

[^{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

2.1. Standards

- 2.1.1. The *Brucella abortus* biovar 1 Weybridge strain No 99 or USDA strain 1119-3 must be used for the preparation of all antigens used in the rose Bengal test (RBT), serum agglutination test (SAT), complement fixation test (CFT) and the milk ring test (MRT).
- 2.1.2. The standard reference serum for the RBT, SAT, CFT and MRT shall be the OIE international reference standard serum (OIEISS) formerly named WHO second international anti-*Brucella abortus* Serum (ISAbS).
- 2.1.3. The standard reference sera for enzyme-linked immunosorbent assays (ELISAs) shall be:
- the OIEISS,
 - the weak positive OIE ELISA standard serum (OIEELISA_{WPSS}),
 - the strong positive OIE ELISA standard serum (OIEELISA_{SPSS}),
 - the negative OIE ELISA standard serum (OIEELISA_{NSS}).
- 2.1.4. The standard reference sera for fluorescence polarisation assays (FPAs) shall be:
- the weak positive OIE ELISA standard serum (OIEELISA_{WPSS}),
 - the strong positive OIE ELISA standard serum (OIEELISA_{SPSS}),
 - the negative OIE ELISA standard serum (OIEELISA_{NSS}).
- 2.1.5. The standard sera listed in 2.1.3 and 2.1.4 are available from the Community reference laboratory for brucellosis or the Veterinary Laboratories Agency (VLA), Weybridge, United Kingdom.
- 2.1.6. The OIEISS, the OIEELISA_{WPSS}, the OIEELISA_{SPSS} and the OIEELISA_{NSS} are international primary standards from which secondary reference national standards serum (working standards) must be established for each test referred to in 2.1.1 in each Member State.]]]