Ministry for Primary Industries
Manatū Ahu Matua

Import Health Standard

# Biological Products

BIOLOGIC.ALL

**14 March 2022**

Issued under the Biosecurity Act 1993

New Zealand Government

# TITLE

Import Health Standard: Biological Products

# COMMENCEMENT

This consolidated Import Health Standard comes into force on 14 March 2022.

This Import Health Standard amends the *Import Health Standard: Biological Products*, which came into force on 17 December 2021 and consolidates all amendments up to 14 March 2022.

The amendment history to this Import Health Standard is set out in *Schedule 1: Document History*.

# ISSUING AUTHORITY

This Import Health Standard is issued under section 24A of the Biosecurity Act 1993 and incorporates amendments made in accordance with section 24B(1)(a) of that Act.

Dated at Wellington, 14 March 2022

Vicki Melville
Manager, Animal Health
Ministry for Primary Industries
(acting under delegated authority of the Director-General)

Contact for further information
Ministry for Primary Industries (MPI)
Biosecurity New Zealand
Animal Imports
PO Box 2526
Wellington 6140

Email: animal.imports@mpi.govt.nz

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# Introduction

This introduction is not part of the Import Health Standard (IHS), but is intended to indicate its general effect.

## Purpose

This IHS specifies the minimum requirements that must be met when importing biological products into New Zealand.

## Background

The Biosecurity Act 1993 (the Act) provides the legal basis for excluding, eradicating and effectively managing pests and unwanted organisms.

Import health standards issued under the Act set out requirements to be met to effectively manage biosecurity risks associated with importing goods. They include requirements that must be met in the exporting country, during transit, and before biosecurity clearance can be given.

Guidance boxes are included within this IHS for explanatory purposes. The guidance included in these boxes is for information only and has no legal effect.

A guidance document also accompanies this IHS providing information on how requirements may be met.

## Who should read this Import Health Standard?

This IHS applies to importers of biological products.

## Why is this important?

It is the importer's responsibility to ensure the requirements of this IHS are met. Consignments that do not comply with the requirements of this IHS (and any other applicable IHS) may not be cleared for entry into New Zealand and/or further information may be sought from importers. Consignments that do not comply with the requirements of this IHS may be re-shipped or destroyed under the Act or tested/treated in accordance with this IHS prior to release or equivalence determined. Importers are liable for all associated expenses.

The costs to MPI in performing functions relating to the importation of biological products will be recovered in accordance with the Act and any regulations made under the Act. All costs involved with documentation, transport, storage and obtaining a biosecurity clearance must be covered by the importer or agent.

## Equivalence

The Chief Technical Officer (CTO) may issue a direction under section 27(1)(d) of the Act that measures different from those set out in this IHS may be applied to effectively manage risks associated with the importation of goods to which this IHS applies.

If an equivalent measure is approved, an import permit may be issued under section 24D(2) of the Act if the Director-General considers it appropriate to do so. The details of the CTO direction on equivalence will be included as notes in the special conditions section of the permit to inform the inspector's assessment of the commodity.

MPI's preference is that the exporting country's Competent Authority makes equivalence requests. Equivalence requests can be lodged with animal.imports@mpi.govt.nz.

# Transitional facility

Any containers not intact on arrival will be required to be made secure before the consignment is moved to a transitional facility. Any material which has leaked from the container will be destroyed at the port of entry.

Biological products may only proceed to an appropriately approved transitional facility if required by an import permit and authorised by an inspector. Such biological products must proceed directly to the transitional facility named on the import permit.

The documentation will be checked to ensure it meets all requirements set out in *Part 1* and any specific requirements (including veterinary certification) in *Schedules 3 to 5* of this IHS.

# Biosecurity clearance

A biosecurity clearance, under section 26 of the Act, may be issued when the biological products meet all the requirements of this IHS (and any other applicable IHS), provided the applicable requirements of section 27 in the Act are met.

Products subject to a restricted import permit must remain in the transitional facility and will not be given biosecurity clearance unless further treated to mitigate any risk.

# Inspection

On arrival, all documentation accompanying the consignment may be verified by an inspector.

# Document History

Refer to Schedule 1.

# Other information

This is not an exhaustive list of compliance requirements and it is the importer's responsibility to be familiar with and comply with all relevant New Zealand laws.

### Medicines Act 1981

Medicines and medical devices imported into New Zealand must comply with the requirements of the Medicines Act 1981.

### Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997

Agricultural compounds and veterinary medicines imported into New Zealand must comply with the requirements of the Agricultural Compounds and Veterinary Medicines Act 1997.

### Import Health Standards

Any other relevant IHSs must also be complied with before biosecurity clearance will be issued.

## Trade Single Window (TSW) and Customs clearance

All goods imported into New Zealand need to be cleared by the New Zealand Customs Service (Customs) and the Ministry for Primary Industries (MPI). This is achieved by lodging required documentation in through the Trade Single Window (TSW) portal.

For more information about TSW please visit https://www.customs.govt.nz/business/trade-single-window/

# Part 1: Requirements

## 1.1 Application

(1) This IHS applies to imports of biological products from any country into New Zealand.

(2) For the purposes of this IHS, a biological product is defined as a non-viable (not capable of living, replicating, reproducing or developing) product derived from a living organism, other than from a human being, including a sample of animal origin and non-viable products derived from microorganisms.

(3) This IHS does not apply to biological products derived from plants.

(4) This IHS applies to biological products imported for one of the following purposes:

a) Laboratory research, diagnostic and analytical purposes (including equipment calibration and validation); or
b) Animal product samples for evaluation and/or proficiency testing; or
c) Environmental use; or
d) Use in, or on, humans, animals and/or plants (e.g. medical, veterinary or horticultural use).

**Guidance**

- See *Guidance Document* for more information about:
  - the four eligible categories (section 5.5 of guidance).
  - biological products derived from humans (section 5.6 of guidance).

## 1.2 Incorporation by reference

(1) The following material is incorporated by reference in this IHS under section 142M of the Act:

a) MPI *Treatment Requirement: Approved Biosecurity Treatments, MPI-STD-ABTRT*
b) OIE list of FMD-free countries: Foot and mouth disease - OIE - World Organisation for Animal Health
c) OIE Terrestrial Animal Health Code.

(2) Under section 142O(3) of the Act, it is declared that section 142O(1) does not apply. That is, a notice under section 142O(2) of the Act is not required to be published before material that amends or replaces the standards, guideline or lists incorporated under clause 1.2(1) above has legal effect as part of this IHS.

**Guidance**

- Incorporation by reference means that standards, guidelines or lists are incorporated into the IHS and they form part of the requirements

## 1.3 Definitions

(1) For the purposes of this IHS and the associated guidance, terms used that are defined in the Act have the meanings set out there. The Act is available at the following website: http://www.legislation.govt.nz/.

(2) See Schedule 2 for additional definitions that apply.

## 1.4 Requirements for clearance

(1) A biological product may only be granted biosecurity clearance if:

a) It is a biological product described in *Schedule 3, 4, or 5* and it meets the applicable requirements specified in that Schedule.
b) Any packaging for the biological product complies with clause 1.6.
c) The biological product is accompanied by an import permit (where required by the applicable Schedule), and the biological product complies with any conditions of that import permit.
d) The biological product is accompanied by a veterinary certificate (where required by the applicable Schedule) and the veterinary certificate complies with the requirements of clause 1.7.1.
e) The biological product is accompanied by a manufacturer's declaration (where required by the applicable Schedule) and the declaration complies with clause 1.7.2.

(2) Any biological product that is not described in *Schedule 3, 4,* or *5*, but where the biosecurity risks associated with the biological product have been assessed by MPI and concluded to be managed effectively, must be accompanied by an import permit and meet the conditions of that permit before it is eligible to receive biosecurity clearance.

**Guidance**

- See *Guidance Document* for more information about:
  - biological products and samples eligible for biosecurity clearance under another IHS (section 6 of guidance).
  - Products registered, approved or exempt under the ACVM Act (section 7.2 of guidance).
  - biosecurity risk assessment (section 7.3 of guidance).

## 1.5 Requirements that apply before a biological product can be moved to a transitional facility

(1) A biological product may only be moved to an appropriately approved transitional facility if the biological product is:

a) Described in *Schedule 5* and meets the requirements for import that are specified in that Schedule.
b) Accompanied by an import permit as required in *Schedule 5* and meets any conditions of that import permit, including being moved only to the transitional facility named on the import permit.

**Guidance**

- See *Guidance Document* for more information about biological products for use within a transitional facility (section 7.4 of guidance).

