

EUROPEAN COMMISSION HEALTH & CONSUMERS DIRECTORATE-GENERAL

Unit G5 - Veterinary Programmes

SANCO/10741/2012

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

Survey programme for Bovine Spongiform Encephalopathy (BSE) and Scrapie

Approved* for 2012 by Commission Decision 2011/807/EU

Ireland

^{*} in accordance with Council Decision 2009/470/EC

Ireland

Monitoring Control and Eradication Programme for BSE 2012 (amended version)

Department of Agriculture, Fisheries and Food Ireland.

ANNEX III

Standard requirements for the submission of programmes of eradication and monitoring of TSEs¹ co-financed by the Community

1. Identification of the programme

Member State: Ireland

Disease(s)²: **BSE**

Year of implementation: 2012

Reference of this document: BSE Programme 2012

Contact (name, phone, fax, e-mail): Mary Butler.

Phone: 00353 1 607 2989 Fax: 00353 1 607 2763/4

e-mail: mary.butler@agriculture.gov.ie

Date sent to the Commission: 27 April 2011

Bovine Spongiform Encephalopathy (BSE) and Scrapie.

One document per disease is used unless all measures of the programme on the target population are used for the control and eradication of different diseases.

2. <u>Description of the submitted programme</u>

Ireland's Programme is intended to monitor, control and ultimately eradicate BSE from the national herd. It includes the slaughter of cohort and progeny animals and active surveillance of animals over 48 months of age (72 months of age from 1 July 2011) slaughtered for human consumption, fallen casualty and emergency slaughter animals over 48 months of age, in accordance with Regulation (EC) No. 999/2001 of the European Parliament and the Council as amended.

3. <u>Epidemiology of the disease</u>

The situation with regard to BSE in Ireland continues to improve. In 2010, 2 cases of BSE were confirmed. This compares with 9 cases in 2009, 23 cases in 2008, 25 cases in 2007 and represents a reduction of over 99% in case numbers since the peak of 333 cases in 2002. Ireland continues to see an upward shift in the age profile in BSE cases. The shift in the age profile of BSE cases as well as the reduction in the prevalence of test positives provides clear evidence that the additional controls introduced in Ireland in 1996 and 1997 have been effective at controlling disease. It is expected that the incidence of disease will continue to decline as older cows leave the system. A small number of cases have occurred in animals born after the introduction of the EU wide feed –ban in 2001, 10 cases to date. Detailed investigations were carried out on each of these 6 cases. No breaches of the control programme have been detected. The continued implementation of SRM controls and the feed- ban controls ensure these cases do not pose a risk to human or animal health

The testing of all slaughtered cattle over 48 months of age (including all bovine animals > 48 months of age depopulated for BSE reasons), all fallen stock over 48 months of age and all casualty/emergency slaughter cattle over 48 months of age continued up to June 2011. From 1st July 2011 following changes to EC Reg. 999/2001 the BSE surveillance age thresholds for healthy slaughter animals increased to 72 month of age.

- 4. Measures included in the Programme
- 4.1 Central Authority: Department of Agriculture, Fisheries and Food
- 4.2 Geographical and Administrative Areas: Ireland to be treated as a single area.
- 4.3 System in Place for the Registration of Holdings: Each holding containing bovine animals is registered with the Department and is identified by a specific herd number allocated following an inspection by DAFF staff to ensure compliance with certain criteria. Slaughter of BSE cohort and progeny animals currently takes place at a designated slaughterhouse outside of the food chain, which is licensed by DAFF. Slaughterhouses and knackeries where rapid testing is carried out are also approved by DAFF.
- 4.4 System in place for identification of animals: A very extensive range of measures is now in place to ensure the integrity of the national herd and cattle presented for slaughter. These include an animal traceability system. All calves are tagged at birth with a unique identification number, registered at a central registration database and issued with a passport. This passport records all movements and it accompanies the bovine animal throughout its life. The Herdowner also maintains a Herd Register which contains information on all births, purchases, sales and deaths of bovine animals. Information in relation to all births, deaths, and bovine animal movements in Ireland is also captured and maintained on a central database. This system became fully operational at the beginning of 2000 and was subsequently enhanced by the National Beef Assurance Scheme. At slaughterhouses, strict procedures are in place to verify both the origin and health status of the animals presented for slaughter. These include checks of ear tags and documentation (including checks against the Department's database) and ante mortem inspections. In addition each individual animal is assigned a carcase number which can be cross referenced to its individual tag number and therefore back to the farm of origin.
- 4.5 *Measures in place as regards the notification of the disease*: S.I. 61 of 1989 stipulates that "a person who has in his possession or under his charge an affected or a suspected animal, or the carcase of such an animal, and any

