IMPORT HEALTH STANDARD FOR THE IMPORTATION INTO NEW ZEALAND OF FOETAL BOVINE SERUM, CALF SERUM AND BOVINE SERUM FOR FURTHER PROCESSING FROM AUSTRALIA

14 October 2019

As per CTO direction 2019 049[B], the following modified model zoosanitary certificate clauses are acceptable:

Clause 10.2
The products were derived from cattle born and reared in Australia **and/or New Zealand**. In the case of foetal bovine serum, it was obtained from blood collected from foetuses whose dams were born and raised in Australia **and/or New Zealand**.

Clause 10.3.1
Product sourced from abattoirs was derived from animals which passed ante-mortem and post-mortem inspection and were processed in premises under the supervision of the controlling authority and in accordance with the regulations of Australia **or New Zealand**.

It is acceptable for the wording of clause 10.2 to appear as part of clause 10.4 of the model zoosanitary certificate.

17 July 2013

As per CTO Direction 2013 003, the following modified manufacturer declaration clause is acceptable:

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.

USER GUIDE

The information in MAF animal and animal product import health standards is presented in numerically ordered sections with descriptive titles. Sections are grouped into one of four parts, designated alphabetically.

Part A. GENERAL INFORMATION contains sections of general interest, including those relating to the legal basis for MAF import health standards and the general responsibilities of every importer of animals and animal products.

Part B. IMPORTATION PROCEDURE contains sections that outline the requirements to be met prior to and during importation. Whether a permit to import is required to be obtained prior to importation is noted, as are conditions of eligibility, transport and general conditions relating to documentation accompanying the consignment.

Part C. CLEARANCE PROCEDURE contains sections describing the requirements to be met at the New Zealand border and, if necessary, in a transitional facility in New Zealand prior to any consignment being given biosecurity clearance.

Part D. ZOOSANITARY CERTIFICATION contains model health certification which must be completed by the appropriate personnel as indicated in the certification and accompany the consignment to New Zealand. When MAF has accepted health certification produced by a government authority in the exporting country as meeting the requirements of the model health certification this is noted. When no health certification is required to accompany consignments Part D. will note "none required".

PART A. GENERAL INFORMATION

1 IMPORT HEALTH STANDARD

1.1 Pursuant to section 22 of the Biosecurity Act 1993, this document is the import health standard for the importation into New Zealand of foetal bovine serum, calf serum and bovine serum for further processing from Australia.

1.2 Obtaining biosecurity clearance for each consignment of commodity imported into New Zealand from Australia is dependent upon the consignment meeting the requirements of this import health standard.

1.3 This import health standard may be reviewed, amended or revoked if there are changes in New Zealand's import policy or the animal health status of the originating country, or for any other lawful reason, at the discretion of the Director Animal Biosecurity.

2 IMPORTER'S RESPONSIBILITIES

2.1 The importer must obtain a permit to import prior to proceeding with importation (See PART B. IMPORTATION PROCEDURE).

2.2 The costs of MAF in performing functions relating to the importation of a commodity shall be recovered in accordance with the Biosecurity Act and any regulations made under that Act.

2.3 All costs involved with documentation, transport, storage and obtaining a biosecurity direction and/or biosecurity clearance shall be borne by the importer or agent.

3 DEFINITION OF TERMS

biosecurity clearance
Means a clearance under section 26 of the Biosecurity Act 1993 for the entry of goods into New Zealand.

Director Animal Biosecurity
The Director Animal Biosecurity, New Zealand Ministry of Agriculture and Forestry, or any person who for the time being may lawfully exercise and perform the power and functions of the Director Animal Biosecurity.

equivalence
Acceptance by MAF that the circumstances relating to the importation of a consignment are such that the health status of the consignment is equivalent to the health status of a consignment that complies with the requirements of the import health standard.

New Zealand Inspector
As defined by the Biosecurity Act 1993.

MAF
The New Zealand Ministry of Agriculture and Forestry.

permit to import
A permit issued by the Director General of MAF pursuant to section 22 1(A) of the Biosecurity Act 1993 upon an importer's demonstration that certain requirements of the import health standard have been met in advance of an importation being made, such that a transitional facility is available to accept the consignment/s. The procedure for application and the information required for a permit to import are detailed within the import health standard.

Official Veterinarian
A civil service veterinarian or a specially appointed veterinarian, as authorised by the Veterinary Administration of the country.

transitional facility
As defined by the Biosecurity Act 1993. Specifically, a facility registered to the *MAF Regulatory Authority Standard 154.02.18 Transitional Facilities for Animal Products* or the *MAF Regulatory Authority Standard 154.02.17 Transitional Facilities for Biological Products.*

4. EQUIVALENCE

4.1 It is expected that the animal product will meet the conditions of this import health standard in every respect. If the products do not comply with the requirements, an application for equivalence may be submitted to MAF for consideration. Detailed information supporting the application for equivalence must be forwarded to MAF for a decision.

PART B. IMPORTATION PROCEDURE

5 PERMIT TO IMPORT

5.1 An application for a permit to import shall provide the following information:

(i) Name and address of importer
(ii) Name and address of exporter
(iii) Description and quantity of the product to be imported
(iv) Name and address of the TRANSITIONAL FACILITY to which the consignment is to proceed following importation
(v) Whether a permit for multiple consignments is required; in this case a permit will be issued for a period of 12 months.

