



About this dossier

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Eradication: Final report for Transmissible Spongiform Encephalopathies 2019

For each approved annual or multi-annual programme Member States shall submit to the Commission by the 30 April each year an annual detailed technical and financial report covering the previous year. That report shall include the results achieved and a detailed account of eligible costs incurred (Art 14 of Regulation (EU) No 652/2014).

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Reporting period

From: 2019

To: 2019

Year of implementation: 2019

1. Technical implementation of the programme

1.1 Description and evaluation of the evolution of the epidemiological situation, the technical implementation of the activities foreseen under the programme and the cost-effectiveness of the programme.

The description and evaluation of the evolution of the epidemiological situation of scrapie and BSE and the technical implementation of the activities covered by the program are described in the attached reports (Scrapie report2019 and BSE report2019). As for the implementation of the program, Italy, as every year, has tried to implement the surveillance and monitoring plan, with the greatest possible effectiveness, based on available resources. The regulation states that "Member States in which a breeding program is in place may decide to authorize the sampling and genotyping of breeding rams only in flocks that do not participate in the breeding program". Based on this, a new program has been adopted in all Italian regions. All rams of Italian breeding (both rams from high herds of genetic merit and those from raw (especially commercial herds) are subjected to genotyping.

The revision of the BP, applied with the Ministry of Health Decree of 25 November 2015, is totally in line with point 1 of Part 1 of Chapter C of Annex VII of Regulation (EC) no. 999/2001. The sampling activity is performed by both veterinarians of Local Health Units (ASL) and, mainly for high genetic merit flocks, by technicians of the National Association of shepherds (ASSONAPA). There is quite substantial progress in this area thanks to the new compulsory breeding plan adopted since the end of 2015.

In 2019 were: that 16.230 flocks were involved in the breeding plan: 85 were holdings involved in Scrapie outbreaks (40 new outbreaks) and 16.145 were flocks without Scrapie. The share of new flocks involved in

the breeding program was about 43%; 5,334 was the number of flocks never selected before. In relation to 40 new confirmed outbreaks of scrapie in sheep and goats, 15,205 animals were genotyped in the outbreak and 59,567 ovines (about 91% rams and 9% ewes) in flocks without Scrapie (in Breeding Programme - BP -). For ovine genotyping: 54,145 males and 5,422 females (for BP) table F. We genotyped goats in search of resistant animals, according to EFSA's opinion (10 August 2017): "Genetic resistance to transmissible spongiform encephalopathies (TSE) in goats". Italy, after EFSA opinion (10 August 2017), "Genetic resistance to transmissible spongiform encephalopathies (TSE) in goats", is using this information to disseminate the resistance also in goats. Italy will start (in the year 2020) with a specific and regular programme of genotyping in male goats to contribute to the eradication and to limit the spread of the disease also in goat herds, building up, at the same time, general knowledge on the existence and distribution of billy goats carrying the resistant allele at National and Regional level. This information will be utilized for increasing the resistant in caprine animals.

There were a total of 73,678 surveillance tests in sheep and goats.

From an epidemiological point of view, Italy in 2019 allowed reaching a confidence level of 99.99% (above 95% required). The positive animal small ruminants were 221.

Among the 190 positive ovine samples detected in 2019, 11 resulted inconclusive on Discriminatory WB because of their very low content of PrPSc in the available brain tissues. These 11 ovine samples were all secondary cases deriving from flocks in which the presence of BSE has been excluded based on the Discriminatory WB results (Classical Scrapie) obtained from the index case and other secondary cases deriving from the same affected flock.

One case, in an outbreak of classical scrapie, showed molecular features strongly similar to scrapie strain CH1641like.

Among the 31 positive caprine samples detected in 2019, 2 resulted inconclusive on Discriminatory WB because of their very low content of PrPSc in the available brain tissues. These were 1 index case from an outbreak in which 2 index cases were first detected, and 1 secondary case from a different caprine herd. In both caprine outbreaks, BSE has been excluded based on the Discriminatory WB results (Classical Scrapie) obtained from the index cases.