## 1.6 Packaging and transport

(1) Packaging must be clean, secure, free of any organic contaminants, and must be appropriate to effectively contain any potential biosecurity risks during transport.

**Guidance**

- See *Guidance Document* for more information about packaging and transport (section 5.7 of guidance).

# 1.7 Documentation that must accompany goods

(1) The consignment must arrive in New Zealand with the documentation that is specified in, and meets the requirements of, clauses 1.7.1 and 1.7.2, as applicable, below.

(2) All documentation that is required by this clause 1.7 to accompany biological products must, unless otherwise stated:

a) Be in English or have an English translation that is clear and legible.
b) Be original.

(3) Documentation that is in a paper format must, unless otherwise stated, be endorsed on every page by the Official Veterinarian with their original stamp, signature and date or be endorsed in the space allocated and all pages have paper based alternative security features.

(4) Documentation that is in an electronic format must, unless otherwise stated, be transmitted directly from the Competent Authority of the exporting country to MPI, using an electronic system approved by MPI for that purpose.

**Guidance**

- See *Guidance Document* for more information about applying for an import permit (section 5.8 of guidance).

## 1.7.1 Veterinary certificate

(1) If required by this IHS, a veterinary certificate from the exporting country's Official Veterinarian is required. The veterinary certificate must include the following:

a) A unique consignment identifier.
b) The description, source species, and amount of product.
c) Name and address of the importer (consignee) and exporter (consignor).
d) Name, signature and contact details of the Official Veterinarian.
e) Certification and endorsement by the Official Veterinarian that the general requirements outlined in Part 1 of this IHS have been met.
f) Certification and endorsement by the Official Veterinarian that the relevant requirements outlined in either Schedule 4 (biosecurity clearance) or Schedule 5 (direction to a transitional facility) of this IHS have been met.

**Guidance**

- See *Guidance Document* for more information about equivalence (section 5.1 of guidance).

## 1.7.2 Declarations

### Manufacturer's declaration

(1) If required by this IHS, a manufacturer's declaration must accompany the consignment. The manufacturer's declaration must:

a) Include any declarations required by the applicable Schedule of this IHS.
b) Include product descriptors that match with official or commercial shipping and/or invoice documents
c) Be prepared by the manufacturer on letterhead.
d) Be signed and dated by the quality manager of the manufacturer or equivalent.

(2) The manufacturer's declaration will be valid for 12 months from date of signing, or when there is a change in product formulation, whichever occurs soonest.

### Certificate of irradiation

(3) If required by this IHS, a certificate of irradiation must accompany the consignment. The certificate of irradiation must:

a) Include any declarations required by the applicable Schedule of this IHS.
b) Be prepared by the irradiation service provider on letterhead.
c) Be issued by an official government department or a recognised institution.
d) Be signed and dated by the official government department or the quality manager (or equivalent) of the irradiation service provider or equivalent.

### Declaration for naked DNA, RNA, and/or nucleic acid; preserved/fixed whole animal or animal tissue

(4) A declaration for naked DNA, RNA, and/or nucleic acid and preserved/fixed whole animal or animal tissue is a requirement of this IHS. This declaration must:

a) Include a declaration confirming the requirements of this IHS have been met.
b) Be prepared by the supplier on letterhead of the appropriate organisation.
c) Be signed and dated by the supplying organisation's Head of Department, their delegate, or equivalent.

## 1.8 Transitional arrangements for importers with a valid import permit issued under the *Import Health Standard for Biological Products (including samples), BIOPRODIC.ALL*

(1) For importers with a valid import permit issued under the *Import Health Standard for Biological Products (including samples), BIOPRODIC.ALL*, the requirements of this import health standard for importing biological products *(BIOLOGIC.ALL)* may be met by complying with the requirements of *BIOPRODIC.ALL* in force immediately before the revocation of the *BIOPRODIC.ALL*.

# Part 2: Specified Requirements for Biological Products

## 2.1 Biological products for therapeutic use on or in humans

(1) Biological products described in *Schedule 3* can be cleared on entry to New Zealand provided that they meet the requirements specified in that Schedule.

## 2.2 Biological products that can be cleared on entry to New Zealand

(1) The biological products described in *Schedule 4* can be cleared on entry to New Zealand provided that they meet the requirements specified in *Schedule 4*.

**Guidance**

- See *Guidance Document* for more information on biological products that can be cleared on entry to New Zealand (section 7.1 of guidance).

