (only Confirmatory tests other than rapid tests), the discriminatory test is carried out at the ISS based in Rome (ISS / NRL).
Italy don't use rapid tests for confirmation.
Bovine spongiform encephalopathies (BSE) shall be suspected in bovine animals which have produced a positive result from a rapid test specifically for BSE. The same holds for scrapie.

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	0	0	0
Risk animals born in MS listed in Annex to CD 2009/719/EC	48	58 500	58 500
Healthy slaughtered bovine animals NOT born in MS liisted in Annex to CD 2009/719/EC	30	217	217
Risk animals NOT born in MS listed in Annex to CD 2009/719/EC	24	42	42

Suspect animals (as referred to in Art 12.2 of Regulation (EC) No 999/2001)		25	25

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	0	0	0
Risk animals born in MS listed in Annex to CD 2009/719/EC	48	58 700	58 700
Healthy slaughtered bovine animals NOT born in MS liisted in Annex to CD 2009/719/EC	30	200	200
Risk animals NOT born in MS listed in Annex to CD 2009/719/EC	24	45	45
Suspect animals (as referred to in Art 12.2 of Regulation (EC) No 999/2001)		25	25

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

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Estimated population of adult ewes and ewe lambs put to the ram.	5 571 900

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	4 500
Ovine animals from holdins affected by atypical scrapie	40
Ovine animals from holdings affected by BSE	0
Suspect animals (c)	235
Total number of tests	24 775

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	4 500
Ovine animals from holdins affected by atypical scrapie	42
Ovine animals from holdings affected by BSE	0
Suspect animals (c)	235
Total number of tests	24 777

(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 .	877 576

Targets for year **2021**

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	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	930
Caprine animals from holdins affected by atypical scrapie	30
Caprine animals from holdings affected by BSE	0
Suspect animals (c)	115
Total number of tests	**21 075**

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	930
Caprine animals from holdins affected by atypical scrapie	30
Caprine animals from holdings affected by BSE	0
Suspect animals (c)	115
Total number of tests	**21 075**

(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	30
Confirmatory tests in Ovine an Caprine animals	400

Targets for year **2022**

	Estimated number of tests

Confirmatory tests in Bovine animals	30
Confirmatory tests in Ovine an Caprine animals	400

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	1
Primary molecular testing on ovine and caprine animals	150
Total	**151**

Targets for year **2022**

	Estimated number of tests
Primary molecular testing on bovine animals	1
Primary molecular testing on ovine and caprine animals	160
Total	**161**

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	150
Random genotyping	650

Targets for year **2022**

	Estimated number
Genotyping of TSE cases	160
Random genotyping	670

4.7 Eradication

4.7.1 Measures following confirmation of a TSE case in bovine animals

4.7.1.1 Description

(max. 32000 chars) :

In Italy BSE cases, both classical and atypical, are considered confirmed once that the test screening positivity detected by the regional approved laboratories has been confirmed by the NRL CEA and once that this test according to Annex X Chapter C point 3.1 c) is carried out by ISS.
Since the year 2001, in case of BSE confirmation, we choice one of the two options in accordance with Regulation (EC) 999/2001 killing of all bovine animals of that holding, or killing of the cohort.
The decision to apply one of the two eradication options is taken, in cooperation with the owner/keeper, after the control of the right identification and registration of the animals present in the holding and on the basis of epidemiological and cost-benefit evaluation.
It must be identified the positive's progeny and animals of the cohort moved to other holdings.
Moreover the measures laid down in the annex VII, Reg. 999/2001 may be applied, by providing health guarantees required in the Regulation.
Since January 2002, the milk is not excluded from the human and animal consumption.

