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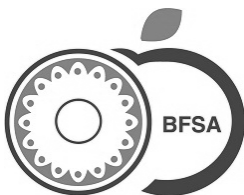
*Programmes for the eradication, control and monitoring of certain
animal diseases and zoonoses*

**The programme for the monitoring of
transmissible spongiform encephalopathies (TSE) and for
the eradication of bovine spongiform encephalopathy
(BSE) and of scrapie**

Bulgaria

Approved* for 2013 by Commission Decision 2012/761/EU

* in accordance with Council Decision 2009/470/EC



MINISTRY OF AGRICULTURE AND FOOD

BULGARIAN FOOD SAFETY AGENCY

☒ Sofia, 1606, “Pencho Slaveikov” blvd. 15 A
☎ +359 (0) 2 915 98 20, ☏ +359 (0) 2 954 95 93, www.babh.government.bg

PROGRAMME FOR MONITORING OF TSEs IN THE REPUBLIC OF BULGARIA, CO-FINANCED BY THE COMMUNITY

1. Identification of the programme:

Member state: Republic of Bulgaria
Disease: Transmissible spongiform encephalopathies
Year of implementation: 2013

Reference of this document:

- Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies
 - Commission Decision 2003/100/EC of 13 February 2003 laying down minimum requirements for the establishment of breeding programmes for resistance to transmissible spongiform encephalopathies in sheep
 - Law on Veterinary Activities (State Gazette No 87/1 November 2005 in force since 1 May 2006)
- “Art. 123. (1) The Bulgarian Food Safety Agency (BFSA) shall develop draft national surveillance programs for certain specific contagious diseases
(2) The Minister of Agriculture and Food approves the programs referred to in par. 1 following a proposal from the Executive Director of BFSA.”

Contact: (name, phone, fax, e-mail):

Dr Tsviatko Alexandrov,
Bulgarian Food Safety Agency
”Animal Health and Welfare” Directorate
phone: + 359 2 915 98 42,
fax: +359 2 952 38 35
e-mail: tsv.alexandrov@nvms.government.bg

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2. Description of the programme

This programme describes the surveillance of bovine spongiform encephalopathy (BSE) and scrapie in small ruminants in the Republic of Bulgaria.

Program objectives:

- Surveillance of transmissible spongiform encephalopathies in ruminants (bovine spongiform encephalopathies – BSE and scrapie in small ruminants) in the Republic of Bulgaria and testing of sheep for resistance to scrapie.
- Rapid detection of transmissible spongiform encephalopathies in ruminants and immediate implementation of safety measures for limiting the spread of products from infected animals and eradication of the infection.
- Ensuring consumer safety in the consumption of meat and products obtained from large and small ruminants.
- To provide evidence that the Republic of Bulgaria carries out control on the diseases belonging to the group of transmissible spongiform encephalopathies in the frame of intra-Community trade and international trade network.

3. Description of the epidemiological situation of the disease:

Since 2002, the National Veterinary Service* of Bulgaria (Bulgarian Food Safety Agency, since 25.01.2011) carries out strict active surveillance of TSE in ruminants under the requirements of Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies and its amendments. Since then no BSE positives have been detected in Bulgaria. During 2008 - 4 scrapie cases in sheep were detected on the territory of Bulgaria. In 2009 two scrapie cases (one goat and one sheep) were confirmed and in 2010 – another 6 cases were detected in sheep and goats (2 sheep and 2 goats positives from one herd + 1 sheep and 1 goat from other separate herds) .

The Total feed ban was introduced by Order of the minister of agriculture and food at the beginning of January 2006.

4. Measures included in the programme

4.1. Designation of the central authority charged with supervising and coordinating the departments responsible for implementing the programme:

Competent Authorities:

- Bulgarian Food Safety Agency (BFSA) at the Ministry of Agriculture and Food;
 - 28 Regional Food Safety Departments (RFSDs) at BFSE;
 - National Reference Laboratory for TSE at the National Diagnostic Research Veterinary Institute (NDRVI), Sofia, No 15 A Pencho Slaveikov Blvd., tel.: 02-9521277;
 - TSE laboratory at the Regional Diagnostic Veterinary Institute (RDVI) Veliko Turnovo No 5 Slavianska Str., tel.: 062-620275;
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* Note: National veterinary service of Bulgaria (NVS) is as of 25th of January 2011 part of the Bulgarian food safety agency (BFSA)- State gazette 8/25.01.2011

- TSE laboratory at the Regional Diagnostic Veterinary Institute (RDVI) Stara Zagora, No 58 Slavianski Blvd., tel.: 042-634104.

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

The regional structure of BFSE corresponds to the administrative division of the country - Bulgaria is divided into 28 administrative regions and in each of them is applied the TSE monitoring programme.

