



Ref: CTO 2013 002

Tested, filtered and irradiated foetal bovine serum, calf serum and bovine serum from Australia

CTO direction to biosecurity inspectors for the clearance of products that are tested, filtered and irradiated foetal bovine serum, calf serum and bovine serum from Australia

Pursuant to section 27(1)(d)(iii) of the Biosecurity Act 1993 I, Marnie Thomas, Manager Animal Imports (team 2), Ministry for Primary Industries (under delegated authority), give the following directions for products that are tested, filtered and irradiated foetal bovine serum, calf serum and bovine serum from Australia, to be given clearance in accordance with the following measures, different from those in the applicable import health standard (BOVFBSIC.AUS 2001):

Clause 10.1

The product(s) must be accompanied by a competent authority endorsed manufacturer's declaration that specifies the product was manufactured using processes which comply with an industry accepted code of good manufacturing practice and using a quality system equivalent to **the current version of ISO 9001** that records details of the product description, the origin and nature of each batch of product, the manufacturing process, the quality control testing carried out and packaging and consignment details.

ISO 9002 has been replaced by ISO 9001:2008. Additional changes to ISO 9001:2008 have been future proofed by just referencing ISO 9001.

Other requirements applicable in clause 10.1 of the manufacturer's declaration for the import health standard tested, filtered and irradiated foetal bovine serum, calf serum and bovine serum from Australia (BOVFBSIC.AUS) must be met.

Clause 10.2.2

The product(s) must be accompanied by a competent authority endorsed manufacturer's declaration that specifies the product has been tested and found free of mycoplasma. It has also been tested and found free from bovine virus diarrhoea, infectious bovine rhino tracheitis, bluetongue and parainfluenza-3 using the methods described in the **relevant Australian standard or, in its absence, described by relevant OIE guidelines**.

The *Australian Standard Diagnostic Techniques for Animal Diseases* has been superseded by the *Australian and New Zealand Standard Diagnostic Procedures* and, where this is not the case, the *OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* is used as a standard.

Other requirements applicable in clause 10.2.2 of the manufacturer's declaration for the import health standard for tested, filtered and irradiated foetal bovine serum, calf serum and bovine serum from Australia (BOVFBSIC.AUS) must be met.

This direction takes effect from the date of signing and continues in effect until amended or revoked.

Signed at Wellington this seventeenth day of July 2013

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Marnie Thomas
Manager Animal Imports (team 2)
Ministry for Primary Industries
(Acting under delegated authority)