This document is meant purely as documentation tool and the institutions do not assume any liability for its contents

►**B**

COMMISSION DECISION

of 23 April 1998

on epidemio-surveillance for transmissible spongiform encephalopathies and amending Decision 94/474/EC

(Text with EEA relevance)

(98/272/EC)

(OJ L 122, 24.4.1998, p. 59)

Amended by:

		Official Journal		
		No	page	date
►**M1**	Commission Decision 2000/374/EC of 5 June 2000	L 135	27	8.6.2000
►**M2**	Commission Decision 2000/764/EC of 29 November 2000	L 305	35	6.12.2000
►**M3**	Commission Decision 2001/8/EC of 29 December 2000	L 2	28	5.1.2001

▼B

COMMISSION DECISION

of 23 April 1998

on epidemio-surveillance for transmissible spongiform encephalopathies and amending Decision 94/474/EC

(Text with EEA relevance)

(98/272/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 89/662/EEC of 11 December 1989 concerning veterinary checks in intra-Community trade with a view to the completion of the internal market [1], as last amended by Directive 92/118/EEC [2], and in particular Article 9(4) thereof,

Having regard to Council Directive 90/425/EEC of 26 June 1990 concerning veterinary and zootechnical checks applicable in intra-Community trade in certain live animals and products with a view to the completion of the internal market [3], as last amended by Directive 92/118/EEC, and in particular Article 10(4) thereof,

(1) Whereas new information has been published in the United Kingdom further supporting the hypothesis that exposure to the bovine spongiform encephalopathy (BSE) agent is linked to the new variant of Creutzfeldt Jacob Disease (CJD) in humans; whereas on 16 September 1997 the Spongiform Encephalopathy Advisory Committee (SEAC) of the United Kingdom concluded that recent research provided compelling new evidence that the agent which causes BSE is identical to the agent which causes the new variant of CJD in humans; whereas on 18 September 1997 the Advisory Committee on Dangerous Pathogens (ACDP) concluded that the BSE agent should now be classified as a human pathogen under Directive 90/425/EEC, the Member State of origin or dispatch is required to implement on its territory the appropriate measures to prevent all situations likely to constitute a serious hazard to animals or to human health;

(2) Whereas, pursuant to Council Directive 82/894/EEC [4], as last amended by Commission Decision 98/12/EC [5], Member States have since 1990 been obliged to notify all cases of BSE to the Commission and to the other Member States;

(3) Whereas pursuant to Council Directive 91/68/EEC [6], as last amended by Commission Decision 94/953/EC [7], since 1993 scrapie must be an officially notifiable disease in all Member States;

(4) Whereas the Scientific Veterinary Committee has stated on the basis of its risk assessment that several Member States including the United Kingdom have reported scrapie in native-born sheep, that the presence of scrapie cannot be excluded in any Member State where sheep are present and that only a thorough epidemiological investigation conducted to common standards will give the necessary information about the scrapie status of each country;

(5) Whereas inspections were carried out in Member States in 1996 and 1997 to check the implementation of Community measures on BSE; whereas the results of those inspections have revealed certain deficiencies, in particular in surveillance and implementation of the prohibition on use of mammalian protein in ruminant feed;

(6) Whereas in view of previous trade in certain products, in particular meat and bone meal and live animals, the possible presence of transmissible spongiform encephalopathy (TSE) agents cannot be

(1) OJ L 395, 30. 12. 1989, p. 13.
(2) OJ L 62, 15. 3. 1993, p. 49.
(3) OJ L 224, 18. 8. 1990, p. 29.
(4) OJ L 378, 31. 12. 1982, p. 58.
(5) OJ L 4, 8. 1. 1998, p. 63.
(6) OJ L 46, 19. 2. 1991, p. 19.
(7) OJ L 371, 31. 12. 1994, p. 14.