4.7.1.2 Summary table

Targets for year **2021**

	Estimated number
Bovine animals culled and destroyed	2

Targets for year **2022**

	Estimated number
Bovine animals culled and destroyed	2

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

4.7.2.1 Description

(max. 32000 chars) :

Scrapie cases (ovine and caprine) are considered confirmed once the screening positivity to the rapid test detected by the regional approved laboratories has been confirmed by CEA - Turin as well as by ISS – Rome, the latter carrying out genotyping and discriminatory testing to exclude BSE and to differentiate the classical scrapie from the atypical NOR-98. The eradication measures (annexe VII reg. 999/2001 + national legislation) are subsequent at that confirmation.
To not delay the application of measures and the elimination of animals, the genotyping of animals in the holding confirmed as outbreak shall starts just after the confirmation of positivity of the rapid test (by National Reference Center).
The Local veterinary Unit (LVU), after sanitary evaluation by National Reference Center for TSE (CEA/ BEAR-Turin), applies the more appropriate measures considering the epidemiological situation, risk factors and cost-benefit evaluation.
If the disease is confirmed in animals (ovine and caprine) with genotype resistent ARR/ARR or K/K , the

total depopulation of all animals is applied.
In most cases selective elimination is applied using genetic information. The selective depopulation foresees the elimination of all sheep with the exclusion, of the males ARR/ARR and the females with at least one allele ARR and without the allele VRQ (for ovine) , the animals without at least one allele K222, for caprine.
Since July 2020, in the application of the EU regulation 772/2020, in Italy, the elimination of goats has been restricted only to those susceptible to classical scrapie, without K222.
Since June 2012, It's allowed the derogation to slaughter susceptible animals from the outbreaks of scrapie for human consumption.
When at the holding level, the resistant allele (ARR and K222) is rare or to avoid inbreeding or for economic factors, it is allowed under sanitary evaluation, to delay the killing and complete destruction or slaughtering for human consumption of the susceptible animals or to maintain alive the animals (option 3 annexe VII).
In the holding may be introduced only animals ARR/ARR (male) or ARR/XXX, not VRQ (female). Referring to annex VII regulation (CE) 999/2001, there are no different conditions, for movements of animals ARR/ ARR f, while for animals ARR/XXX is allowed to go directly for slaughter for human consumption or to holding with the same TSE's status.
For goats, to apply the new regulation Reg.UE 772/2020 (which modifies the Reg. CE 999/2001), in order to increase genetic resistance in the holding population, it is allowed to introduce, preferably, K / K animals or animals carrying at least one K222 allele. In the holding reasoned animal breeding with male animals carried K222 allele are programmed.
In case of presence of female goats with K222 and bucks of high genetic value without K222 allele, these animals can be maintained for mating in order to increase the resistance allele. Subsequently the bucks must be eliminated.

Surveillance intensified (Regulation (EU) 2021/1176): The holding shall be subject to an intensified TSE monitoring protocol: testing for the presence of TSE in animals over the age of 18 months, which have died or have been killed in the holding but not in the framework of a disease eradication campaign.
Only following the decision to implement option 3 laid down in point 2.2.2(d) or the derogation provided for in point 2.2.2(c)(iii) the measures laid down 4.1 shall immediately apply to the holding.

In case common grazes are applied specific restrictions.
In the outbreak holding must be used only semen from rams of the ARR/ARR o goats of the K/K genotype and embryos carrying at least one ARR allele and no VRQ allele or K222 allele per goats.
Lambs and kids less than three months of age, if BSE is excluded, may be slaughtered for human consumption. Similarly, susceptible animals may be slaughtered for human consumption, if above 12 months of age, after removal of specified risk materials (SRM).
Milk and milk products are destroyed only if BSE cannot be excluded or in case of BSE confirmation.
After the exclusion of BSE, the milk cannot be used for the feeding of the ruminants outside the holding, while there are no restrictions for the ruminants in that holding and for human consumption.
Where a case of atypical scrapie has been confirmed, the restriction measures on the movement of ovine and caprine animals are no longer applied. In case of an outbreak caused by an atypical strain, it's applied annexe VII for atypical scrapie. A two years monitoring (surveillance intensified) is applied on all animals of the flock and their products.
The Adoption and publication of the draft Commission Regulation amending to Regulation (EC) No 999/2001 of the European Parliament and of the Council as regards the genotyping of positive TSE cases in goats, the determination of age in ovine and caprine animals, the measures applicable in a herd or flock with atypical scrapie (Regulation (EU) 2021/1176 of 16 July 2021) will lead to consequent adjustments of Italian health measures.