## 2.3 Biological products for use within a transitional facility

(1) Biological products described in *Schedule 5* cannot be imported into New Zealand unless they meet the specified requirements outlined in that Schedule. The biological products must be moved to an appropriately approved transitional facility in accordance with this IHS.

**Guidance**

- See *Guidance Document* for more information on biological products for use within a transitional facility (section 7.4 of guidance).

# Schedule 1 – Document History

| Date First Issued | Title | Shortcode |
|---|---|---|
| 17 December 2021 | Import Health Standard: Biological Products | BIOLOGIC.ALL |
| **Date of Issued Amendments** | **Title** | **Shortcode** |
| 14 March 2022 | Import Health Standard: Biological Products | BIOLOGIC.ALL |

# Schedule 2 – Definitions

### ACVM Act

Agricultural Compounds and Veterinary Medicines Act 1997.

### Agricultural compound

An agricultural compound has the same meaning as given in section 2 of the Agricultural Compounds and Veterinary Medicines Act 1997.

### Appropriately approved transitional facility

An MPI-approved transitional facility that has been approved for the type of uncleared biological products.

### Catgut suture

A surgical suture manufactured from collagenous fibres of the submucosa of animals.

### Commercially manufactured and packaged

A product manufactured in a commercial environment by a commercial enterprise and is packaged and labelled in sealed containers or in tamper-proof packaging and is intended for retail or wholesale. This does not include home-made products.

### Competent Authority

The Veterinary or other Governmental Authority of an OIE Member country that has the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and recommendations in the OIE *Terrestrial Code* and the OIE *Aquatic Animal Health* Code in the whole territory of that OIE member.

### Director-General

The chief executive of the Ministry for Primary Industries or his/her delegate.

### General import permit

A permit issued by the Director-General of MPI pursuant to section 24D(2) of the Act where the biosecurity risks associated with the product listed in the permit have been assessed by MPI and concluded to be managed effectively.

### Good Manufacturing Practice

A Competent Authority-approved system aimed at ensuring medicinal products are consistently produced and controlled according to quality standards appropriate to their intended use and as required by the product specification.

### Highly purified

A product that is pure and free of any foreign, extraneous or objectionable elements.

### *In-vitro*

A process or reaction carried out outside a living organism (including, but not limited to, in a culture dish or test tube).

### *In-vivo*

A process or reaction (such as a study or experiment) carried out inside a living organism.

### Medicine

A medicine for human use, as defined in the Medicines Act 1981.

### Microorganism

A microscopic organism including protozoa, fungi, bacteria, bacteriophage (phage), viruses, unicellular algae and prions.

### MPI

Ministry for Primary Industries, New Zealand.

### Official Veterinarian

A veterinarian authorised by the Competent Authority of the relevant OIE member country to perform certain designated official tasks associated with animal health and/or public health and inspections of commodities and, when appropriate, to certify in conformity with the provisions of the OIE *Code* Chapter for certification procedures.

### OIE

The World Organisation for Animal Health.

### OIE *Code*

The OIE Terrestrial Animal Health Code as found on the OIE website.

### Quality Management System (QMS)

Documented policies and procedures carried out to meet the requirements of an MPI-approved transitional facility. Referred to previously as an operating manual.

### Restricted import permit

A permit issued by the Director General of MPI pursuant to section 24D(2) of the Act where the product is assessed by MPI and concluded to pose a risk to New Zealand. Such products are required to be held and/or used in an appropriate MPI approved transitional facility.

### Sample

A small part intended as a representative of the whole.

### Sterilised

A process applied to completely remove viable microorganisms or render the microorganisms non-viable.

### Test kit

A product containing reagents and other items necessary to conduct an *in-vitro* test to detect the presence of, or to measure a given quantity of, a specific factor.

### Therapeutic use

Applies only to humans and has the same meaning as *therapeutic purpose* as defined in section 4 of the Medicines Act 1981.

### Veterinary biological implant

Biological tissue harvested from a donor animal for insertion or grafting into a recipient animal. The term includes autograft, allograft, and xenograft.

### Veterinary certificate

A certificate, issued in conformity with the provisions of the OIE Code Chapter for certification procedures, describing the animal health and/or public health requirements which are fulfilled by the exported commodities.

### Veterinary medicine

Veterinary medicine has the same meaning as given in section 2 of the Agricultural Compounds and Veterinary Medicines Act 1997.