▼B

ruled out in any of the Member States, subject to further scientific evaluation;

(7) Whereas the World Organisation for Animal Health (Office International des Epizooties (OIE)) in its international animal health code on bovine spongiform encephalopathy of May 1997 has recommended minimum requirements for effective surveillance; whereas the OIE has adopted guidelines for continuous surveillance and monitoring of bovine spongiform encephalopathy in its Code of January 1997;

(8) Whereas the Scientific Veterinary Committee in its report on surveillance of transmissible spongiform encephalopathies of 11 June 1997 has laid down guidelines taking account of the recommendations of the OIE;

(9) Whereas the measures provided for in this Decision are in accordance with that opinion and represent a harmonised approach towards effective TSE surveillance in the Member States; whereas more detailed rules will be laid down in Council legislation based on Article 100a of the Treaty;

(10) Whereas the measures provided for in this Decision will be applied in conjunction with Commission Decision 97/534/EC of 30 July 1997 on the prohibition of the use of material presenting risks as regards transmissible spongiform encephalopathies [1], as last amended by Council Decision 98/248/EC [2];

(11) Whereas investigation requirements for ante-mortem inspection in slaughterhouses of bovine animals were laid down in Commission Decision 94/474/EC [3], as last amended by Council Decision 98/256/EC [4]; whereas those requirements are now set out in this Decision; whereas, therefore, the corresponding provisions of Decision 94/474/EEC should be deleted;

(12) Whereas the measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,

HAS ADOPTED THIS DECISION:

Article 1

Member States shall ensure that staff of the competent authority, of diagnostic laboratories and colleges of agriculture and veterinary medicine, official veterinarians, veterinary practitioners, slaughterhouse personnel and animal breeders, keepers and handler have the knowledge of the clinical signs, epidemiology and, as appropriate, laboratory findings relating to TSEs.

Article 2

1. Member States shall ensure that it is compulsory for the suspected presence of any TSE in any animal to be notified immediately to the competent veterinary authority.

2. BSE shall be suspected in bovine animals aged over 20 months displaying behavioural or neurological signs where the disease cannot be ruled out either on the basis of response treatment or following laboratory examination.

3. Scrapie shall be suspected in ovine and caprine animals aged over 12 months displaying behavioural or neurological signs where the disease cannot be ruled out either on the basis of response to treatment or following laboratory examination.

Article 3

1. Any animal which shows clinical signs giving rise to the suspicion of a TSE shall be placed under official movement restrictions pending the outcome of a clinical and epidemiological investigation by the competent authority.

[1] OJ L 216, 8. 8. 1997, p. 95.
[2] OJ L 102, 2. 4. 1998, p. 26.
[3] OJ L 194, 29. 7. 1994, p. 96.
[4] OJ L 113, 15. 4. 1998, p. 32.

▼B

2. Where the competent authority decides that the possibility of infection with a TSE cannot be ruled out, the animal shall be killed and its brain and such other tissues as the competent authority may determine shall be removed and sent to an approved laboratory for testing for the presence of TSE using the methods set out in Article 5. ►M1 All parts of the body of the suspect animal, including the hide, shall be retained under official supervision until a negative diagnosis has been made or until it has been destroyed by incineration or, under exceptional circumstances, burned or buried in strict compliance with the conditions laid down in Article 3(2) of Council Directive 90/667/EEC ([1]). ◄

Article 4

1. In order to give early warning of the emergence or occurrence of BSE or scrapie, each Member State shall carry out an annual programme of monitoring in accordance with the conditions laid down in ►M1 Annex I ◄.

▼M1

2. Member States shall submit an annual report to the Commission covering at least the information referred to in Annex II, part A. The report for each calendar year shall be submitted at the latest by 31 March of the following year. The Commission shall present a summary of the country reports for each period covering at least the information referred to in Annex II, part B, to the Standing Veterinary Committee within three months of the receipt of the country reports.

3. Member States shall ensure that all official investigations and laboratory examinations are recorded in accordance with Annex III.

Article 5

1. Sampling and laboratory testing for the presence of BSE in bovine animals shall be carried out using the methods and protocols laid down in Annex IV. Sampling and laboratory testing for the presence of scrapie in sheep shall be carried out using the methods and protocols laid down in the Manual of Standards for Diagnostic Tests and Vaccines of the World Organisation for Animal Health (Office international des épizooties), May 1999 edition.

2. The national reference laboratory in each Member State, as set out in Annex V, shall ensure coordination of diagnostic methods and protocols between the laboratories approved for testing for the presence of TSEs and regularly verify the use of those diagnostic methods and protocols.

