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COMMISSION DECISION

of 4 March 2004

approving tests for the detection of antibodies against bovine brucellosis within the framework of Council Directive 64/432/EEC

(notified under document number C(2004) 654)

(Text with EEA relevance)

(2004/226/EC)

(OJ L 68, 6.3.2004, p. 36)

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(Text with EEA relevance)

(2004/226/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 64/432/EEC of 26 June 1964 on health problems affecting intra-Community trade in bovine animals and swine ([1]), and in particular Article 6(2)(b) thereof,

Whereas:

(1) Commission Decision 2000/330/EC of 18 April 2000 approving tests for the detection of antibodies against bovine brucellosis within the framework of Council Directive 64/432/EEC ([2]) has been substantially amended ([3]). In the interests of clarity and rationality the said Decision should be codified.

(2) Bovine animals intended for intra-Community trade must, with regard to bovine brucellosis, come from a holding officially free of bovine brucellosis and, in addition, be tested within 30 days of dispatch by use of either a serum-agglutination test or any other test approved by the Standing Committee on the Food Chain and Animal Health procedure following the adoption of the relevant protocols.

(3) In accordance with Article 16 of Directive 64/432/EEC, the Commission, in accordance with the procedures of Article 17 and on the basis of the opinion of the Scientific Committee on Veterinary Measures relating to Public Health, is to update and if necessary amend Annexes B, C and D (Chapter II) to adapt them to scientific developments.

(4) The Commission has received the final report of the Scientific Committee on Animal Health and Animal Welfare on the modification of the technical Annexes to Directive 64/432/EEC to take account of scientific developments regarding tuberculosis, brucellosis and enzootic bovine leucosis ([4]).

(5) In that report the Scientific Committee recommended the preferential use of ELISA tests, the complement fixation test and the buffered brucella antigen tests for the detection of antibodies against bovine brucellosis, carried out, *inter alia*, on samples of blood taken from individual bovine animals. The recommended procedures are in line with the internationally recognised standards set out by the Manual of standards for diagnostic tests and vaccines, third edition, 1996, of the Office International des Epizooties (OIE).

(6) In August 2001 the OIE published the fourth edition 2000 of the said manual, including certain modifications in the description of tests for brucellosis.

([1]) OJ 121, 29.7.1964, p. 1977/64. Directive as last amended by Regulation (EC) No 21/2004 (OJ L 5, 9.1.2004, p. 8).
([2]) OJ L 114, 13.5.2000, p. 37. Decision as amended by Regulation (EC) No 535/2002 (OJ L 80, 23.3.2002, p. 22).
([3]) See Annex I.
([4]) Doc. SANCO/B3/R10/1999.

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(7) It was therefore necessary to amend Annex C to Directive 64/432/EEC so as to lay down test procedures applicable for surveillance and trade purposes within the Community which reflect as much as possible the OIE standards but take also into account the advice of the Scientific Committee and of the national reference laboratories in the Member States cooperating within the framework of the European Union network of national reference laboratories for brucellosis.

(8) It appears appropriate to recognise for certification purposes the brucellosis test results produced by use of ELISA tests, the complement fixation test and the buffered brucella antigen tests, if the tests were carried out in accordance with the approved protocols on samples of blood taken from individually identified bovine animals within the 30 days prior to certification of the tested animals for intra-Community trade.

(9) Therefore, pending the update of the technical Annex D (Chapter II) in accordance with Article 16 of Directive 64/432/EEC, the ELISA tests, as specified in the report of the Scientific Committee, and the complement fixation test and the buffered brucella antigen tests, as specified in Annex C to that Directive, should be approved for brucellosis testing for certification purposes as provided for in Article 6(2)(b) and the animal health certificate in Annex F, model 1.

(10) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

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Article 1

The complement fixation test, the buffered *Brucella* antigen test (rose Bengal test (RBT)), the ELISA tests and the fluorescence polarisation assay (FPA) carried out in accordance with Annex C to Directive 64/432/EEC are hereby approved for certification purposes.

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Article 2

Where, for the purposes referred to in Article 6(2)(b) of Directive 64/432/EEC, a test referred to in Article 1 of this Decision is used, the test shall be specified in the column ‘Test’ of the tables in point 3, second indent, and in point 5 of Section A in Annex F, Model 1 (health certificate) to Directive 64/432/EEC.

Article 3

Decision 2000/330/EC is repealed.

References to the repealed Decision shall be construed as references to this Decision and shall be read in accordance with the correlation table in Annex II.

Article 4

This Decision is addressed to the Member States.

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ANNEX I

Repealed Decision with its amendment

Commission Decision 2000/330/EC	(OJ L 114, 13.5.2000, p. 37)
Commission Regulation (EC) No 535/2002 (Article 2 only)	(OJ L 80, 23.3.2002, p. 22)

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ANNEX II

Correlation Table

Decision 2000/330/EC	This Decision
Articles 1 and 2	Articles 1 and 2
—	Article 3
Article 3	Article 4
—	Annex I
—	Annex II