4.3. System in place for the registration of holdings:

Pursuant to Article 51, paragraph 3, of the LVA the BFSA is the official competent authority for animal identification which shall maintain a computerized information system for entering data for the identified animals and registered animal holdings. The terms and rules of animal identification, registration of animal holdings and the possibilities for access to the information is regulated by an ordinance of the Minister of Agriculture and Food. (ORDINANCE № 61/9.05.2006 on the measures and procedures for identification of animals, registration of animal holdings and the availability to access the data base for identified animals and registered animal holdings (*Published in SG 47/09.06.2006*) - REGULATION (EC) OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL No 1760/2000 of 17 July 2000 establishing a system for the identification and registration of bovine animals; COUNCIL REGULATION (EC) No 21/2004 of 17 December 2003 establishing a system for the identification and registration of ovine and caprine animals and amending Regulation (EC) No 1782/2003 and Directives 92/102/EEC and 64/432/EEC, COUNCIL DIRECTIVE 92/102/EEC of 27 November 1992 on the identification and registration of animals)

Pursuant to same article (51, paragraph 1) of the Law on the veterinary activity the animal holdings are subject of obligatory registration.

At the central data base there are registers of all animal holdings for large and small ruminants and registers of the owners of the animals and of the holdings.

4.4. System in place for the identification of animals:

The BFSA maintains computerized information system for entry of data on the identified animals, their owners and registered animal holdings. The modules are elaborated for registration and notifications of movements of animals and for additional data. The system for identification of farm animals includes the data about the identification of animal keeper; location, movement of animals; health status and the veterinary activities.

The requirements for the identification of small and large ruminants are ordered in Regulation № 1760/2000 and Regulation № 21/2001.

Large ruminants shall be identified until the twentieth day of their birth but in any cases identification is performed before the animals leave the animal holding of origin. The ear tags shall be put by registered veterinarian. Ear tags contain the following information: the code of the Republic of Bulgaria "BG", 2 digit code and 6-digit serial number.

Small ruminants (SR) are identified until the sixth month of their birth but in all cases before leaving the animal holding of origin. The identification of each animal shall be made by approved by BFSA ear tag attached to the left ear and which contain the following information: the code of the Republic of Bulgaria “BG”, 2 digit code, letter “D”, referring to SR and a 7-digit serial number.

4.5. Measures in place as regards the notification of the disease:

The contagious diseases are subject to notification pursuant to Art.50 of LVA. TSEs are notified according the requirements of ORDINANCE № 23/ 14.12.2005 laying down the terms and procedure for notification and registration of contagious animal diseases (*Published in SG 6/20.01.2006*) transposing COUNCIL DIRECTIVE 82/894/EEC of 21 December 1982 on the notification of animal diseases within the Community

The Bulgarian Food Safety Agency ensures that it is notified immediately of any animal suspected of being infected by a TSE.

The Executive Director of the BFSA informs the European Commission and the Member States of the occurrence of BSE as well as of any other cases of TSE different from BSE.

4.6. Monitoring

The surveillance of TSEs is carried out in compliance with the requirements of Art. 6 and Annex III of Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies.

4.6.1. Monitoring in bovine animals

	Estimated number of tests
Animals referred to in Annex III, Chapter A, Part I, points 2.1, 3 and 4 to Regulation (EC) No 999/2001 of the European Parliament and of the Council	5000
Animals referred to in Annex III, Chapter A, Part I, point 2.2 of Regulation (EC) No 999/2001	15 000

4.6.2. Monitoring in ovine animals

	Estimated Number of tests
Ovine animals referred to in Annex III, Chapter A, Part II, point 2 of Regulation (EC) No 999/2001	10000
Ovine animals referred to in Annex III, Chapter A, Part II, point 3 of Regulation (EC) No 999/2001	10000
Ovine animals referred to in Annex III, Chapter A, Part II, point 5 of Regulation (EC) No 999/2001	200

4.6.3. Monitoring in caprine animals

	Estimated Number of tests
Caprine animals referred to in Annex III, Chapter A, Part II, point 2 of Regulation (EC) No 999/2001	1500
Caprine animals referred to in Annex III, Chapter A, Part II, point 3 of Regulation (EC) No 999/2001	1500
Caprine animals referred to in Annex III, Chapter A, Part II, point 5 of Regulation (EC) No 999/2001	200

4.6.4. Discriminatory tests

	Estimated number of tests
Primary molecular testing referred to in Annex X, Chapter C, point 3.2(c)(i) of Regulation (EC) No 999/2001	50

4.6.5. Genotyping of positive and randomly selected animals

	Estimated number of tests
Animals referred to in Annex III, Chapter A, Part II, point 8.1 of Regulation (EC) No 999/2001	20
Animals referred to in Annex III, Chapter A, Part II, point 8.2 of Regulation (EC) No 999/2001	200

4.7. Eradication

4.7.1. Measures following confirmation of a BSE case:

4.7.1.1. Description:

When the presence of a BSE has been officially confirmed, the following measures shall be applied as soon as possible:

- all parts of the body of the animal shall be disposed of in accordance with Regulation (EC) No 1069/2009;
- an inquiry shall be carried out to identify all animals at risk in accordance with Annex VII, point 1 of Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies;
- all animals and products thereof at risk, as listed in Annex VII, point 2, of Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies, identified by the inquiry shall be killed and disposed of in accordance with Regulation (EC) No 1774/2002.