▼B

Article 6

Community inspections may be carried out, in particular where the annual report is not submitted in accordance with Article 4(2).

Article 7

Article 2 of Decision 94/474/EC is hereby deleted.

Article 8

This Decision shall apply from 1 May 1998.

▼M1

Article 8a

Without prejudice to Article 4(2), Member States shall submit a report covering January-June 2001 including at least the information referred to in Annex II, part A, to the Commission by 1 October 2001, at the latest.

The provisions of Annex I and II shall be reviewed every six months in the light of the results of the monitoring and experience gained in implementing the programme. The provisions of Annex IV shall be reviewed in the light of the development of the Manual of Standards for Diagnostic Tests and Vaccines of the World Organisation for Animal Health (Office international des épizooties). The provisions of Annex IV A shall be reviewed in the light of further evaluation of diagnostic methods.

([1]) OJ L 363, 27.12.1990, p. 51.

▼B

Article 9

This Decision is addressed to the Member States.

▼M1

ANNEX I

▼M2

A. MINIMUM REQUIREMENTS FOR A PROGRAMME FOR MONITORING BSE IN BOVINE ANIMALS

1. Selection of sub-populations

Dead bovine animals over 30 months of age not slaughtered for human consumption (excluding animals referred to in Commission Regulation (EC) No 716/96).

2. Sample size

The number of samples tested annually in each Member State from the subpopulation referred to in point 1 shall not be less than the sample sizes indicated in the table. The selection of samples shall be random. The sampling shall be representative for each region and continuous.

Total population over 30 months (1)	Sample size (2)
100 000	950
200 000	1 550
300 000	1 890
400 000	2 110
500 000	2 250
600 000	2 360
700 000	2 440
800 000	2 500
900 000	2 550
1 000 000	2 590
1 500 000	3 000
2 000 000	3 500
2 500 000	4 000
3 000 000	4 500
3 500 000	5 000
4 000 000	5 500
4 500 000	6 000
5 000 000	6 500
5 500 000	7 000
6 000 000	7 500
6 500 000	8 000
7 000 000	8 500
7 500 000	9 000
8 000 000	9 500
8 500 000	10 000
9 000 000	10 500
9 500 000	11 000
10 000 000	11 500
10 500 000	12 000
11 000 000	12 500
11 500 000	13 000

▼M2

Total population over 30 months (1)	Sample size (2)
12 000 000	13 500

(1) Where the size of the total population over 30 months of age is not known, the population over 24 months of age shall be used instead.

(2) The sample size has been calculated to detect a prevalence of 0,1 % with a 95 % confidence in the sub-population referred to in point 1, based on the assumption that the proportion of this sub-population in the total population of bovine animals over 30 months of age is 1 %. Where the size of the total population of bovine animals over 30 months of age is 1 500 000 animals or more, the sample size has been increased by 500 samples per 500 000 animals as a proportionality adjustment, to take account of the larger likelihood of variation in risk for BSE within the population.

▼M1

B. MINIMAL REQUIREMENTS FOR A PROGRAMME FOR MONITORING SCRAPIE IN OVINE AND CAPRINE ANIMALS

1. Selection of sub-populations

Selection must be by means of a risk assessment of sub-populations of native-born animals displaying clinical signs compatible with scrapie. Within each sub-population and age group, selection must be random.

The following shall be the criteria for the selection:

— animals displaying behavioural or neurological signs lasting for at least 15 days and resistant to treatment,

— moribund animals without signs of infectious or traumatic illness,

— animals displaying other progressive disease conditions.

2. Age of targeted animals

The sample must target the oldest animals in the sub-population. However, all targeted animals must be over 12 months of age.

3. Sample size

The minimum number of animals to be examined on an annual basis must comply with the sample sizes referred to in the table. Animals examined in accordance with Article 3 may be included within the minimum sample size.

Table

Minimum number of annual neurohistological investigations of animals showing clinical signs compatible with scrapie

Total population over 12 months (1)	Sample size
100 000	10
300 000	30
500 000	50
700 000	69
1 000 000	99
2 500 000	195
5 000 000	300
7 000 000	336
10 000 000	367
20 000 000	409
30 000 000	425
40 000 000	433

(1) Where the size of the total population over 12 months of age is not known, the sample size shall be based on the total population over six months of age.