For the situations where it is not possible to recovering and sampling the animals that died in the

remote pastures (Regulation 1069/2009, art 19), we replace the quota of dead animals with double the regularly slaughtered. This monitoring allows the sampling to detect the disease at 95% confidence if it is present with a prevalence index of 0.1%.

4.7.2.2 Summary table

Targets for year **2021**

	Estimated number
Ovine and caprine animals culled and destroyed (due to classical scrapie)	400
Ovine and caprine animals compulsory slaughter (due to classical scrapie)	4 500
Genotyping tests - monitoring and eradication measures	20 100

Targets for year **2022**

	Estimated number
Ovine and caprine animals culled and destroyed (due to classical scrapie)	300
Ovine and caprine animals compulsory slaughter (due to classical scrapie)	3 980
Genotyping tests - monitoring and eradication measures	20 300

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) :

The first breeding programme for resistance to TSEs in sheep has been enforced with the Decree of the MoH of 17 December 2004, which transposed the requirements provided to in Regulation (EC) 999/2001 (art. 6a).
The programme was mandatory for all flocks of high genetic merit and since November 2006 for all holdings confirmed as outbreak, but the participation to the programme was not total.
For this reasons, Italy, during the year 2015, has amended the Decree of the MoH of 17 December 2004 including also commercial flocks, in all Regions. That is the reason to eradicate scrapie by increasing percentage of resistant sheep above a certain threshold.
The overall objective over time is to eradicate the disease and to select flocks at low TSE risk in order to achieve a shift of the genetic structure of the sheep population at least from the fourth generation, by implementing the following specific objectives:
– extending the breeding programme,

– increasing the frequency of ARR allele will occur the fade-out of the causative agent of Scrapie,
– genotyping all young rams, disseminating resistant rams in the ovine population,
– the individual identification of small ruminants is associated with an efficient system of traceability of the movements of the animals within the breeding programs.
This new programme provides the compulsory registration (BDN) of all animals genotyped and used for the reproduction. Furthermore, the Ministry of Agriculture (MoA) has provided economic incentives to encourage breeders trying to eradicate scrapie from their flock.
To raise awareness regarding TSE and genotyping for resistance, as central competent authority the main actions are carried out in the frame of both 'audit' sessions, to the regional and local authorities, and training events, where is widely and deeply explained the efficacy of breeding program to prevent and eradicate scrapie, by selecting resistant flocks, and to promote their implementation.
Since 2014 the Ministry jointly to the NRL (CEA - Turin) has planned to deliver dedicated events to the breeders to raise awareness, explaining the importance and efficacy of genotyping and how they could apply. The majority of regions have regulated the breeding programmes.
The MoH provided the general guidelines and on the basis DM 25/11/2015 all the regional authorities elaborated the breeding programs taking into account the breeds present on their territory and the kind of breeding.
For some breeds with low frequency of the resistant genotypes, are used alternative control programme to avoid a high decreasing of the breed or inbreeding.
Genotyping testing is carried out by the network of the public laboratories the 'Istituti Zooprofilattici Sperimentali (IZSs)' and by two private laboratories, authorized by the MoH, the 'LGS' in Cremona and the 'Agenzia per la ricerca in agricoltura della Sardegna – AGRIS'. All information about each ovine (individual data) and each flock (flock data) involved in the breeding plan are collected by the National reference laboratory for TSE, c/o the Institute of Zooprophilaxis of Piemonte, Liguria and Valle d'Aosta, and organized in a database (BDNSG). The ISS, as a reference laboratory for the genetics of prion diseases, support the Ministry of Health and to the official laboratories that carry out the genotyping analysis. The ISS plays the verifications and inspections by territorial laboratories, organize ring tests.
The random genotyping will allow the monitoring of the PRNP genotype frequency in the Italian ovine population. Italy will use a sampling strategy repeated each year, to permit the evaluation of breeding program evolution within the Country: for ovine animals, the sample is formed of at least 600 animals each year.
This sampling design will allow, taking into account epidemiological data collected during previous sampling campaigns carried out in Italy, to detect a change of 5 % in genotype prevalence over a 3-year period, with a level of confidence of 95 %.
According to the EFSA Opinion (10th of August 2017): "Genetic resistance to transmissible spongiform encephalopathies (TSE) in goats", We continue genotype goats to look for resistant animals.
In this regard, we have achieved a good level of information that we are using on caprine farms: whit outbreak and whiteout outbreak.