# Schedule 3 – Biological products for therapeutic use on or in humans

| **NO IMPORT PERMIT REQUIRED** | |
|---|---|
| **Commodity** | **Requirements** |
| Biological products for therapeutic use in or on humans that do not contain viable microorganisms. | (1) If the products are commercially manufactured and packaged, a declaration from the importer or their delegate is required to state the products do not contain viable microorganisms and are for human use. The declaration must accompany the shipping documents and must link to the air waybill or invoice; or<br>(2) If the products are not commercially manufactured and/or packaged but are manufactured in a good manufacturing practice approved facility, a signed and dated manufacturer's declaration is required. The declaration must comply with clause 1.7.2 of this IHS and confirm:<br>a) The products are intended for human use;<br>b) The products do not contain viable microorganisms; and<br>c) The batch numbers of the imported commodity.<br>(3) For surgical implants, packaging must also identify the product is sterile. |

# Schedule 4 – Biological products that can be cleared on entry to New Zealand

**Guidance**

- See *Guidance Document* for more information about the:
  - biosecurity requirements for agricultural compounds and veterinary medicines (section 7.2 of guidance).
  - recommended format for model manufacturer declarations (section 7.5 of guidance).
  - recommended format for veterinary certificates (section 5.4 of guidance).
  - recommended declaration to use if clearance is sought under *Schedule 4* (section 7.1(2) of guidance).
  - supporting documentation for the tested, filtered and irradiated Australian-origin and/or New Zealand-origin fetal bovine serum, calf serum and bovine serum from Australia (section 5.4 of guidance).
  - commercially manufactured and packaged risk goods (section 7.4.1 of guidance).

| **NO IMPORT PERMIT REQUIRED** | |
|---|---|
| **Commodity** | **Requirements** |
| Amino acids | A signed and dated manufacturer's declaration is required. The declaration must comply with clause 1.7.2 of this IHS and confirm that the commodity:<br>(1) Is commercially manufactured and packaged; and<br>(2) Is for laboratory use. |
| Antibiotics and antimicrobials | A signed and dated manufacturer's declaration is required. The declaration must comply with clause 1.7.2 of this IHS and confirm that the commodity:<br>(1) Is commercially manufactured and packaged; and<br>(2) Is for laboratory use; and<br>(3) Is not for use in production of products destined for use in and/or on animals. |
| Dried, non-viable invertebrates for scientific research or display at an institution | A signed and dated declaration is required. The declaration must comply with clause 1.7.2 of this IHS and confirm that the commodity is:<br>(1) Free of visible, viable pests; or<br>(2) Treated pre-export by fumigation with methyl bromide; or |

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| | (3) Commercially prepared **insects** in glass display cases.<br>An alternative measure is treatment by fumigation with methyl bromide at the port of entry at the importer's expense. |
| Highly purified or sterilised laboratory reagents **or** highly purified sterile products produced from egg | A signed and dated manufacturer's declaration is required. The declaration must comply with clause 1.7.2 of this IHS and confirm that the commodity:<br>(1) Is commercially manufactured and packaged; and<br>(2) Is highly purified and sterilised; and<br>(3) Is not for use in the production of products destined for use in and/or on animals. |
| Highly purified and/or sterilised products derived from blood for laboratory use that do not contain risk goods and that are not bovine serum albumin (BSA) or fetal calf serum (FCS) | A signed and dated manufacturer's declaration is required. The declaration must comply with clause 1.7.2 of this IHS and confirm that the commodity:<br>(1) Is commercially manufactured and packaged; and<br>(2) Has been sterilised or purified to completely remove viable microorganisms or render any microorganisms non-viable; and<br>(3) Is not for use in the production of products destined for use in and/or on animals. |
| Irradiated whole animal specimens | Certificate of irradiation issued by the irradiation service provider is required that complies with clause 1.7.2 of this IHS and confirms the whole animal specimen has been:<br>(1) Subjected to a minimum dose of 5 mrad (50 kGy); and<br>(2) Sealed in a hermetically sealed container that is clearly linked to the certificate of irradiation. |
| Laboratory culture media containing biological products of animal origin | (1) Must be commercially manufactured and packaged; and<br>(2) Must be labelled for *in-vitro* use only; and<br>(3) Either:<br>a) The packaging identifies the media as sterile; or<br>b) A signed and dated manufacturer's declaration is required. The declaration must comply with clause 1.7.2 of this IHS and confirm the media:<br>i) Has been sterilised to completely remove viable microorganisms or render any microorganisms non-viable; and |