CWD is an infectious disease belonging to the group of transmissible spongiform encephalopathies (TSE). Several cervids species are susceptible to the disease, including mule deer (*Odocoileus hemionus*), white-tailed deer (*Odocoileus virginianus*), red deer (*Cervus elaphus*), moose (*Alces alces alces*) and reindeer/caribou (*Rangifer tarandus*). CWD is endemic in North America.

the epidemiological context changed in spring 2016 when the CWD was diagnosed in a Norwegian reindeer that showed symptoms compatible with the disease (VKM, 2016, NFSA, 2016; EFSA, 2017). Then, another 24 cases were confirmed not only in reindeer but also in a few moose and in a red deer so far (as of 29/03/2019). In 2018, for the first time a case was reported in the EU: it is a Finnish moose. Two additional moose cases have been detected in Sweden. Italy voluntarily (without European co-financing) has started a monitoring plan for sensitive species. The results are in the CWD_Report_2019.

1.2 Details on the level of achievement of the targets set in the approved programme and technical difficulties.

Details on the level of achievement of the targets set in the approved programme and technical difficulties are described in the attached reports (Report scrapie_2019 and Report BSE_2019).

In Italy, the compliance of the monitoring plan has some difficulties due to the peculiarity of the small ruminant breeding system and of the territory. Despite we introduced the mandatory testing of all small ruminant fallen stock, we are often not able to comply with the minimum national sample size of 10,000 animals for this specific category. This is largely due to the inability of recovering and sampling the animals dead on remote pastures (Regulation 1069/2009, art 19). It must be possible the replacement of the missing quota of fallen stock with double size of healthy slaughtered adult sheep. In Italy the surveillance for categories Healthy slaughtered is many.

However, From an epidemiological point of view, the total number of animals that were tested is sufficient to provide a 95% level of confidence of detecting classical scrapie if it is present in that population at a prevalence rate exceeding 0,1%. To solve this problem we have sampled more animals of categories: died and healthy slaughtered. We are working, even more, in collaboration with other offices of the Ministry of Health and of other Ministries.

The current 'general surveillance' should be further detailed in more specific surveillance activities tailored to the individual territories. Regarding the cost-benefit, with better balance, you could achieve a consequent greater efficacy of the control programme in terms of results and eradication. Indeed, better use of the fund should be addressed taking into account the needs of the different territories in the country.

1.3 Epidemiological maps for infection and other relevant data on the disease/activities (information on serotypes involved,...) (Please attach files of data using the PDF attachment feature) Use the textbox below to provide clarifications for the maps you attach, if needed.

Epidemiological maps for infection and other relevant data on the disease/activities are described in the attached reports (Scrapie_Report_2019 and BSE_Report_2019).

The data evolution for the breeding programme is shown in the attached file (BP_Report_2019). A Report on the activity carried out in the framework of the 2019 Italian monitoring plan for the chronic wasting disease of cervids is in CWD_REPORT_2019.

2. Tables for TSE monitoring outcome of the year

VERY IMPORTANT: Please fill out the following tables with figures corresponding to measures performed during the implementing period (1/1 to 31/12).

NB: the Regulation (EC) No 999/2001 is thereafter quoted as the TSE Regulation.

