



Ref: CTO 2013 003

Foetal bovine serum, calf serum and bovine serum from Australia for further processing

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

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 foetal bovine serum, calf serum and bovine serum from Australia for further testing, to be given clearance in accordance with the following measures, different from those in the applicable import health standard (BOVSFPIC.AUS 2001):

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ISO 9002 has been replaced by ISO 9001:2008.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 the import health standard for foetal bovine serum, calf serum and bovine serum from Australia for further processing (BOVSFPIC.AUS) must be met.

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