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| | ii) Is not for use in the production of products destined for use in and/or on animals as veterinary medicines; and<br>iii) The manufacturer's declaration is linked to the batch number(s) of the media being imported. | | |
| Laboratory reagents and products produced from animal tissue, excluding bloods, serum and/or serum proteins | A signed and dated manufacturer's declaration is required. The declaration must comply with clause 1.7.2 of this IHS and confirm that the commodity:<br>(1) Is commercially manufactured and packaged; and<br>(2) Is for laboratory use; and<br>(3) Is highly purified or sterilised. | | |
| Microscope slides of animal tissue, bacteria, and protozoa | (1) Must be fixed onto glass microscope slides; and<br>(2) Must be under glass coverslips. | | |
| Naked DNA, RNA, and/or nucleic acid | A signed and dated declaration is required. The declaration must comply with clause 1.7.2 of this IHS and confirm that the DNA, and/or RNA, and/or nucleic acid is naked (not contained within a vector) and purified. | | |
| Non-sterile laboratory culture media, not containing any ingredients of animal origin | A signed and dated manufacturer's declaration is required. The declaration must comply with clause 1.7.2 of this IHS and confirm that the media:<br>(1) Is commercially manufactured and packaged; and<br>(2) Does not contain any ingredients of animal origin, including blood, whole serum, animal proteins, and/or animal tissues; and<br>(3) Is not for use in the production of products destined for use in and/or on animals as veterinary medicines. | | |
| Preserved/fixed specimens of animal tissues | **Preservation method one**: Preserved with a minimum of:<br>(1) 10% liquid formalin; or<br>(2) 70% alcohol | **Preservation method two**: Fixed in 2% to 4% glutaraldehyde for tissues:<br>(1) Less than 2 mm thick for electron microscope imaging; or | **Preservation method three**:<br>(1) Fixed in glyoxal if equal to, or less than, 2 mm thick. |

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| | | (2) Larger samples by intravascular active perfusion | |
| | A signed and dated declaration is required. The declaration must comply with clause 1.7.2 of this IHS and confirm the preservation method used. | | |
| Preserved whole animal specimens (including invertebrates), specimens of parasites, and animal faecal specimens | A signed and dated declaration is required. The declaration must comply with clause 1.7.2 of this IHS and confirm that the commodity:<br>(1) Is preserved with a minimum of:<br>a) 10% liquid formalin; or<br>b) 70% alcohol<br>(2) Or, for invertebrates, also embedded in amber, resin, or similar solid coating. | | |
| Purified products derived from microorganisms | A signed and dated manufacturer's declaration is required. The declaration must comply with clause 1.7.2 of this IHS and confirm that the commodity:<br>(1) Is commercially manufactured and packaged; and<br>(2) Is for laboratory use. | | |
| Restriction enzymes, defined as an enzyme which cleaves DNA at specific sites to allow the splicing of DNA from one source (or species) into another | A signed and dated manufacturer's declaration is required. The declaration must comply with clause 1.7.2 of this IHS and confirm that the commodity:<br>(1) Is commercially manufactured and packaged; and<br>(2) Is for laboratory use. | | |
| Tested, filtered and irradiated Australian-origin and/or New Zealand-origin fetal bovine serum, calf serum and bovine serum from Australia | (1) The product must be commercially manufactured, packaged, and sealed; and<br>(2) A signed and dated manufacturer's declaration is required. The declaration must comply with clause 1.7.2 of this IHS and must state:<br>I, ....., being the manager of the factory where the tested, filtered and irradiated fetal bovine serum, calf serum and bovine serum identified in this manufacturer's declaration has been processed, certify that:<br>a) This 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 | | |