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	6 300

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Rams to be genotyped under the framework of a breeding programme referred to in Article 6a of Regulation (EC) No 999/2001	62 980
Total	69 280

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	6 000
Rams to be genotyped under the framework of a breeding programme referred to in Article 6a of Regulation (EC) No 999/2001	62 980
Total	68 980

5. Costs

5.1 Detailed analysis of the costs

(max. 32000 chars) :

The national legislation, Law 218/1988 lays down provisions concerning the reimbursement to the owner for killed/slaughtered animals and their products.
As reference to determine the amount, the market values are reported by a weekly bulletin by ISMEA, institution under the control of the Ministry of Agriculture, which indicates the average value of the market on several selling points all over the country and for many categories of animals. In case the breed and category are not reported by the above bulletin, ad hoc Committees are established, representing both professionals and stakeholders, responsible to define the value of the animal to be reimbursed.
As regards the request of reimbursement, it considers the period from the date of the official request made by the owner, (after slaughter or killing of animals), to the date of the authorization of the payment by the regional/local authorities.
Until 2018 was possible to report the costs (VAT excluded) that occurred to depopulate animals in outbreaks confirmed in previous years, considering the long period of measures application, at the condition that all the administrative papers have been carried out during the year of reporting. Starting in 2019 there was an alignment whit guide line UE cofinancing.

The unit cost of rapid test, both screening and confirmation, genotyping and discriminatory tests is done by the sum of all costs occurred for the processing of the sample as follows: kit or examination, diagnostic examination, reagents, consumables, salary of the personnel performing the analysis for TSEs as amount related to the time dedicated to such testing. The unit cost includes also general costs for the laboratory, important for testing activities and equipment functionality (energy, water, gas, etc.), for an amount not higher than 7% of the total costs above mentioned.
The cost of the diagnostic kit is established at national level by the MoH, on the basis of a national tender launched and managed by the NRL CEA on behalf of the MoH. Since July 2013, the prices of kit is increased because the number of tests for BSE is significantly reduced (for application Decision 2013/76/EU). Whilst all the other costs are defined by each approved territorial laboratory because of their administrative and financial independence.
Since 2009, Regions and Laboratories report all the costs occurred by the national IT system “SIR rendicontazione (reporting)”.
Italy does not apply to the EU cofinancing all the costs occurred for the implementation of the programs. Indeed, the costs occurred to dispose of the milk, killing and destruction of animals and all the other related costs (disinfectants, transport, personnel if the disposed of at farm level) are not included to the reporting and not requested.

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	0	15.76	0	yes	30	0	X
Testing	Rapid tests on bovine animals born in MSs listed in CD 2009/719 | Risk animals	58 500	15.76	921,960	yes	30	276 588	X
Testing	Rapid tests on bovine animals not born in MSs listed in CD 2009/719 | Healthy slaughtered animals	217	15.76	3419.92	yes	30	1 025,98	X
Testing	Rapid tests on bovine animals not born in MSs listed in CD 2009/719 | Risk animals	42	15.76	661.92	yes	30	198,58	X
Testing	Rapid tests on suspect bovine animals	25	15.76	394	yes	30	118,2	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	24 775	15.76	390,454	yes	30	117 136,2	X
Testing	Rapid Tests - caprine	21 075	15.76	332,142	yes	30	99 642,6	X

