Ministry for Primary Industries
Manatū Ahu Matua

Import Health Standard

Biological Products

BIOLOGIC.ALL

[Document Date]

Issued under the Biosecurity Act 1993

New Zealand Government

TITLE

Import Health Standard: Biological Products

COMMENCEMENT

This Import Health Standard comes into force on [Effective Date]

ISSUING AUTHORITY

This Import Health Standard is issued under section 24A of the Biosecurity Act 1993.

Dated at Wellington, [Document Date]

Vicki Melville
(Acting) Manager, Import and Export Animals
Ministry for Primary Industries
(acting under delegated authority of the Director-General)

Contact for further information
Ministry for Primary Industries (MPI)
Agriculture & Investment Services
Animal Imports
PO Box 2526
Wellington 6140

Email: animal.imports@mpi.govt.nz

Contents

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 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.

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, and includes a sample of animal origin.

(3) 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.
  - biological products derived from humans.

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: http://www.oie.int/animal-health-in-the-world/fmd-portal/country-freedom/

(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.

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.
  - ACVM registered, approved or exempt products.
  - biosecurity risk assessment.

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.

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.

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 to accompany biological products by *Schedules 3, 4 or 5* must, unless otherwise stated:

a) Be original or be an electronic copy of the original document.
b) Accompany the imported goods and be securely attached to the outside of the external packaging.

c) Be in English or have an English translation that is clear and legible.
d) Where applicable, 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.

Guidance

- See *Guidance Document* for more information about applying for an import permit.

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 the applicable Schedule of this IHS have been met.

Guidance

- See *Guidance Document* for more information about equivalence.

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) Be prepared by the manufacturer on letterhead paper.
c) Be signed and dated by the quality manager of the manufacturer or equivalent.

Certificate of irradiation

(2) 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 paper.
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

(3) 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 an importer declaration confirming the requirements of IHS have been met.
b) Be prepared by the supplier on letterhead paper of the appropriate organisation.
c) Be signed and dated by the Head of Department of the appropriate organisation or equivalent

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.

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.

Schedule 1 – Document History

Date First Issued	Title	Shortcode
TBA	Import Health Standard: Biological Products	BIOLOGIC.ALL
Date of Issued Amendments	**Title**	**Shortcode**

Schedule 2 – Definitions

ACVM Act

Agricultural Compounds and Veterinary Medicines Act 1997

Appropriately Approved Transitional Facility

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

Chemically Synthesised

Chemical synthesis, the construction of complex chemical compounds from simpler ones

Commercially Manufactured and Packaged

A product that has been manufactured in a commercial manner by a commercial enterprise and is packaged for retail trade in tamper-proof packaging.

Competent Authority

The Veterinary or other Governmental Authority of an OIE Member 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 Code in the whole territory of that OIE member.

Director-General

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

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.

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.

Highly Purified

Pure and free of any foreign, extraneous or objectionable elements.

In-vitro

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

In-vivo

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

Medicine

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

Microorganism

A microscopic organism including protozoa, fungi, bacteria, 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 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.

Restricted 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;
- MPI has concluded the product poses a risk to New Zealand; and
- MPI has concluded that the risk can be mitigated by requiring the product to be held and/or used only in an appropriate approved transitional facility.

Sample

A small part intended as a representative of the whole.

Sterilised

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

Therapeutic Use

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

> *…, unless the context otherwise requires, **therapeutic purpose** means any of the following purposes, or a purpose in connection with any of the following purposes:*
> *a) preventing, diagnosing, monitoring, alleviating, treating, curing, or compensating for, a disease, ailment, defect, or injury; or*
> *b) influencing, inhibiting, or modifying a physiological process; or*
> *c) testing the susceptibility of persons to a disease or ailment; or*
> *d) influencing, controlling, or preventing conception; or*
> *e) testing for pregnancy; or*
> *f) investigating, replacing, or modifying parts of the human anatomy.*

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.

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.	(1) If the products are commercially manufactured and packaged, a declaration on the shipping documents is required that confirms the products are intended for human use; or (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 that complies with clause 1.7.2 of this IHS and confirms: a) The products are intended for human use; and b) The batch numbers of the imported commodity. (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.
  - recommended format for model manufacturer declarations.
  - recommended format for veterinary certificates.
  - recommended declaration to use if clearance is sought under *Schedule 4*.
  - supporting documentation (section 4.4 of the *Guidance Document*) for the tested, filtered and irradiated Australian-origin foetal bovine serum, calf serum and bovine serum from Australia.