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| | 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.<br>b) Either *(strikethrough or delete non-applicable statement)*:<br>i) This product has been filtered to 0.22 micron or less and has been irradiated with a single or multiple irradiation dose totalling 5 mrad (50 kGy); or<br>ii) This product has been subject to triple 0.1-micron membrane filtration and has been irradiated with a single or multiple irradiation dose totalling 2.5 mrad (25 kGy), and<br>iii) The product has been tested and found free of mycoplasma. It has also been tested and found free from bovine virus diarrhoea, infectious bovine rhinotracheitis, bluetongue and parainfluenza-3 using the methods described in the relevant Australian standard or, in its absence, described by relevant OIE guidelines.<br>c) The products were derived from cattle born and reared in Australia or New Zealand. In the case of fetal bovine serum, it was obtained from blood collected from fetuses whose dams were born and raised in Australia or New Zealand.<br>d) Either *(strikethrough or delete non-applicable statement)*:<br>i) Product sourced from abattoirs was derived from animals that passed antemortem and postmortem inspection and were processed in premises under the supervision of the controlling authority and in accordance with the regulations of Australia or New Zealand; or<br>ii) 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; and<br>(3) A signed and dated veterinary certificate is required that complies with clause 1.7.1 of this IHS and states that after due enquiry, there is no reason to doubt the veracity of the manufacturer's declaration. |
| Test kits that do not contain viable microorganisms | A signed and dated manufacturer's declaration is required. The declaration must comply with clause 1.7.2 of this IHS and confirm that the commodity:<br>(1) Is commercially manufactured and packaged; and<br>(2) Does not contain viable microorganisms; and<br>(3) Is for laboratory use. |

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| Veterinary medicines that are authorised under sections 21 (registration), 27 (provisionally registered), 8C (research approval), and 8C (special circumstances approval) of the ACVM Act.<br>Excludes veterinary medicines that are blood plasma products. | (1) Must be subject to a biosecurity assessment, and<br>(2) If the biosecurity assessment concludes the risks are effectively managed, this will be communicated in an appropriate ACVM authorisation.<br>(3) For veterinary medicines authorised under section 21 (registration) of the ACVM Act, must be in ACVM-approved packaging. |

| **GENERAL IMPORT PERMIT REQUIRED (copy acceptable)** | |
|---|---|
| **Commodity** | **Requirements** |
| Agricultural compounds described in Column 1 of Schedule 2 of the *Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011* | (1) Must be commercially manufactured and packaged; and<br>(2) If a biosecurity assessment concludes the risks are effectively managed for agricultural compounds that do not meet the requirements for biosecurity clearance under another IHS, a general import permit is required. |
| Antisera and antibodies derived from laboratory-raised guinea pigs, hamsters, mice, rabbits, and rats | (1) Must be commercially manufactured and packaged; and<br>(2) A specific biosecurity risk assessment of the commodity is required to be undertaken by MPI; and<br>(3) If the biosecurity risk assessment concludes the risk is effectively managed, a general import permit is required. |
| Biological ingredients for inclusion in growing media for bioproduction of veterinary vaccines | (1) Must be commercially manufactured and packaged; and<br>(2) If a biosecurity assessment concludes the risks are effectively managed, a general import permit is required. |
| Biological ingredients imported for formulation into agricultural compounds in New Zealand. | (1) Must be commercially manufactured and packaged; and<br>(2) If a biosecurity assessment concludes the risks are effectively managed, a general import permit is required. |
| Biological products not specifically listed but where the biosecurity risks associated with the biological products have been assessed by MPI and concluded to be managed effectively. | (1) Commercially manufactured and packaged; and<br>(2) A specific biosecurity risk assessment is required to be undertaken by MPI; and<br>(3) If the biosecurity risk assessment concludes the risk is effectively managed, a general import permit is required. |

| **GENERAL IMPORT PERMIT REQUIRED (copy acceptable)** | |
|---|---|
| **Commodity** | **Requirements** |
| Catgut suture | (1) Must be commercially manufactured and packaged; and<br>(2) A specific biosecurity risk assessment is required to be undertaken by MPI; and<br>(3) If the biosecurity risk assessment concludes the risk is effectively managed, a general import permit is required.<br>a) Information required to support the biosecurity assessment must confirm:<br>i) That the relevant bovine spongiform encephalopathy (BSE) recommendations of the OIE's Terrestrial Animal Health Code are met if the product is manufactured from bovine tissues;<br>ii) That the relevant scrapie recommendations of the OIE's Terrestrial Animal Health Code are met if the product is manufactured from ovine tissues;<br>iii) The manufacturing process; and<br>iv) Any other relevant factors. |
| Veterinary biological implants | (1) If a biosecurity assessment concludes the risks are effectively managed, a general import permit is required. |