veterinary surgeon or other person who, in the course of his duties, examines or inspects any such animal or carcase shall, with all practicable speed, notify the fact to (a) the Secretary, Department of Agriculture, Fisheries and Food or (b) an inspector at a District Veterinary Office of the Department of Agriculture, Fisheries and Food.

4.6 *Monitoring:*

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 of Regulation (EC) 999/2001 ³	65,000
Animals referred to in Annex III, Chapter A, Part I, points 2.2, of Regulation (EC) 999/2001	250,000
Animals referred to in Annex III, Chapter A, Part I, points 5 of Regulation (EC) 999/2001 ⁴ (cohorts, progeny and BSE suspects)	150

4.7 Eradication

4.7.1. Measures following confirmation of a BSE case:

Following the confirmation of BSE in a herd, tracing of cohorts - as defined by Regulation (EC) No. 999/2001 - and the last two progeny born to the infected animal is carried out. Any live animals identified under this tracing programme are slaughtered at a designated slaughterhouse outside of the food chain after the value attributed to the specific animal/s has been agreed with the herd owner. All animal by-products (ABP)

OJ L 147, 31.5.2001, p. 1, Regulation as last amended by Regulation (EC) No 2245/2003 (OJ L 283, 19.12.2003, p. 28).

OJ L 147, 31.5.2001, p. 1, Regulation as last amended by Regulation (EC) No 2245/2003 (OJ L 283, 19.12.2003, p. 28).

produced by the slaughter of BSE cohorts and progeny animals are treated as Category 1 ABP material and are disposed of in accordance with Regulation (EC) 1069/2009 and implemented by Regulation (EU) 142/2011. The number of animals slaughtered under this regime is a function of the number of cases in which the disease is identified and the year of birth of the positive case. It is estimated that the number of animals to be slaughtered under this part of the programme in 2012 should not exceed 150. However, it is difficult to predict this number with accuracy as one case of BSE may have less than ten or multiple cohort animals.

5 <u>Costs</u>

5.1 Detailed analysis of the costs:

The costs of this programme will include costs of sampling, collection and testing of samples, and the provision of compensation to farmers in respect of the partial depopulation of herds from this programme. Estimated Costs in 2012 may be broken down roughly as follows:

Activity	Estimated Cost Net of VAT
*Active Surveillance at Factories:	€2.0m
250,000 tests at €8 per test	
Active Surveillance – Fallen Animals: 65,000 tests	€2.17m
$65,000 \times €33.31 \text{ per test} = €2,165,150 + VAT @21\%$	
= € 2,619,831.50	
Active Surveillance – Monitoring Cohort /Progeny animals: 150	€0.005
tests at €33.31 per test = €4,996.50+ VAT	
@21% € 6,045.77	
Additional costs associated with testing (Equipment, protective	€0.84m
clothing transport and collection of samples):	
Partial Depopulation Compensation (115 animals)	€0.085m (average price of animal/s
	slaughtered in 2010 =€740
Haulage, Slaughter and other costs associated with Depopulation	€0.207m
Total	€5.307m

*The competent authority only pays the EU co-funding amount in respect of over 72 months at factory testing. However, it continues to bear the full cost of the testing of fallen, progeny and cohort animals.