NO IMPORT PERMIT REQUIRED	
Commodity	**Requirements**
Agricultural compounds (as defined in the ACVM Act), excluding specified serological products, and agricultural compounds intended for potency testing in animals.	(1) A specific biosecurity assessment of the commodity is required to be undertaken by MPI prior to ACVM Act authorisation. If the biosecurity risk assessment concludes the risk is effectively managed a biosecurity approval letter will be issued; and (2) The agricultural compound must be: a) Listed on the ACVM Register with the ACVM registration number printed on the product label; or b) Accompanied by special circumstances approval granted by the Director-General under section 8C of the ACVM Act; or c) Accompanied by provisional registration granted by the Director-General under section 27 of the ACVM Act; or d) Accompanied by research approval for special use granted by the Director-General under section 8C(1) of the ACVM Act 1997.
Amino acids	A signed and dated manufacturer's declaration is required that complies with clause 1.7.2 of this IHS and confirms the commodity: (1) Is commercially manufactured and packaged; and (2) Is for laboratory use.

NO IMPORT PERMIT REQUIRED	
Commodity	**Requirements**
Antibiotics and antimicrobials	A signed and dated manufacturer's declaration is required that complies with clause 1.7.2 of this IHS and confirms the commodity: (1) Is commercially manufactured and packaged; and (2) Is for laboratory use; and (3) Is not for use production of products destined for use in and/or on animals or plants.
Highly purified, sterilised or chemically synthesised laboratory reagents **or** highly purified sterile products produced from egg	A signed and dated manufacturer's declaration is required that complies with clause 1.7.2 of this IHS and confirms the commodity: (1) Is commercially manufactured and packaged; and (2) Is not for use in the production of products destined for use in and/or on animals; and a) Has been chemically synthesised; or b) Is highly purified and sterilised.
Highly purified and/or sterilised products derived from blood for laboratory use	A signed and dated manufacturer's declaration is required that complies with clause 1.7.2 of this IHS and confirms the commodity: (1) Is commercially manufactured and packaged; and (2) Has been sterilised or purified to completely remove viable microorganisms or render any microorganisms non-viable; and (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: (1) Subjected to a minimum dose of 5 mrad (50kGy); and (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 (2) Must be labelled for *in-vitro* use only; and (3) Either:

NO IMPORT PERMIT REQUIRED	
Commodity	**Requirements**
	a) The packaging identifies the media as sterile; or b) A signed and dated manufacturer's declaration is required that complies with clause 1.7.2 of this IHS and confirms the media: i) Has been sterilised to completely remove viable microorganisms or render any microorganisms non-viable; and ii) Is not for use in the production of products destined for use in and/or on animals as veterinary medicines; and 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 that complies with clause 1.7.2 of this IHS and confirms the commodity: (1) Is commercially manufactured and packaged; and (2) Is for laboratory use; and (3) Is highly purified or sterilised.
Microscope slides of animal tissue, bacteria, and protozoa	(1) Must be fixed onto glass microscope slides; and (2) Must be under glass coverslips.
Naked DNA, RNA, and/or nucleic acid	A signed and dated declaration is required that complies with clause 1.7.2 of this IHS and confirms 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 that complies with clause 1.7.2 of this IHS and confirms the media: (1) Is commercially manufactured and packaged; and (2) Does not contain any ingredients of animal origin, including blood, whole serum, animal proteins, and/or animal tissues; and (3) Is not for use in the production of products destined for use in and/or on animals as veterinary medicines.

<table>
<tr><th colspan="4">NO IMPORT PERMIT REQUIRED</th></tr>
<tr><th>Commodity</th><th colspan="3">Requirements</th></tr>
<tr><td rowspan="2">Preserved/fixed specimens of animal tissues</td><td>Preservation method 1:
Preserved with a minimum of:
(1) 10% liquid formalin; or
(2) 70% alcohol</td><td>Preservation method 2:
Fixed in 2 to 4% glutaraldehyde for tissues:
(1) Less than 2mm thick for electron microscope imaging; or
(2) Larger samples by intravascular active perfusion</td><td>Preservation method 3:
Fixed in glyoxal if equal to, or less than, 2mm thick.</td></tr>
<tr><td colspan="3">A signed and dated declaration is required that states the preservation method used.</td></tr>
<tr><td>Preserved whole animal specimens, specimens of parasites, and animal faeces specimens</td><td colspan="3">(1) Preserved with a minimum of:
a) 10% liquid formalin; or
b) 70% alcohol
(2) A signed and dated declaration is required that states the preservation method used.</td></tr>
<tr><td>Purified products derived from microorganisms</td><td colspan="3">A signed and dated manufacturer’s declaration is required that complies with clause 1.7.2 of this IHS and confirms the commodity:
(1) Is commercially manufactured and packaged; and
(2) Is for laboratory use.</td></tr>
<tr><td>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</td><td colspan="3">A signed and dated manufacturer’s declaration is required that complies with clause 1.7.2 of this IHS and confirms the commodity:
(1) Is commercially manufactured and packaged; and
(2) Is for laboratory use.</td></tr>
<tr><td>Tested, filtered and irradiated Australian-origin foetal bovine serum, calf serum and bovine serum from Australia</td><td colspan="3">(1) Commercially manufactured, packaged, and sealed; and
(2) A signed and dated manufacturer’s declaration is required that complies with clause 1.7.2 of this IHS and states:</td></tr>
</table>