Table A

| | Total positive cases detected during the implementing period | | |
|----------------------------------|---|-----------------------|----------------|
| | Classical cases | Atypical cases | Unknown |
| TSE | 0 | 0 | 0 |
| Scrapie (ovine animals) | 171 | 7 | 11 |
| Scrapie (caprine animals) | 26 | 3 | 2 |

Table B

| RAPID TESTS ON BOVINE ANIMALS | | |
|--|--------------------------------------|------------------------------|
| | Age limit applied (in months) | Number of tests cases |
| Risk bovine animals from MSs listed in Annex to Decision 2009/719/EC | 48 | 61,236 |
| Risk bovine animals from MSs NOT listed in Annex to Decision 2009/719/EC | 24 | 43 |
| Healthy slaughtered bovine animals from MSs listed in Annex to Decision 2009/719/EC | 0 | 0 |
| Healthy slaughtered bovine animals from MSs NOT listed in Annex to Decision 2009/719/EC | 30 | 231 |
| Suspect animals and confirmatory tests | | 0 |
| Total | | 61,510 |

Table C

Population of ewes and ewe lambs put to the ram in the Member State

| | |
|--|------------------------|
| | 6287568 |
| RAPID TESTS ON OVINE ANIMALS | |
| | Number of tests |
| Healthy slaughtered ovine animals | 12,380 |
| Dead ovine animals | 16,148 |
| 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 | 6,731 |
| Ovine animals from holdings affected by atypical scrapie | 34 |
| Ovine animals from holdings affected by BSE | 0 |
| Suspect animals | 9 |
| Total number of tests | 35,302 |

Table D

Population of goats which have already kidded and goats mated in the Member State

| | |
|--|------------------------|
| | 1003823 |
| RAPID TESTS ON CAPRINE ANIMALS | |
| | Number of tests |
| Healthy slaughtered caprine animals | 27,282 |
| Dead caprine animals | 9,223 |
| 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 | 1,838 |
| Caprine animals from holdings affected by atypical scrapie | 27 |
| Caprine animals from holdings affected by BSE | 0 |
| Suspect animals | 6 |
| Total number of tests | 38,376 |

Table E

| Confirmatory and discriminatory tests | |
|--|------------------------|
| | Number of tests |
| Confirmatory tests other than rapid tests on bovine animals | 33 |
| Confirmatory tests on ovine and caprine animals | 489 |
| Discriminatory tests on bovine animals | 0 |
| Discriminatory tests on ovine and caprine animals | 222 |
| Total number of confirmatory tests | 522 |
| Total number of discriminatory tests | 222 |

Table F

| Genotyping tests | |
|---|------------------------|
| | Number of tests |
| Positive TSE case | 222 |
| Randomly selected ovine animals | 601 |
| Animals in scrapie infected flocks | 15,205 |
| Breeding programme - ewes | 5,422 |
| Breeding programme - rams | 54,145 |
| Total of number of tests | 75,595 |

Table G

| COMPENSATION FOR ANIMALS In the context of suspicion, control and eradication of TSEs | |
|---|--------------------------------------|
| | Number of animals compensated |
| Animals culled and destroyed | |
| Bovine animals | 0 |
| Ovine animals | 562 |
| Caprine animals | 115 |
| Animals slaughtered | |
| Ovine animals | 3,411 |
| Caprine animals | 1,541 |
| Total Bovine | 0 |
| Total Ovine + Caprine | 5,629 |

COMMENT / ADDITIONAL CLARIFICATION

Regarding the EU program co-financing, other expenses should be considered, such as those dedicated to animal killing and rendering (provided in Annex VII 2.2.2. B) as well as the costs of milk destruction. Particularly, this product undergoes to degradation during the period of time between the discriminatory examination (to exclude BSE) and the date of complete destruction of the animals (Annex VII 2.2.1.4 ° paragraph). Indeed, consequently, the disposal is arranged in accordance with Article 12 of Regulation (EC) No. 1069/2009 of the European Parliament and of the Council.

All surveillance numbers were maintained for the EFSA opinion recommendations 2014 (EFSA Journal 2014;12(7):3781, 155 pp): a number of additional and alternative measures aimed at obtaining control of classical scrapie in sheep and goats, including the intensification of surveillance and control measures.

For the category of dead goat animals, these considerations have been made: The missing share of caprine fallen stock was replaced with a double size of healthy slaughtered adult caprine.