▼M1

C. MONITORING IN HIGHER RISK ANIMALS

Monitoring in higher risk animals

In addition to the monitoring programmes set out in parts A and B, Member States may on a voluntary basis carry out targeted surveillance for TSEs in higher risk animals, such as:

— animals originating from countries with indigenous TSE,

— animals which have consumed potentially contaminated feedingstuffs,

— animals born or derived from TSE infected dams.

D. COMMON PROVISIONS

Member States shall ensure that no parts of the body of animals sampled pursuant to this Annex are used for human food, animal feed, fertilisers, cosmetic or medicinal products or medical devices until the laboratory examination has been concluded with negative results.

▼M2

ANNEX II

A. INFORMATION TO BE PRESENTED IN THE REPORT BY MEMBER STATES

1. The number of suspected cases per animal species placed under movement restrictions in accordance with Article 3(1).
2. The number of suspected cases per animal species subject to laboratory examination in accordance with Article 3(2) and the outcome of the examination.
3. The estimated size of the sub-population referred to in Annex I(A)(1).
4. The number of bovine animals tested within each sub-population as referred to in Annex I(A)(1), Annex I(C) and Article 1 to Decision 200/764/EC, method for sample selection and the outcome of the tests.
5. The number of ovine and caprine animals examined within each sub-population as referred to in Annex I(B)(1) and Annex I(C) and the outcome of the examination.
6. Number, age distribution and geographical distribution of positive cases of BSE and scrapie. The year and, where possible, month of birth should be given for BSE cases born after the introduction of a feed ban.
7. Positive TSE cases confirmed in animals other than bovine, ovine, and caprine animals.

B. INFORMATION TO BE PRESENTED IN THE SUMMARY BY THE COMMISSION

The summary shall be presented in a tabled format covering at least the information referred to in part A for each Member State.

▼M1

ANNEX III

RECORDS

1. The competent authority shall keep records of

   — the number and types of animals placed under movement restrictions as referred to in Article 3(1),

   — the number and outcome of clinical and epidemiological investigations as referred to in Article 3(1),

   — the number and outcome laboratory examinations as referred to in Article 3(2),

   — the number, identity and origin of animals sampled in the framework of the monitoring programmes as referred to in Annex I and, where possible, age, breed and anamnestic information.

   The records shall be kept for seven years.

2. The investigating laboratory shall keep all records of testing, in particular laboratory workbooks, paraffin blocks and, where appropriate, photographs of Western blots.

   The records shall be kept for seven years.

▼M3

ANNEX IV

SAMPLING AND LABORATORY TESTING FOR THE PRESENCE OF BSE IN BOVINE ANIMALS

1. **Collection of samples**

The competent authority shall ensure that samples ae collected using the methods and protocols laid down in the Manual of standards for diagnostic tests and vaccines of the World Organisation for Animal Health (Office International des Epizooties), latest edition. In the absence of such methods and protocols, the competent authority shall ensure that the samples are collected in a manner appropriate for the correct application of tests.

The competent authority shall ensure that samples are correctly marked as to the identity of the sampled animal.

2. **Laboratory testing**

2.1. *Suspect cases*

Tissues from bovine animals sent for laboratory testing pursuant to the provisions of Article 3(2) shall be subject to a histopathology examination as laid down in the Manual of standards for diagnostic tests and vaccines of the World Organisation for Animal Health (Office International des Epiziooties), latest edition, except where the material is autolysed. Where the result of the histopathology examination is inconclusive or negative or where the material autolysed, the tissues shall be subjected to an examination by one of the other diagnostic methods laid down in the above Manual (immunocytochemistry, immuno-blotting or demonstration of characteristic fibrils by electron microscopy).

2.2. *Animals examined in the framework of the annual monitoring programme or subject to routine examination at slaughter*

Bovine animals examined in the framework of the annual monitoring programme as laid down in Annex I(A), the targeted surveillance programme as laid down in Annex I(C) or examined in accordance with Article 1 of Decision 2000/764/EC shall be examined in an approved laboratory by one of the tests listed in Annex IVA.