5.2. Summary of the costs

Costs related to	Specification	Number of units	Unitary cost in €	Total amount in €	Community funding requested (yes/no)
1. BSE testing ⁵					
	Test:				
Factory O72M's	Test: Approved Rapid Test	250,000	€8	€2.0m	Υ
Fallen and Casualty Animals	Test: Approved Rapid Test	65,000	€ 33.31	€2.17m	Υ
Cohorts and Suspects	Test: Approved Rapid Test	150	€ 33.31	€0.005m	Υ

4.	Compulsory Slaughter						
4.1.	Compensation for animals to be killed under the requirements of Annex VII, Point 2 (b) of Regulation (EC) 999/2001		115	€740	€0.085m	Υ	
тоти	TOTAL				€4.26m	Y	

⁵ As referred to in point 4.6.1.

Ireland

Monitoring and Control and Eradication Programme for Scrapie

2012

Department of Agriculture, Fisheries and Food, Ireland.

Identification of the Programme

Submitting Member State: Ireland

Year of Implementation: 2012

Reference of this Document: Scrapie Programme 2012

Contact Person: Mary Butler, Assistant Principal, Animal Health and Welfare Division, Department of Agriculture, Fisheries and Food, Ireland.

email address: mary.butler@agriculture.gov.ie

Date Sent to Commission: 27 April 2011

Description of the Programme

This is a Programme for the control and eradication of scrapie involving genotyping and partial depopulation of infected sheep flocks and full depopulation of infected goatherds, active surveillance in meat factories, in fallen animal at intermediate plants and the continued implementation of a National Genotyping Programme. Control and Eradication is also achieved by passive surveillance on farm

3. Description of the Epidemiology of the Disease

3.1 General

Scrapie has been known internationally for over 200 years. In common with other TSEs it has a long incubation period. Peak incidence of clinical signs is seen in 3 to 4 year old sheep. There is evidence that significant infection of the tissues of infected animals with the scrapie agent occurs months before clinical signs appear. The course of the clinical disease may be weeks or months. The signs of scrapie are variable and non-specific and can include itchiness (resulting in "scraping" against fences etc.), nervous signs (including lack of co-ordination, head pressing and teeth grinding) and change in temperament. Weight loss may be variable. The disease is non-febrile. Diagnostic methods for pre-clinical cases are still under development. Tests currently proposed for the diagnosis of scrapie in live animals are impractical for large-scale screening and a confirmatory diagnosis can be made on histological examination, immunohistochemistry or immunoblotting of tissues after death.

Lambs can be infected by their infected dams and other dams around the time of birth with the placenta and foetal fluids being a major source of the agent. It is traditionally recognised that horizontal transmission may occur at this time also via the oral route.

The incubation period of scrapie is determined by the size of the infective dose and genetic make-up of the host animal. Sheep of certain genetic types have a shorter incubation period from infection to when clinical signs of the disease become apparent than do others. It has been shown that the single autosomal gene which determines the

length of the incubation period in mice is similar to, if not in fact the same as, the gene which codes for the prion protein. It has also been recognised that (normal) PrP gene in sheep is a major factor controlling the development of the clinical signs of scrapie. Variations in the coding areas of the PrP gene in sheep (at locations 136, 154 and 171) determine susceptibility (or "resistance") to the clinical signs of classical scrapie and variations in the coding areas of the PrP gene in sheep (at locations 136, 141, 154 and 171) determine susceptibility (or "resistance") to the clinical signs of atypical scrapie.

3.2 The Situation in Ireland

The number of scrapie positive flocks since 1989 as follows:

Year	Number of (New Flocks)
1989 to 2001	126
2002	69
2003	37
2004	27
2005	19
2006	39
2007	16
2008	8
2009	12
2010	7
2011 up to 27/04/2011	6

3.3 Scrapie 2002 - 2006

The initial implementation of the active surveillance provisions in Council Regulation 999/2001 lead to a significant increase in the number of scrapie cases identified in Ireland in 2002. The reduction in the number of positive flocks identified since 2002 has been very significant with 6 new positive flocks identified to date in 2011.

