II

(Acts whose publication is not obligatory)

COMMISSION

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

[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.

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 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 antemortem 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.

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. The carcase and remaining internal organs of the animal shall be retained under official supervision until a diagnosis has been made or until it has been destroyed in accordance with Article 4 of Decision 97/534/EC.

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 the Annex.

2. Member States shall inform the Commission and the Member States, within the Standing Veterinary Committee, of the results obtained from the monitoring programme and of the emergence of TSEs other than BSE or scrapie. The information shall be presented by way of an annual report, submitted to the Commission within three months after the end of each year. It shall at least cover the information referred to in the Annex.

Article 5

1. Sampling and laboratory testing for the presence of a TSE 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 Epizooties), May 1997 edition. The tests performed shall at least comprise histopathology examination of brain tissue. The competent authority may also require the use of other laboratory tests such as immunocytochemic and immunodiagnostic tests for the detection of scrapie associated fibrils (SAFs), where their use is considered appropriate.

2. The competent authority shall ensure coordination of diagnostic methods and protocols between the laboratories approved for testing for the presence of TSEs and verify the use of those diagnostic methods and protocols.

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.

Article 9

This Decision is addressed to the Member States.

Done at Brussels, 23 April 1998.

For the Commission

Franz FISCHLER

Member of the Commission

ANNEX

A. MINIMAL REQUIREMENTS FOR A PROGRAMME FOR MONITORING BSE AND SCRAPIE

Selection of subpopulations

Selection must be by means of a risk assessment of subpopulations of native-born animals displaying clinical signs compatible with TSEs and, in a decreasing order of relevance, of higher-risk animals. Within each subpopulation and age group, selection must be random.

1. The following shall be the criteria for the selection of *native-born animals displaying clinical signs compatible with TSEs:*
   - — 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. The following risks must be taken into account for the selection of *higher risk animals:*
   - — animals originating from countries with indigenous TSE,
   - — animals which have consumed potentially contaminated feedstuffs,
   - — animals born or derived from TSE infected dams, and/or sires.

Animal species and type of TSE

1. Bovine animals must be examined for the presence of BSE.
2. Ovine and caprine animals must be examined for the presence of scrapie.

Age of the targeted animals

The sample must target the oldest animals in the subpopulation. However, all targeted bovine animals must be over 20 months of age and all targeted ovine and caprine animals must be over 12 months of age. Targeted bovine animals displaying progressive disease conditions without showing neurological signs must be over 4 years of age.

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 for animals in subpopulations of native-born animals displaying clinical signs compatible with TSEs. Animals in which infection with a TSE cannot be ruled out and as such have to be examined in accordance with Article 3 may be included within the minimum sample size. Samples from the subpopulations of higher-risk animals must be collected at the time when the animals are slaughtered or killed.

Table

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

Native-born cattle population 20 months of age or older or native-born ovine and caprine population 12 months of age or older	Minimum number of brains to be examined
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

B. ANNUAL REPORT

The annual report must contain data on:

1. the total number of animals and age structure examined within the different groups of the respective populations of bovine, ovine and caprine animals categorised according to epidemiological criteria;
2. the overall mortality and mortality due to neurological diseases per animal species;
3. records of the competent authority on the number and types of animals or carcases placed under movement restrictions in accordance with Article 3;
4. the number and outcome of the clinical and epidemiological investigations carried out in accordance with Article 3; these records must be kept for seven years;
5. TSEs in animals other than bovine, ovine and caprine animals;
6. training with respect to knowledge referred to in Article 1.