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	30	102.32	3069.6	yes	30	920,88	X
Testing	Confirmatory Tests in Ovines and Caprines	400	102.32	40928	yes	30	12 278,4	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	151	205.65	31053.15	yes	30	9 315,94	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	20 100	40.43	812,643	yes	30	243 792,9	X
Testing	Genotyping test (standard) - breeding programme	69 280	40.43	2,800,990.4	yes	30	840 297,12	X
Testing	Genotyping test - TSE cases	150	154.7	23205	yes	30	6 961,5	X
Testing	Genotyping test (standard) - random sample	650	40.43	26279.5	yes	30	7 883,85	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	2	1000	2000	yes	30	600	X
Compensation	Ovine and caprine animals culled and destroyed	400	140	56000	yes	30	16 800	X
Compensation	Ovine and caprine animals - compulsory slaughter	4 500	100	450,000	yes	30	135 000	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	yes		0	X

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Total with Union funding request (€):	5,895,200.49	including	1,768,560.15
Total without Union funding request (€):	0		= 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	0	15.76	0	yes	30	0	X
Testing	Rapid tests on bovine animals born in MSs listed in CD 2009/719 | Risk animals	58 700	15.76	925,112	yes	30	277 533,6	X
Testing	Rapid tests on bovine animals not born in MSs listed in CD 2009/719 | Healthy slaughtered animals	200	15.76	3152	yes	30	945,6	X
Testing	Rapid tests on bovine animals not born in MSs listed in CD 2009/719 | Risk animals	45	15.76	709.2	yes	30	212,76	X
Testing	Rapid tests on suspect bovine animals	25	15.76	394	yes	30	118,2	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	24 777	15.76	390,485.52	yes	30	117 145,66	X
Testing	Rapid Tests - caprine	21 075	15.76	332,142	yes	30	99 642,6	X

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	30	102.32	3069.6	yes	30	920,88	X

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Testing	Confirmatory Tests in Ovines and Caprines	400	102.32	40928	yes	30	12 278,4	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	161	205.65	33109.65	yes	30	9 932,9	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	20 300	40.43	820,729	yes	30	246 218,7	X
Testing	Genotyping test (standard) - breeding programme	68 980	40.43	2,788,861.4	yes	30	836 658,42	X
Testing	Genotyping test - TSE cases	160	154.7	24752	yes	30	7 425,6	X
Testing	Genotyping test (standard) - random sample	670	40.43	27088.1	yes	30	8 126,43	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	2	1000	2000	yes	30	600	X
Compensation	Ovine and caprine animals culled and destroyed	300	140	42000	yes	30	12 600	X
Compensation	Ovine and caprine animals - compulsory slaughter	3 980	100	398,000	yes	30	119 400	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 (€):	5,832,532.47	including	1,749,759.75
Total without Union funding request (€):	0		= 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) :

The sanitary state budget, where regularly flow the reimbursements from the EU cofinancing, is used to reimburse the entities (Regional competent authorities – Labs) in charge for the implementation of the eligible measures planned in this programme. The state budget is basically divided in two sections: one managed by the Ministry of Finance and one by the Ministry of Health.
The Ministry of Finance every year transfers to the Regions an overall sanitary budget covering all the activities carried out by the regional and local vet services regarding the control of animal diseases.
The sampling is carried out by the local vet services and the Ministry of Finance every year transfers to the Regions an overall sanitary budget covering all the activities carried out by the regional and local vet services regarding the control of animal diseases.
The Sampling of obex for rapid testing and of blood for genotyping are carried out by the official and/or approved veterinarians administrative.
Sampling equipment is provided by the local vet services. All the costs for the sampling carried out by the local vet services are paid with the regional

sanitary (state) budget.
Blood samples for genotyping, in the frame of the breeding programme for animals registered in the breed book, are carried out by veterinarians/ technicians belonging to the breeder associations (ASSONAPA).
Sampling equipment is provided by the local vet services or by laboratories (LGS Cremona, AGRIS Sardegna: in case screening genotyping in the frame of the breeding programme for animals registered in the breed book).
All the costs for the sampling carried out by the local vet services are paid with the regional sanitary (state) budget. The sampling carried out by the breeder associations is reimbursed by the MoH on the basis of the provided and verified reporting.

