

COMMISSION DECISION
of 5 June 2000
amending Decision 98/272/EC on epidemio-surveillance for transmissible spongiform encephalopathies

(notified under document number C(2000) 1144)

(Text with EEA relevance)

(2000/374/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,

Whereas:

- (1) Commission Decision 98/272/EC of 23 April 1998 on epidemio-surveillance for transmissible spongiform encephalopathies ⁽⁴⁾ lays down the rules for measures to be taken by Member States where a transmissible spongiform encephalopathy (TSE) is suspected in an animal, the minimum requirements for the monitoring of bovine spongiform encephalopathy (BSE) and scrapie and the rules for sampling and laboratory testing for the presence of a TSE.
- (2) It is necessary to further clarify the measures in relation to animals killed following a suspicion of a TSE.
- (3) A report of the evaluation of tests for the diagnosis of TSE in bovines was published by the Commission on 8 July 1999 and three tests were found to have an excellent sensitivity and an excellent specificity in detecting TSE in animals in the clinical stage of the disease.
- (4) The use of the test in monitoring for BSE in bovine animals could significantly improve the efficacy of the monitoring, in particular if targeted on fallen stock and emergency slaughtered animals, as demonstrated in a monitoring programme carried out in Switzerland.
- (5) The monitoring programme should be reviewed on a regular basis in the light of the results and experience gained in implementing the programme, therefore it is necessary to amend the rules on reporting and records

and to introduce an additional report covering the first six months.

- (6) The rules for laboratory testing for the diagnosis of BSE in bovine animals should be revised in the light of the recommendations of the Manual of Standards for Diagnostic Tests and Vaccines of the World Organisation for Animal Health (Office international des épizooties) and the evaluation of the tests.
- (7) It is necessary to list the national reference laboratories for TSEs.
- (8) The measures provided for in this Decision are in accordance with the opinion of the Standing Veterinary Committee,

HAS ADOPTED THIS DECISION:

Article 1

Decision 98/272/EC is amended as follows:

1. The last sentence in Article 3(2) is replaced by the following:

‘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 (*).

(* OJ L 363, 27.12.1990, p. 51.’

2. In Article 4, paragraph 1, the word ‘Annex’ is replaced by ‘Annex I’.
3. In Article 4, paragraph 2 is replaced by the following:

‘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.’

⁽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 122, 24.4.1998, p. 59.

4. In Article 4, the following paragraph 3 is added:

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

5. Article 5 is replaced by the following:

'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.'

6. The following Article 8a is added:

'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.'

7. The Annex is replaced by the Annex to the present Decision.

Article 2

This Decision shall apply from 1 January 2001.

Article 3

This Decision is addressed to the Member States.

Done at Brussels, 5 June 2000.

For the Commission

David BYRNE

Member of the Commission

ANNEX

'ANNEX I

A. MINIMAL REQUIREMENTS FOR A PROGRAMME FOR MONITORING BSE IN BOVINE ANIMALS**1. Selection of sub-populations**

Bovine animals over 24 months of age as follows:

- 1.1. Animals subject to "special emergency slaughtering"; as defined in Article 2(n) and animals slaughtered in accordance with Annex I, Chapter VI, point 28(c) of Council Directive 64/433/EEC ⁽¹⁾ (including animals referred to in Commission Regulation (EC) No 716/96 of 19 April 1996 adopting exceptional support measures for the beef market in the United Kingdom ⁽²⁾), and subject to "special emergency slaughtering" as defined in Article 2(n) or slaughtered in accordance with Annex I, Chapter VI, point 28(c) of Directive 64/433/EEC.
- 1.2. Dead animals not slaughtered for human consumption (excluding animals referred to in Regulation (EC) No 716/96).

2. Sample size

The combined number of samples tested annually in each Member State from the sub-populations referred to in point 1.1 and 1.2 shall not be less than the sample sizes indicated in the table. As many as possible, but in any case at least 10 % of the samples must be collected from the sub-population referred to in point 1.2. The selection of samples within each sub-population shall be random. The sampling shall be representative for each region and continuous. Member States may however decide to sample only the sub-population referred to in point 1.1 in remote areas where the animal density is low.

Total population over 24 months	Sample size ⁽¹⁾	Total population over 24 months	Sample size ⁽¹⁾
100 000	950	4 500 000	6 000
200 000	1 550	5 000 000	6 500
300 000	1 890	5 500 000	7 000
400 000	2 110	6 000 000	7 500
500 000	2 250	6 500 000	8 000
600 000	2 360	7 000 000	8 500
700 000	2 440	7 500 000	9 000
800 000	2 500	8 000 000	9 500
900 000	2 550	8 500 000	10 000
1 000 000	2 590	9 000 000	10 500
1 500 000	3 000	9 500 000	11 000
2 000 000	3 500	10 000 000	11 500
2 500 000	4 000	10 500 000	12 000
3 000 000	4 500	11 000 000	12 500
3 500 000	5 000	11 500 000	13 000
4 000 000	5 500	12 000 000	13 500

⁽¹⁾ The sample size has been calculated to detect a prevalence of 0,1 % with a 95 % confidence in the sub-populations referred to in point 1, based on the assumption that the proportion of these sub-populations in the total population of bovine animals over 24 months of age is 1 %. Where the size of the total population of bovine animals over 24 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.

⁽¹⁾ OJ L 21, 29.7.1964, p. 2012/64.

⁽²⁾ OJ L 99, 20.4.1996, p. 14.

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.

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.

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 each 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) and Annex I(C), 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 following information for each Member State:

1. the total population of bovine animals over 24 months of age and the estimated size of each sub-population referred to in Annex I(A)(1);
2. the number of suspected cases as referred to in part A(1) and (2), per animal species;
3. the number of bovine animals tested as referred to in part A(4);
4. the number of ovine and caprine animals examined as referred to in part A(5);
5. the number and age distribution of positive BSE cases;
6. positive BSE cases born after the introduction of a feed ban and the year and month of birth;
7. positive cases of scrapie;
8. positive TSE cases in animals other than bovine, ovine and caprine animals.

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.

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 are 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 épizooties), May 1999 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.

2. Laboratory testing**2.1. Suspect cases**

Tissues from bovine animals sent for laboratory testing following 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 épizooties), May 1999 edition, except where the material is autolysed. 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 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

Bovine animals examined in the framework of the annual monitoring programme as laid down in Annex I(A) and the targeted surveillance programme as laid down in Annex I(C) shall be examined by one of the tests listed in Annex IV(A).

Where the result of the monitoring test is inconclusive or positive, the tissues shall be subject to a histopathology 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 épizooties), May 1999 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.

ANNEX IV A

1. Immunoblotting test based on a Western blotting procedure for the detection of the protease-resistant fragment Pr^{Pr^{Res}} (Prionics check test).
2. Chemiluminescent ELISA involving an extraction procedure and an ELISA technique, using an enhanced chemiluminescent reagent (Enfer test).
3. Sandwich immunoassay for Pr^{Pr^{Res}} carried out following denaturation and concentration steps (CEA test).

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
Bilowsvej 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
- Portugal: Laboratório Nacional de Investigação Veterinária
Estrada de Benfica, 701
P-1500 Lisboa

Spain: Veterinary School Laboratory
Animal Pathology Department
Pathological Anatomy
E-Zaragoza

Sweden: The National Veterinary Institute
S-751 89 Uppsala

United Kingdom: The Veterinary Laboratories Agency
Woodham Lane
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Surrey KT15 3NB
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