

[^{F1}][^{F2}][^{F3} ANNEX 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).

2. IMMUNOLOGICAL TESTS

2.2. Enzyme-linked immunosorbent assays (ELISAs) or other binding assays for the detection of bovine brucellosis in serum or milk

2.2.2. Standardisation of the test

2.2.2.1. Standardisation of the test procedure for individual serum samples:

- (a) a 1/150 pre-dilution⁽¹⁾ of the OIEISS or a 1/2 pre-dilution of the OIEELISA_{WP}SS or a 1/16 pre-dilution of the OIEELISA_{SP}SS made up in a negative serum (or in a negative pool of sera) must give a positive reaction;
- (b) a 1/600 pre-dilution of the OIEISS or a 1/8 pre-dilution of the OIEELISA_{WP}SS or a 1/64 pre-dilution of the OIEELISA_{SP}SS made up in a negative serum (or in a negative pool of sera) must give a negative reaction;
- (c) the OIEELISA_NSS must always give a negative reaction.

2.2.2.2. Standardisation of the test procedure for pooled serum samples:

- (a) a 1/150 pre-dilution of the OIEISS or a 1/2 pre-dilution of the OIEELISA_{WP}SS or a 1/16 pre-dilution of the OIEELISA_{SP}SS made up in a negative serum (or in a negative pool of sera) and again diluted in negative sera by the number of samples making up the pool must give a positive reaction;
- (b) the OIEELISA_NSS must always give a negative reaction;
- (c) the test must be adequate to detect evidence of infection in a single animal of the group of animals, of which samples of serum have been pooled.

2.2.2.3. Standardisation of the test procedure for pooled milk or whey samples:

- (a) a 1/1 000 pre-dilution of the OIEISS or a 1/16 pre-dilution of the OIEELISA_{WP}SS or a 1/125 pre-dilution of the OIEELISA_{SP}SS made up in a negative serum (or in a negative pool of sera) and again diluted 1/10 in negative milk must give a positive reaction;
- (b) the OIEELISA_NSS diluted 1/10 in negative milk must always give a negative reaction;
- (c) the test must be adequate to detect evidence of infection in a single animal of the group of animals, of which samples of milk or whey have been pooled.]]]]

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- (1) ^{F1}^{F2}^{F3}For the purpose of this Annex, dilutions given for making up liquid reagents are expressed as, for example, 1/150 shall mean a 1 in 150 dilution.]]]

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- 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\) \(Text with EEA relevance\) \(2008/984/EC\).](#)