Pending the implementation of the measures, the holding on which the animal was present when the presence of a BSE was confirmed shall be placed under official control and all movement of animals susceptible to BSEs and products of animal origin derived from them from or to the holding shall be subject to authorisation by the competent authority, with a view to ensuring immediate tracing and identification of the animals and products of animal origin concerned.

If there is an evidence that the holding where the affected animal was present when the BSE was confirmed is not likely to be the holding where the animal was exposed to the BSE, the

BFSA may decide that both holdings or only the holding of exposure shall be placed under official control.

Owners shall be compensated without delay for the loss of the animals that have been killed or products of animal origin destroyed in accordance with Article 12(2) and Article 13 (1a and 1b) of Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies.

4.7.1.2. Summary table

	Estimated number
Animals to be killed under the requirements of Annex VII, Chapter A, point 2.1 of Regulation (EC) No 999/2001:	50

4.7.2. Measures following confirmation of a scrapie case:

4.7.2.1. Description:

When the presence of a Scrapie has been officially confirmed, the following measures shall be applied as soon as possible:

- all parts of the body of the animal shall be disposed of in accordance with Regulation (EC) No 1069/2009;
- an inquiry shall be carried out to identify all animals at risk in accordance with Annex VII, point 1 of Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies;
- all animals and products thereof at risk, as listed in Annex VII, point 2, of Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies, identified by the inquiry shall be killed and disposed of in accordance with Regulation (EC) No 1774/2002.

Pending the implementation of the measures, the holding on which the animal was present when the presence of a Scrapie was confirmed shall be placed under official control and all movement of animals susceptible to TSEs and products of animal origin derived from them from or to the holding shall be subject to authorisation by the competent authority, with a view to ensuring immediate tracing and identification of the animals and products of animal origin concerned.

If there is evidence that the holding where the affected animal was present when the Scrapie was confirmed is not likely to be the holding where the animal was exposed to the TSE, the BFSA may decide that both holdings or only the holding of exposure shall be placed under official control.

Owners shall be compensated without delay for the loss of the animals that have been killed or products of animal origin destroyed in accordance with Article 12(2) and Article 13 (1a and 1b) of Regulation (EC) No 999/2001 of the European Parliament and of the Council of 22 May 2001 laying down rules for the prevention, control and eradication of certain transmissible spongiform encephalopathies.

4.7.2.2. Summary table

	Estimated number
Animals to be killed under the requirements of Annex VII, Chapter A, point 2.3 of Regulation (EC) No 999/2001:	100
Animals to be genotyped under the requirements of Annex VII, Chapter A, point 2.3 of Regulation (EC) No 999/2001:	100

4.7.3. Breeding programme for resistance to TSEs in sheep

4.7.3.1. General description (1):

Research has shown that sheep of certain prion protein genotypes are resistant to the disease. There are different alleles for the prion genes. In the prion protein alleles with occupied Alanine and Arginine positions 136, 154 and 171 a combination ARR is obtained which is resistant to scrapie. In sheep having alleles with Valine, Arginine and Glutamine at the same positions at the same positions the combination VRQ is obtained which is susceptible to scrapie.

The breeding programme includes a framework to recognise the TSE-resistant status of certain flocks based on scientific evidence corroborating the resistance to TSE of particular genotypes of those species.

BFSA shall submit regular reports to the Commission in order to enable the programmes to be scientifically evaluated, in particular with regard to their impact on the incidence of TSEs but also on genetic diversity and variability and on the maintenance of old or rare ovine breeds or of those that are well-adapted to a particular region.

4.7.3.2. Summary table

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

5. Costs

5.1. Detailed analysis of the costs: - 2013

Costs related to	specification	Number of units -2013	Unitary costs in euro - 2013	Total amount in euro- 2013	Community funding requested (yes/no)
1. BSE testing					
1.1. Rapid tests	Test:	20 000	10	200 000	yes
2. Scrapie testing					
	Test:	23 400	15	351 000	yes
3. Discriminatory testing					
3.1. Primary molecular test	Test:	50	65	3 250	yes
	Test:				
4. Genotyping					
4.1 Determination of genotype of animals in the framework of the measures laid down by Regulation (EC) No 999/2001/EC		270	25	6 750	yes
4.2 Determination of genotype of animals in the framework of breeding programme as established in Decision 2003/100/EC		-	-	-	-
5. Complalsory slaughter					
5.1 Compensation for bovine animals to be killed/slaughtered under requirements of Annex VII, Chapter A, point 2.1 of Regulation (EC) No 999/2001/EC		100	500	50 000	yes
5.2 Compensation for ovine and caprine animals to be killed/slaughtered under requirements of Annex VII, Chapter A, point 2.3 of Regulation (EC)No 999/2001/EC		100	100	50 000	yes
TOTAL				661 000	yes