# Schedule 5 – Biological products for use within a transitional facility

**Guidance**

- See *Guidance Document* for more information about:
  - commercially manufactured and packaged risk goods (section 7.4.1 of guidance).
  - non-commercially manufactured and/or packaged laboratory un-sterilised/un-purified products (section 7.4.2 of guidance).
  - samples for analytical testing (section 7.4.3 of guidance).
  - the recommended format for model manufacturer declarations (section 7.5 of guidance).
  - the recommended format for veterinary certificates (section 5.4 of guidance).
  - supporting documentation for the Australian-origin and/or New Zealand-origin fetal bovine serum, calf serum or bovine serum for further processing from Australia (section 5.4 of guidance).
- The facility standard relating to biological products contains further information regarding *in vivo* use of biological products of animal origin.

| **RESTRICTED IMPORT PERMIT REQUIRED (copy acceptable)** | | |
|---|---|---|
| **Commodity** | **Importation requirements** | **Clearance requirements** |
| Animal samples for testing | (1) Must be from clinically healthy animals; and<br>(2) Must be used for chemical and nutritional analysis; and<br>(3) Must be moved to an appropriately approved transitional facility. | Will only be eligible for clearance if the commodity is further processed in accordance with the requirements in the relevant transitional facility standard/Quality Management System (QMS) or *MPI-STD-ABRT* so that after processing, it is no longer considered by MPI to be a risk good. |
| Australian-origin and/or New Zealand-origin fetal bovine serum, calf serum or bovine serum for further processing from Australia | (1) Must be commercially manufactured, packaged, and sealed; and<br>(2) A signed and dated manufacturer's declaration is required. The declaration must comply with clause 1.7.2 of this IHS and must state:<br>I, ....., being the manager of the factory where fetal bovine serum, calf serum and bovine serum identified in this manufacturer's declaration has been processed, certify that:<br>a) This product was manufactured using processes that comply with an industry-accepted code of good | (1) Filtered to 0.22 micron or less; and<br>(2) Irradiated with a single or multiple irradiation dose totalling 5 mrad (50 kGy) |

| RESTRICTED IMPORT PERMIT REQUIRED (copy acceptable) | | |
|---|---|---|
| **Commodity** | **Importation requirements** | **Clearance requirements** |
| | 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.<br>b) The products were derived from cattle born and reared in Australia or New Zealand. In the case of fetal bovine serum, it was obtained from blood collected from fetuses whose dams were born and raised in Australia or New Zealand.<br>c) Either *(strikethrough or delete non-applicable statement)*:<br>i) Product sourced from abattoirs was derived from animals which passed antemortem and postmortem inspection and were processed in premises under the supervision of the controlling authority and in accordance with the regulations of Australia or New Zealand; or<br>ii) 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; and<br>(3) A signed and dated veterinary certificate is required. The certificate must comply with clause 1.7.1 of this IHS and must state that after due enquiry, there is no reason to doubt the veracity of the manufacturer's declaration. | |
| Biological products of animal origin not listed specifically under **Schedule 3** or **Schedule 4**. | A specific biosecurity assessment is required to be undertaken by MPI to determine whether the biosecurity risk associated with the commodity can be effectively mitigated by moving the product to an appropriately approved transitional facility. | Will only be eligible for clearance if the commodity is further processed in accordance with the requirements in the relevant transitional facility standard/QMS or *MPI-STD-ABRT* so that after processing, it is no longer considered by MPI to be a risk good. |

| **RESTRICTED IMPORT PERMIT REQUIRED (copy acceptable)** | | |
|---|---|---|
| **Commodity** | **Importation requirements** | **Clearance requirements** |
| | If the biosecurity assessment concludes the risk can be mitigated by moving the product to an appropriately approved transitional facility, a restricted import permit is required. | |
| Products for laboratory use and/or catalogued items comprised of animal products that are not specifically listed under *Schedule 3* or *Schedule 4.* | (1) Commercially manufactured and packaged; and<br>(2) Must be moved to an appropriately approved transitional facility. | Will only be eligible for clearance if the commodity is further processed in accordance with the requirements in the relevant transitional facility standard/QMS or *MPI-STD-ABRT* so that after processing, it is no longer considered by MPI to be a risk good. |
| Un-sterilised/un-purified laboratory products | (1) Non-commercially manufactured and/or packaged; and<br>(2) Must be moved to an appropriately approved transitional facility. | Will only be eligible for clearance if the commodity is further processed in accordance with the requirements in the relevant transitional facility standard/QMS or *MPI-STD-ABRT* so that after processing, it is no longer considered by MPI to be a risk good. |