Where the result of the monitoring test is inconclusive or positive, the tissues shall immediately be subject to confirmatory examinations in an official laboratory. The confirmatory examination shall start by a hystopathology examination of the brainstem as laid down in the Manual of standards for diagnostic tests and vaccines of the World Organisation for Animal Health (Office International des Epizooties), latest edition, except where the material is autolysed or otherwise not suitable for examination by histopathology. Where the result of the histopathology examination is inconclusive or negative or where the material is autolysed, the tissues shall be subjected to an examination by one of the other diagnostic methods mentioned in point 2.1, however, the method must not be the same as the method used in the monitoring test.

3. **Interpretation of results**

An animal examined as referred to in point 2.1 shall be regarded a positive BSE case, if the result of one of the tests is positive.

An animal examined as referred to in point 2.2 shall be regarded as a positive BSE case if the result of the monitoring test is positive or inconclusive, and

— the result of the subsequent histopathology examination is positive, or

— the result of another diagnostic method mentioned in point 2.1. is positive.

4. **Reporting of results**

All positive BSE cases shall immediately be reported to the competent authority. The competent authority shall notify positive BSE cases in accordance with Directive 82/894/EEC [1].

(1) OJ L 378, 31.12.1982, p. 58.

▼**M3**

ANNEX IVA

1. Immunoblotting test based on a western blotting procedure for the detection of the protease-resistant fragment PrP^{Res} (prionics check test).
2. Chemiluminiscent ELISA involving an extraction procedure and an ELISA technique, using an enhanced chemiluminiscent reagent (Enfer test).
3. Sandwich immunoassay for PrP^{Res} carried out following denaturation and concentration steps (Bio-Rad).

▼M1

ANNEX V

NATIONAL REFERENCE LABORATORIES

The national reference laboratories are:

Austria:	Bundesanstalt für Tierseuchenbekämpfung, Mödling Robert-Koch-Gasse 17 A-2340 Mödling
Belgium:	CERVA-CODA-VAR Centre d'étude et de recherches vétérinaires et agrochimiques Centrum voor Onderzoek in Diergeneeskunde en Agrochemie Veterinary and Agrochemical Research Centre Groeselenberg 99 B-1180 Bruxelles
Denmark:	Statens Veterinære Serumlaboratorium Bülowsvej 27 DK-1790 København V
Finland:	Eläinlääkintä- ja elintarvikelaitos Hämeentie 57 FIN-00550 Helsinki
France:	Agence française de sécurité sanitaire des aliments Laboratoire de pathologie bovine 31, avenue Tony Garnier BP 7033 F-69342 Lyon Cédex
Germany:	Bundesforschungsanstalt für Viruskrankheiten der Tiere Anstaltsteil Tübingen Postfach 1149 D-72001 Tübingen
Greece:	1. Department of Pathology, Faculty of Veterinary Medicine University of Thessaloniki Giannitson & Voutyra St. GR-54627 Thessaloniki 2. Athens Centre of Veterinary Institutes Laboratory of Pathology 25 Neapoleos St. GR-14310 Athens
Ireland:	The Central Veterinary Research Laboratory Abbotstown Castleknock Dublin 15 Ireland
Italy:	Istituto Zooprofilattico Sperimentale del Piemonte, Liguria e Valle D'Aosta CEA Via Bologna I-148-10150 Torino
Luxembourg:	CERVA-CODA-VAR Centre d'étude et de recherches vétérinaires et agrochimiques Centrum voor Onderzoek in Diergeneeskunde en Agrochemie Veterinary and Agrochemical Research Centre Groeselenberg 99 B-1180 Bruxelles
Netherlands:	Instituut voor Dierhouderij en Diergezondheid, ID-Lelystad Edelhertweg 15 Postbus 65 8200 AB Lelystad Nederland

▼**M1**

Portugal:	Laboratório Nacional de Investigação Veterinária Estrada de Benfica, 701 P-1500 Lisboa
Spain:	Veterinary School Laboratory Animal Pathology Department Pathological Anatomy E-Zaragoza ►**M3** Laboratorio Central de Veterinaria de Algete Madrid Spain (only BSE tests as referred to in Annex IVA) ◄
Sweden:	The National Veterinary Institute S-751 89 Uppsala
United Kingdom:	The Veterinary Laboratories Agency Woodham Lane New Haw Addlestone Surrey KT15 3NB United Kingdom