6. ELIGIBILITY

6.1 Product must be imported pre-packaged ready for use by the end-user and sealed so that contamination cannot occur during transit.

7. DOCUMENTATION ACCOMPANYING THE CONSIGNMENT

7.1 The consignment shall be accompanied by appropriately completed health certification which meets the requirements of PART D. ZOOSANITARY CERTIFICATION.

7.2 Documentation shall be in English, but may be bilingual (language of specified country/English).

7.3 It is the importer's responsibility to ensure that any documentation presented in accordance with the requirements of this import health standard is original (unless otherwise specified) and clearly legible. Failure to do so may result in delays in obtaining biosecurity direction and/or clearance or rejection of consignments.

PART C. CLEARANCE PROCEDURE

8 BIOSECURITY DIRECTION

8.1 Upon arrival in New Zealand the documentation accompanying the consignment shall be inspected by an Inspector at the port of arrival. The Inspector may also inspect the consignment, or a sample of the consignment.

8.2 A biosecurity direction may be given by an Inspector under section 25 of the Biosecurity Act 1993 authorising the consignment to move to the transitional facility named in the permit to import for further processing, providing that the documentation meets all requirements noted under PART D. ZOOSANITARY CERTIFICATION and the consignment meets the conditions of ELIGIBILITY.

9 TRANSITIONAL FACILITY

9.1 While in the transitional facility the consignment will be subjected to such testing, treatments or procedures required by the Director Animal Biosecurity, including:

9.1.1 The product must be filtered to 0.221m or less and be irradiated with a single or multiple irradiation dose totalling 5 mrad (50 kgray).

9.1.2 Records are to be kept to ensure that all imported product can be completely traced from acquisition of the product through processing to Biosecurity Clearance or export.

9.1.3 The products and records shall be made available for audit by a MAF inspector at the importer's expense at any reasonable time. In all cases, there shall be a clear audit trail from the importer to the end-use of the product.

9.1.4 The records shall be maintained in a quality system equivalent to ISO 9002 for a minimum of two years.

9.1.5 Permission from a MAF inspector is required prior to transhipment within New Zealand.

9.1.6 Upon completion of further processing, all unused product is to be destroyed on the premises by incineration, autoclaving or other approved method; or be undertaken by the Quarantine Service.

10 BIOSECURITY CLEARANCE

10.1 On successful completion of the terms detailed under TRANSITIONAL FACILITY the consignment may, subject to sections 27 and 28 of the Biosecurity Act 1993, be given a biosecurity clearance pursuant to section 26 of the Biosecurity Act 1993.

PART D. ZOOSANITARY CERTIFICATION

11 NEGOTIATED EXPORT CERTIFICATION

11.1 The following documents are recognised by MAF as equivalent to the requirements of PART D. ZOOSANITARY CERTIFICATION, and are approved to accompany imports of foetal bovine serum, calf serum and bovine serum for further processing into New Zealand from Australia, when appropriately completed by a representative of the exporting country's competent authority:

12 MODEL ZOOSANITARY CERTIFICATION

I. COMMODITY: FOETAL BOVINE SERUM, CALF SERUM AND BOVINE SERUM

II. CERTIFYING AUTHORITY:

i. Agency:
ii. Department:
iii. Country:

III. ORIGIN OF THE CONSIGNMENT

i. Name/s and address/es of processing premises:
ii. Processing premises registration number (if applicable):

IV. CONSIGNMENT DESCRIPTION

i. Number of packages:
ii. Nature of packaging:
iii. Nature of the goods:
iv. Animal species product derived from:
v. Number of the container(s) and container seal number(s):
vi. Weight in kilograms (kg):

V. CONSIGNMENT INFORMATION

i. Name and address of exporter:
ii. Name and address of New Zealand importer:

VI. DESTINATION OF THE CONSIGNMENT

i. Port of loading/disembarkation:
ii. Vessel/voyage number:
iii. Port of destination in New Zealand:

VII. ZOOSANITARY INFORMATION

MANUFACTURER DECLARATION

I, ..., being the manager of the factory where the foetal bovine serum, calf serum and bovine serum identified in this Zoo-Sanitary Certificate has been processed, certify that:

10.1 This product was manufactured using processes which comply with an industry accepted code of good manufacturing practice and using a quality system equivalent to ISO 9002 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.

10.2 The products were derived from cattle born and reared in Australia. In the case of foetal bovine serum, it was obtained from blood collected from foetuses whose dams were born and raised in Australia.

10.3 **EITHER**

10.3.1 Product sourced from abattoirs was derived from animals which passed ante-mortem and post-mortem inspection and were processed in premises under the supervision of the controlling authority and in accordance with the regulations of Australia.

OR

10.3.2 Product sourced from donor herds was derived from herds that were under veterinary supervision and the animals were clinically free from infectious or contagious diseases.

Signature of *Manufacturer*:

Date:

10.4 After due enquiry, I have no reason to doubt the veracity of the Manufacturer's Declaration.

Signature of *Official Veterinarian*:

Date:

Name and Address of Office:

N.B. Official stamp of the government veterinary authority of the exporting country must be applied to all pages of zoosanitary certification.

Ref: AI-AU40I BOVSFPIC.AUS