[F1[F2[F3ANNEX C

BRUCELLOSIS

Textual Amendments

F1 Substituted by Council Directive 97/12/EC of 17 March 1997 amending and updating Directive 64/432/EEC on health problems affecting intra-Community trade in bovine animals and swine.

F2 Substituted by Commission Regulation (EC) No 535/2002 of 21 March 2002 amending Annex C to Council Directive 64/432/EEC and amending Decision 2000/330/EC.

F3 Substituted by Commission Decision of 10 December 2008 amending Annex C to Council Directive 64/432/EEC and Decision 2004/226/EC as regards diagnostic tests for bovine brucellosis (notified under document number C(2008) 7642) (Text with EEA relevance) (2008/984/EC).

3. COMPLEMENTARY TESTS

3.1. Brucellosis skin test (BST)

3.1.1. Conditions for the use of BST

(a) The brucellosis skin test shall not be used for the purpose of certification for intra-Community trade.

(b) The brucellosis skin test is one of the most specific tests for the detection of brucellosis in unvaccinated animals; however diagnosis must not be made on the basis of positive intradermal reactions alone.

(c) Bovine animals, tested with negative result in one of the serological tests defined in this Annex and reacting positively to the BST shall be regarded as infected or suspected to be infected.

(d) Bovine animals, tested with positive result in one of the serological tests defined in this Annex may be subject to a BST in order to support the interpretation of the serological test results; in particular where in officially brucellosis-free or brucellosis-free bovine herds a cross-reaction with antibodies against other bacteria cannot be excluded.

3.1.2. The test must be carried out by use of a standardised and defined brucellosis allergen preparation that does not contain smooth lipopolysaccharide (LPS) antigen, as this may provoke non-specific inflammatory reactions or interfere with subsequent serological tests.

The requirements for the production of brucellin shall comply with Section C1 of Chapter 2.4.3 of the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, Sixth Edition, 2008.

3.1.3. Test procedure

3.1.3.1. A volume of 0.1 ml of brucellosis allergen shall be injected intradermally into the caudal fold, the skin of the flank, or the side of the neck.

3.1.3.2. The test shall be read after 48- to 72-hours.

3.1.3.3. The skin thickness at the injection site shall be measured with vernier callipers before injection and at re-examination.

3.1.3.4. Interpretation of results:
Strong reactions are easily recognised by local swelling and induration.

Skin thickening of 1 to 2 mm shall be considered as positive reaction to the BST.

3.2. Competitive enzyme-linked immunosorbent assay (cELISA)

3.2.1. Conditions for the use of cELISA

The cELISA shall not be used for the purpose of certification for intra-Community trade.

Bovine animals, tested with positive result in one of the other serological tests defined in this Annex may be subject to a cELISA in order to support the interpretation of the other serological test results; in particular where in the officially brucellosis-free or brucellosis-free bovine herds a cross-reaction with antibodies against other bacteria cannot be excluded or to eliminate reactions due to residual antibodies produced in response to vaccination with S19.

3.2.2. Test procedure

The test shall be carried out in accordance with the prescription in Section B(2) of Chapter 2.4.3 of the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, Sixth Edition, 2008.**]]]**