The following details the number of test positives cases from 2002 to 2011 year - to- date:

Scrapie Test Positives 2002 and up to 26/04/2011

Sheep

Active Surveillance

Active Surveillance Year	Factory Surveillance No. Tests	No. Positives cases	Fallen Animal Surveillance No. Tests	No. Positives (cases)	Total Positives (cases)
2002	54,813	13	5,222	33	46
2003	51,588	10	2,843	17	27
2004	10,686	5	9,632	37	42
2005	10,689	1	10,374	21	22
2006	41,677	9	13677	36	45
2007	26,970	3	16,184	23	26
2008	11,687	3	10,747	7	10
2009	8,176	2	8,713	10	12
2010	11,026	2	10,408	22	24

Passive Surveillance

2002 Positives (sheep)	2003 Positives (sheep)	2004 Positives (sheep)	2005 Positives (sheep)	2006 Positives (sheep)	2007 Positives (sheep)	2008 Positives (sheep)	2009 Positives (sheep)	2010 Positives (sheep)
47	16	13	5	8	11	15	11	24

Goats

Active	Factory	No. Positives	Fallen Animal	No. Positives	Total
Surveillance	Surveillance	(Goats)	Surveillance	(Goats)	Positives
Year	No. Tests		No. Tests		(Goats)

2002	-	-	-	-	-
2003	-	-	-	-	-
2004	-	-	1	0	0
2005	-	-	79	0	0
2006	23	0	163	0	0
2007	0	0	163	0	0
2008					
	0	0	132	0	0
2009	1	0	63	0	0
2010	0	0	73	0	0
2011 up to	0	0	14	0	0
26/04/2011					

4. Measures included in the Programme

Active Surveillance

Regulation (EC) 999/2001 as amended by Regulation (EC) 727/2007 requires the annual testing of slaughter sheep over 18 months of age and fallen sheep over 18 months of age. The Commission proposed a level of testing of 10,000 for healthy slaughtered animals over 18 months and 10,000 for fallen animals in 2007 subject to the requirement that in successive sampling years all officially registered holdings with more than 100 animals and where TSE cases have never been detected are subject to TSE testing. It is anticipated that 10,000 healthy slaughtered sheep and 10,000 fallen sheep will be tested for TSE's in 2012.

Ireland's surveillance programme for 2012 will involve:

- Targeted active surveillance which will involve rapid testing a sample of animals over 18 months of age which die (fallen animals) or which are slaughtered for human consumption, this will provide additional information in relation to the incidence of scrapie in the general sheep population. Ireland will, at minimum, conduct the number of tests provided for under EU law.
- Discriminatory Western blotting of all index cases testing positive for scrapie and the first two subsequent cases in each restricted flock each year
- Genotyping of individual sheep which have tested positive for scrapie at the four codons;
- Genotyping of animals in scrapie positive flocks at the four codons
- Rapid testing of all animals (>18 months of age) depopulated from scrapie positive flocks.

- TSE testing of fallen animals (>18months of age) and cull animals (>18mths) from scrapie positive flocks.
- TSE testing of fallen animals (>18months of age) in scrapie monitored flocks

Tests to be Used

For the programme described above Ireland will use one or more rapid tests approved in accordance with the provisions of commission Regulation (EC) 999/2001 as amended. These will be performed in private laboratories that have been approved by the Central Veterinary Research Laboratory (CVRL) of the DAFF i.e. The National Reference Laboratory (NRL). Positive or inconclusive results from these tests will be verified at the CVRL by the NRL using histopathology and immunohistochemistry and/or immunoblotting (where appropriate).

Taking and Analysing the Samples

Samples for rapid testing are taken by veterinarians at slaughterhouses, veterinary college, regional veterinary laboratories and knackeries. These samples are analysed using an approved rapid testing accordance with Council Regulation 999/2001as amended.

Dealing with Infected Flocks

• Ireland operated a Scrapie Depopulation Policy from December 2001 to 1st October 2003. Since 1st October, 2003 Ireland operates a genotyping and partial depopulation policy. Flockowners are permitted to retain Category 1 rams and ewes and Category 2 ewes. Farmers are required to dispose of Category 2 rams, and all Category 3, 4 and 5 breeding animals. Flockowners may opt to avail of the concession to dispose of all un-genotyped male lambs outside the food chain (applicable to male lambs born immediately following restriction date). Additionally, the competent authority has retained the option to fully depopulate where warranted. Since 15th July 2007, restricted flocks are prohibited from re-stocking for 2 years following the removal and disposal of the last susceptible animal.