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 implementing entities are the following:
NRLs (CEA and ISS): CEA – TSEs rapid testing confirmation;
ISS – strain typing and genetic of animal TSEs and discriminatory testing.
Public Laboratories (IZSs): screening testing (rapid and genotyping),
Private/approved Laboratories (2: LGS and AGRIS): genotyping in the frame of the breeding programme for animals registered to in the breed book. Under control of ASSONAPA (breeder associations) and MoH (only TSE genotyping activities).
The sanitary state budget, where regularly flow the reimbursements from the EU cofinancing, is used to reimburse the entities (Regional competent authorities – Labs) in charge for the implementation of the eligible measures planned in this programme.
All the costs for the analisis carried out by CEA, IIZZSS, ISS, and the LGS_Lab. and AGRIS_Lab are reimbursed by the MoH on the basis of the provided and verified reporting.

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 Ministry of Health is the competent authority responsible for the implementation of the eligible measures and for the request of the EU cofinancing once carried out the technical and financial checks in accordance to the EU legislation.
The competent authorities provide all the costs for the implementation of the eligible measures and no costs are reimbursed by other/third entities.
The sanitary state budget, where regularly flow the reimbursements from the EU cofinancing, is used to reimburse the entities (Regional competent authorities – Labs) in charge for the implementation of the eligible measures planned in this programme.
The state budget is basically divided in two sections: one managed by the Ministry of Finance and one by the Ministry of Health.
The reimbursement flow changes based on the eligible measures: animals culled, rapid tests, both screening and confirmatory, genotyping and discriminatory tests. The implementing entities are the following:
Regional and local vet services: sampling, outbreak management and reimbursement to the owners,
Public Laboratories (12: IZSs): screening testing (rapid and genotyping),
Private/approved Laboratories (2: LGS Cremona, AGRIS Sardegna): genotyping in the frame of the breeding programme for animals registered to in the breed book,
NRLs (CEA and ISS): CEA – TSEs rapid testing confirmation; ISS – strain typing and genetic of animal TSEs and discriminatory testing.

The Ministry of Finance every year transfers to the Regions an overall sanitary budget covering all the activities carried out by the regional and local vet services regarding the surveillance, control and eradication of animal diseases: reimbursement to the owners (depopulation animals), equipment for sampling obex (rapid test) or blood (screening genotyping) and sampling activities.
All the costs for the laboratory analisis/testing carried out by CEA, IIZZSS, ISS, and the approved Labs (LGS and AGRIS) are reimbursed by the MoH on the basis of the provided and verified reporting.

The unit cost of rapid test, both screening and confirmation, genotyping and discriminatory tests is done by the sum of all costs occurred for the processing of the sample as follows: kit or examination, diagnostic examination, reagents, consumables, salary of the personnel performing the analysis for TSEs as amount related to the time dedicated to such testing. The unit cost includes also general costs for the laboratory, important for testing activities and equipment functionality (energy, water, gas, etc.), for an amount not higher than 7% of the total costs above mentioned.

Concerning the reimbursement to the owner for killed/slaughtered animals and their products. As reference to determine the amount, the market values

are reported by a weekly bulletin by ISMEA, institution under the control of the Ministry of Agriculture, which indicates the average value of the market on several selling points all over the country and for many categories of animals. In case the breed and category are not reported by the above bulletin, ad hoc Committees are established, representing both professionals and stakeholders, responsible to define the value of the animal to be reimbursed.

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) :

Not applicable

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

(max. 32000 chars) :

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

Please explain for which measures and why co-financing rate should be increased to 75% (max 32000 characters)

Mandatory health measures such as those of EC Regulation 999/2001 should set the maximum rate of co-financing.
The measures for which 75% of reimbursement is requested are the costs regarding the compulsory slaughter, culling and disposal of ovine and caprine

Please explain for which measures and why co-financing rate should be increased to 100% (max 32000 characters)

Mandatory health measures such as those of EC Regulation 999/2001 should set the maximum rate of co-financing.
The measures for which 100% of the reimbursement is requested correspond to the costs regarding the genotyping because they are the only way to

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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
		17579_12971.pdf	17579_12971.pdf	531 kb
		17579_12972.xls	17579_12972.xls	33 kb
		17579_12973.pdf	17579_12973.pdf	1124 kb
		17579_12974.pdf	17579_12974.pdf	574 kb
			Total size of attachments :	2263 kb