NO IMPORT PERMIT REQUIRED	
Commodity	**Requirements**
	I, ..., being the manager of the factory where the tested, filtered and irradiated foetal bovine serum, calf serum and bovine serum identified in this manufacturer's declaration has been processed, certify that: 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 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. b) Either *(strikethrough or delete non-applicable statement)*: 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 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 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 rhino tracheitis, bluetongue and parainfluenza-3 using the methods described in the relevant Australian standard or, in its absence, described by relevant OIE guidelines. c) The products were derived from cattle born and reared in Australia 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 or New Zealand. d) Either *(strikethrough or delete non-applicable statement)*: i) 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; or 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

NO IMPORT PERMIT REQUIRED	
Commodity	**Requirements**
	(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 that complies with clause 1.7.2 of this IHS and confirms the commodity: (1) Is commercially manufactured and packaged; and (2) Does not contain viable microorganisms; and (3) Is for laboratory use.

GENERAL IMPORT PERMIT REQUIRED (copy acceptable)	
Commodity	**Requirements**
Agricultural compounds that contain imported biological ingredients and which are exempt from ACVM Act registration.	A specific biosecurity assessment of the commodity is required to be undertaken by MPI, unless the imported biological ingredients are listed in the Negligible Risk Ingredient Schedule included in the *Biosecurity Approval of Imported Agricultural Compounds and Veterinary Medicines – ACVM Guidance* document. If the biosecurity risk assessment concludes the risk is effectively managed, a general import permit is required unless the product meets the requirements under an existing import health standard.
Antisera and antibodies derived from laboratory-raised guinea pigs, hamsters, mice, rabbits, and rats	(1) Must be commercially manufactured and packaged; and (2) A specific biosecurity risk assessment of the commodity is required to be undertaken by MPI; and (3) If the biosecurity risk assessment concludes the risk is effectively managed, a general import permit is required.
Culture media for use in the manufacture of agriculture compounds (as defined under the ACVM Act and including veterinary medicines and animal feed)	A specific biosecurity assessment is required to be undertaken by MPI. If the biosecurity assessment concludes the risk is effectively managed, a general import permit is required.

GENERAL IMPORT PERMIT REQUIRED (copy acceptable)	
Commodity	**Requirements**
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 (2) A specific biosecurity risk assessment is required to be undertaken by MPI; and (3) If the biosecurity risk assessment concludes the risk is effectively managed, a general import permit is required.
Biological ingredients imported as raw materials for formulation into agricultural compounds in New Zealand.	A specific biosecurity assessment of the commodity is required to be undertaken by MPI, unless the imported biological ingredients are listed in the Negligible Risk Ingredient Schedule included in the *Biosecurity Approval of Imported Agricultural Compounds and Veterinary Medicines – ACVM Guidance* document. If the biosecurity risk assessment concludes the risk is 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.
  - non-commercially manufactured and/or packaged laboratory un-sterilised/un-purified products.
  - samples for analytical testing.
  - the recommended format for model manufacturer declarations.
  - the recommended format for veterinary certificates.
  - supporting documentation (section 4.4 of the *Guidance Document*) for the Australian-origin foetal bovine serum, calf serum or bovine serum for further processing.
- See clause 2.3(8) of *MPI-STD-BIOLOGICAL* for more information about *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 (2) Must be used for chemical and nutritional analysis; and (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/operating manual or *MPI-STD-ABRT* so that after processing, it is no longer considered by MPI to be a risk good.
Australian-origin foetal bovine serum, calf serum or bovine serum for further processing	(1) Must be commercially manufactured, packaged, and sealed; and (2) A signed and dated manufacturer's declaration is required that complies with clause 1.7.2 of this IHS and states: I, ..., being the manager of the factory where foetal bovine serum, calf serum and bovine serum identified in this manufacturer's declaration has been processed, certify that: a) This product was manufactured using processes which comply with an industry accepted code of good manufacturing practice and using a quality system	(1) Filtered to 0.22 micron or less; and (2) Irradiated with a single or multiple irradiation dose totalling 5 mrad (50kGy)

RESTRICTED IMPORT PERMIT REQUIRED (copy acceptable)		
Commodity	**Importation requirements**	**Clearance requirements**
	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. b) The products were derived from cattle born and reared in Australia 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 or New Zealand. c) Either *(strikethrough or delete non-applicable statement)*: i) 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; or 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 (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.	
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/operating manual 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 (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/operating manual 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 (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/operating manual or *MPI-STD-ABRT* so that after processing, it is no longer considered by MPI to be a risk good.