In compliance with the practices and procedures in place at the laboratory for the recording and reporting of test results (fully automated system), the Department's National Reference Laboratory will genotype the animals from infected flocks in 2012

Genotyping/Breeding Programmes:

- The Department established a National Genotyping Programme, (NGP) which has been available to farmers since 2004. Both pedigree and commercial flocks have availed of the Programme and although the focus is primarily on rams, farmers may also elect to have ewes genotyped. This is a voluntary programme and is fully financed by the flockowner.
- The testing component of the NGP will be delivered by an approved commercial laboratory. Official NGP Certificates are issued by the competent authority to applicants in respect of tests carried out in the approved laboratory for sheep showing categories 1 to 3. A computerised database is maintained to include an automated result reporting system and also facilitates the tracking of change of ownership of genotyped sheep.

4.1 Designation of the Central Authority charged with supervising and Co-ordinating the Programme

Department of Agriculture, Fisheries and Food, Kildare Street, Dublin 2, Ireland.

4.2 Geographical and Administrative Areas

For the purposes of this Programme, Ireland will be treated as a single geographical and administrative region.

4.3 System in Place for the Registration of Holdings

Farms and slaughterhouses involved in the programme are registered with the Department of Agriculture, Fisheries and Food. (Larger ovine slaughterhouses are approved and operate under the control of DAFF while the smaller ones are operated under the control of the Local Authority).

4.4 System in Place for the identification of Animals

Sheep

The National Sheep Identification System-(NSIS)

Ireland has had a sheep identification system in place since 2001. The National Sheep Identification System (NSIS) is based on the individual tagging of sheep, the keeping of flock registers and the use of dispatch documents for all movements of sheep between holdings, to the markets or to slaughterhouses. In accordance with Council Regulation (EC) 21/2004, introducing a harmonised EU wide system for sheep ID, electronic identification (EID) of sheep was introduced in Ireland in 2010. Regulation (EC) 21/2004 also provided for a derogation whereby sheep intended for slaughter before they are 12 months old are permanently exempted from electronic tagging requirements. Given that the NSIS was delivering well on individual sheep traceability, Ireland opted to retain as much of the system as possible and therefore opted to apply this derogation. In these circumstances, EID is largely confined to breeding animals over 12 months and sheep for live export.

The following changes have been made to NSIS as a result of the introduction of EID

- > a new numbering system has been put in place to accommodate electronic tags and a number of companies have been approved to supply EID tags to Irish flockowners,
- > The Irish tag system is now based on the principle of one ID for life from the holding of origin; and
- the electronic tagging of breeding animals and of live animals being exported.

Census:

An annual census of the national flock is now a requirement. Flockowners are requested to submit the number of sheep in specific categories on their holding to DAFF within a specified time frame. This information is then co-related and retained electronically by DAFF which formulates the national census register.

The National Goat Identification System (NGIS) was introduced in Ireland in 2005 to provide for a national system of goat identification vital for disease control, traceability and consumer assurance. The system is based on:

- Double tagging of all goats by the age of six months or on movement from a holding, whichever comes first
- Use of herd registers to record details of numbers of goats on a holding and details of movements
- Use of dispatch documents to record all movements.

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From 2010 goats will continue to be double tagged with conventional tags on their holding of birth with one ID number for life by 6 months of age or when they leave the holding of origin whichever comes first.

4.5 Measures in Place as regards the Notification of the Disease

The Disease is compulsorily notifiable under EU and National Legislation. Additionally, on completion all active surveillance results are notified to the relevant TSE staff/section within the Department.

