COMMISSION DECISION

of 29 December 2000

amending Decision 2000/764/EC on the testing of bovine animals for the presence of bovine spongiform encephalopathy and updating Annex IV of Decision 98/272/EC on epidemio-surveillance for transmissible spongiform encephalopathies

(notified under document number C(2000) 4411)

(Text with EEA relevance)

(2001/8/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 2000/764/EC of 29 November 2000 on the testing of bovine animals for the presence of bovine spongiform encephalopathy [4], lays down reinforced rules for the testing of bovine animals entering the food chain.

(2) Commission Decision 98/272/EC of 23 April 1998 on epidemio-surveillance for transmissible spongiform encephalopathies [5], as last amended by Decision 2000/764/EC, lays down the methods and protocols to be followed when examining bovine animals for the presence of bovine spongiform encephalopathy (BSE).

(3) Commission Regulation (EC) No 2777/2000 of 18 December 2000 adopting exceptional support measures for the beef market [6] provides for a scheme where bovine animals over 30 months of age can be purchased for destruction instead of being slaughtered for human consumption. It is necessary to clarify that the obligation to examine certain groups of animals at risk applies where such animals are purchased for destruction.

(4) It is appropriate to clarify the rules on the health marking of carcases from animals having been examined for BSE.

(5) The Council has invited the Commission to specify the modalities under which laboratory testing for bovine spongiform encephalopathy (BSE) shall be carried out and the methods by which the testing shall be controlled by competent authorities and monitored by the Commission.

(6) Decision 2000/764/EC and Decision 98/272/EC need to be amended accordingly.

(7) 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 2000/764/EC is amended as follows:

1. Article 1(1) is replaced by the following:

'1. Member States shall ensure that all bovine animals over 30 months of age:

— subject to "special emergency slaughtering" as defined in Article 2(n) of Council Directive 64/433/EEC (*), or

— slaughtered in accordance with Annex I, Chapter VI, point 28(c) to Directive 64/433/EEC

are examined by one of the approved rapid tests listed in Annex IVA to decision 98/272/EC as of 1 January 2001.

The provisions of this paragraph shall also apply to animals, as referred to in the first subparagraph, which are purchased for destruction in accordance with Regulation (EC) No 2777/2000.

(*) OJ 121, 29.7.1964, p. 2012/64.'

2. Article 2 is replaced by the following:

'Article 2

All parts of the body, including the hide, of animals examined in accordance with Article 1 shall be retained under official supervision until a negative test result has been obtained or until it has been destroyed by incineration or, under exceptional circumstances, burned or

[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 305, 6.12.2000, p. 35.
[5] OJ L 122, 24.4.1998, p. 59.
[6] OJ L 321, 19.12.2000, p. 47.

buried in strict compliance with the conditions laid down in Article 3(2) of Council Directive 90/667/EEC (**). Where an animal slaughtered for human consumption is examined, the health marking provided for in Chapter XI of Annex I to Directive 64/433/EC shall not be carried out on the carcase of that animal until a negative test result has been obtained, unless an official system is in place ensuring that no parts of examined animals leave the slaughterhouse before a negative test result has been obtained except when they are sent under official supervision for destruction by incineration.

(**) OJ L 363, 27.12.1990, p. 51.'

3. Article 3 is replaced by the following:

'*Article 3*

1. Member States shall ensure that any sampling for BSE in bovine animals is carried out in accordnce with Annex IV(1) to Decision 98/272/EC, as amended by the present Decision.

2. Member States shall ensure that any laboratory testing for BSE in bovine animals is carried out in laboratories approved for that purpose and using the methods and protocols laid down in Annex IV(2) and (3) to Decision 98/272/EC, as amended by the present Decision.

3. The national reference laboratory in each Member State, as set out in Annex V to Decision 98/272/EC, shall ensure coordination of diagnostic methods and protocols between laboratories approved for carrying out laboratory testing for BSE in bovine animals, regularly verify the correct use of those diagnostic methods and protocols, and, as appropriate, organise periodical comparative tests.

4. The Commission shall monitor the sampling and laboratory testing for BSE in bovine animals carried out in the Member States by regular inspections on the spot in accordance with Commission Decision 98/139/EC (***) and by organising a comparative test for the national reference laboratories.

(***) OJ L 38, 12.2.1998, p. 10.'

Article 2

Decision 98/272/EC is amended as follows:

1. Annex IV is replaced by the text in the Annex to this Decision.

2. In Annex V, the following national reference laboratory is added for Spain:

'Laboratorio Central de Veterinaria de Algete
Madrid
Spain
(only BSE tests as referred to in Annex IVA)'.

Article 3

This Decision shall apply from 1 January 2001.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 29 December 2000.

For the Commission

David BYRNE

Member of the Commission

ANNEX

'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.

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).'