4.6 Monitoring

4.6.1. Monitoring in Ovine and Caprine animals

	Estimated Number of tests
Animals referred to in Annex III, Chapter A, Part II, point 2 of Regulation (EC) 999/2001 (Healthy Slaughter)	10,000 sheep
Animals referred to in Annex III, Chapter A, Part II, point 3 of Regulation (EC) 999/2001 (Fallen Animals)	10,000 sheep 100 goats
Animals referred to in Annex III, Chapter A, Part II, point 5 of Regulation (EC) 999/2001 (Monitoring in infected flocks)	3,000
Animals referred to in Annex VII, of Regulation (EC) 999/2001	2,000
Animals referred to in Annex VIII, of Regulation (EC) 999/2001 Chapter A Paragraph 1 (a) (ii) Others (specify) Scrapie Monitored Flocks	500

4.6.2. 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) 999/2001 (Scrapie Positive Sheep)	200
Animals referred to in Annex III, Chapter A, Part II, point 8.2 of Regulation (EC) 999/2001((Random Sub Sample of Slaughter survey)	650

4. 6. 3. Discriminatory Tests

	Estimated number of tests
Primary molecular testing referred to in Annex X, Chapter C, point 3.2 (c) (i) of Regulation (EC) 999/2001	150

4.7. Eradication

Measures following confirmation of a Classical Scrapie case:

Description: Restriction and Genotyping of Flock and depopulation of Scrapie Susceptible Animals

(Category 2, 3, 4 and 5 rams and category 3, 4 and 5 breeding ewes).

Current years - male lambs born in year of restriction - which are not genotyped, are disposed of outside the food chain.

4.7.1 Summary Table

	Estimated number
Animals to be killed under the requirements of Annex VII, Chapter A Point 2. 3 (b) (ii) (of Regulation (EC) 999/2001(Slaughter in Positive Flocks)	3,000
Animals to be genotyped under the requirements of Annex VII, Chapter A Point 2. 3 (b) (ii) (of Regulation (EC) 999/2001 (Entire Positive Flock)	4,000

Costs

4.8 Detailed analysis of Full costs:

The costs of Scrapie Programme in 2012 -estimated as follows:

Activity	Estimated Cost Excluding VAT
Active Surveillance at Factories: 10,000 tests at €27 per test. (average cost)	€0.27m
Active Surveillance – Fallen Animals: 10,100 tests (10,000 sheep + 100 goats) at €27 per test. (average cost)	€0.273m
Rapid Testing of Infected Flocks - 3,000 tests at €27 per test	€0. 081m
Genotyping in Scrapie Positive Flocks: 4,000 tests @ €19.25	€0.077m
Cost of animals (3,000) under requirements of (EC) 999/2001 (Slaughter in Positive Flocks)	€0.270m
Total of costs provided for on Standard Form:	€0.971m
Haulage, tagging, certification, sampling and other costs	€0.74m
Laboratory Consumables for Pyrosequencing Equipment	€ 0.5m
Total Costs	€2.211m

4.8.1 Summary of the costs provided for on Standard Form

Costs Related to	Specification	Number of Units	Unitary Cost in €	Total Amount in €	Community Funding Requested (Yes or No)
2. Scrapie testing ¹					
2.1. Rapid testing of fallen sheep & of healthy slaughtered sheep	Test: Approved Rapid Test	20,100	€27.00	€ 0.543 <i>m</i>	Y
2.2 Discriminatory Testing					
Primary molecular tests	Test: VLA Western Blot	150	€150.00	€0.0225m	Y
3 Genotyping					
3.1. Determination of genotype of animals in the framework of the measures laid down by Regulation 999/2001 ²	Method: Pyrosequencing at National Reference Laboratory	4,000	€19.25	€0.077m	Y
4. Compulsory Slaughter					
4.1. Compensation for animals to be killed under the requirements of Annex VII, Point 2 (b) of Regulation (EC) 999/2001	Cost of Animals Slaughtered in 2010	3,000	€105 Market Value (Average based on 2010)	€0.315m	Y
4.7.3 Compensation for animals to be killed under the requirements of a voluntary breeding program.	Compensation for Animals Slaughtered under the Programme in 2010	0	N/A	0	Y

TOTAL €0.9575m Y	T∩T∆I #0 0575m V
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