Ministry for Primary Industries
Manatū Ahu Matua

Import Health Standard

Microorganisms, biological products derived from animals, and cell lines [Date of Signing]

MOBIOCELL.ALL

[Document Date]

Issued under the Biosecurity Act 1993

Te Kāwanatanga o Aotearoa
New Zealand Government

Title

Import Health Standard: Microorganisms, biological products derived from animals, and cell lines [Date of Signing]

Commencement

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

Revocation

This standard revokes and replaces the following:

a) *Import Health Standard: Microorganisms from all countries MICROIC.ALL*
b) *Import Health Standard: Biological Products BIOLOGIC.ALL*
c) *Import Health Standard: Cell cultures from all countries CELCULIC.ALL*

Issuing Authority

This standard is made under section 24A of the Biosecurity Act.

Made at Wellington on [Date of Signing]

[Approver]
Director, Biosecurity Import & Export Standards
Ministry for Primary Industries
(acting under delegated authority of the Director-General)

Contact for further information

This legislation is administered by the Ministry for Primary Industries (MPI). For more information contact:

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Website: Import Health Standards | NZ Government

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Introduction

This introduction is not part of this 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 microorganisms, biological products derived from animals, and cell cultures 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.

Who should read this standard?

This IHS should be read by importers of microorganisms, biological products derived from animals, and cell cultures.

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 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 microorganisms, biological products derived from animals, and cell cultures 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 these goods.

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 the transitional or containment facility. Any material which has leaked from the container will be destroyed at the port of entry.

Following biosecurity authorisation being given under section 25 of the Act, the microorganisms, biological products derived from animals, and cell cultures (where applicable) will proceed directly to the transitional or containment facility named on the import permit.

The documentation will be checked to ensure it meets all requirements noted under general requirements in *Part 1: Requirements* and specific requirements in the relevant sections of *Part 2: Specified requirements* of this IHS.

Biosecurity clearance

A biosecurity clearance, under section 26 of the Act, may be issued when the microorganisms, biological products derived from animals, and/or cell cultures meet all the requirements of this IHS, provided the applicable requirements of section 27 in the Act are met.

Inspection

On arrival, all documentation accompanying the consignment will 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 New Zealand laws.

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.

Ruminant Protein Regulations

Under the Biosecurity (Ruminant Protein) Regulations 1999, feeding of ruminant proteins to ruminant animals is prohibited in New Zealand. See Ruminant feed regulations for preventing BSE for more information.

Import health standards

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

CITES

It is the responsibility of the importer to ensure that the consignment is accompanied by any permit(s) required to meet the legislation of the country of origin and the Convention on the International Trade in Endangered Species (CITES) https://www.cites.org. See the Department of Conservation for further details https://www.doc.govt.nz/cites.

The importer is advised to clarify the status of the species of animal in relation to international agreements on their trade, prior to export. Material arriving in New Zealand without the relevant CITES permits may be subject to seizure by the New Zealand Department of Conservation.

Any requirement for CITES or other conservation-related documentation must be met by the exporter/importer.

Environmental Protection Authority (EPA) and new organisms

Importers of new organisms must meet all requirements of the Hazardous Substances and New Organisms (HSNO) Act 1996.

Before an inspector can authorise a new organism to go to a containment facility, the EPA must have given approval for importation of that organism into containment in accordance with the HSNO Act.

See guidance document for inspection and verification requirements and for more information about HSNO Act requirements.

Harmonised System (HS) Codes

The Harmonised System is an international product numbering classification developed by the World Customs Organisation (WCO). The New Zealand Harmonised System is found here: Harmonized System | WCO Trade Tools

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). To gain customs clearance, the required documentation must be lodged through the Trade Single Window (TSW) portal.

For more information about TSW refer to Trade Single Window (TSW)

Part 1: Requirements

1.1 Application

(1) This IHS applies to imports of microorganisms, biological products derived from animals, and cell lines from all countries into New Zealand.

(2) For the purposes of this IHS:

a) A microorganism is defined as a microscopic organism, and includes protozoa, fungi, bacteria, viruses, unicellular algae, and prions.
b) A biological product is defined as a product derived from a living organism other than a human being or a plant. It is not a live organism, and cannot replicate, reproduce, or develop.
c) Cell lines are defined as cells derived from tissues and grown *in vitro,* also known as cell cultures.

(3) Commodities imported under this IHS are imported for one of the following purposes:

a) Laboratory use, as defined in Schedule 2.
b) Environmental use.
c) Use in or on animals and/or plants i.e. veterinary or horticultural use.

Guidance

- Microorganisms and products containing microorganisms for food use may be imported under the IHS for *Specified Products for Human Use SPECHUMN.ALL* and are not eligible for import under this IHS.
- Microorganisms and products containing microorganisms for animal food may be imported under the IHS for *Animal Food ANIFOOD.ALL* or *Processed Animal Feeds of Plant Origin PAFP.IHS* and are not eligible for import under this IHS.
- Chemically synthesised compounds that do not contain products of animal origin are not risk goods and do not need to be imported under an IHS.
- Biological products and cell cultures derived from plants may be imported under the IHS *Research Samples (excluding animal samples) RESEARCH.IHS* and are not eligible for import under this IHS.
- Animal products for human consumption, including samples for laboratory evaluation that are consumed are not eligible for import under this IHS. These products may be imported under IHS for *Specified Animal Products for Human Use*, SPECHUMN.ALL, or the commodity-specific IHS.
- Cell lines derived from humans are not risk goods and do not need to be imported under an IHS, unless the cells have been genetically modified.
- Cell lines and tissue cultures derived from plants are not eligible for import under this IHS.

1.2 Incorporation by reference

(1) The following international standards are incorporated by reference in this IHS under section 142M of the Act:

a) The World Organisation for Animal Health (WOAH) *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals*, available at: Terrestrial Codes and Manuals - WOAH
b) The World Organisation for Animal Health (WOAH) *Terrestrial Animal Health Code*, available at: Terrestrial Codes and Manuals - WOAH

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

a) The MPI *Specified Approvals for Animal Import Health Standards, MPI-STD-SAA*
b) The WOAH list of FMD-free countries: Foot and mouth disease - WOAH.

c) The WOAH list of countries with a BSE risk status: Bovine spongiform encephalopathy aka BSE-WOAH.
d) The databases of new organisms present in New Zealand maintained by the EPA.
e) The Official New Zealand Pest Register.

(3) 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 clauses 1.2(1) and (2) 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, terms used that are defined in the Act have the meanings set out there. The Act is available at https://www.legislation.govt.nz/.

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

1.4 Requirements for clearance

(1) In order to obtain biosecurity clearance, goods eligible for import under this IHS must meet all the following requirements:

a) The goods must meet the requirements of the relevant clause/s of *Part 1: Requirements*, *Part 2: Specified requirements*, and Part 3: Specified requirements; and
b) Any packaging for the goods must comply with clause 1.6; and
c) The goods must be accompanied by an import permit, where required by this IHS, that must comply with clause 1.7, and the goods must comply with the any conditions of that import permit; and
d) The goods must be accompanied by a veterinary certificate, where required by this IHS, and the veterinary certificate must comply with the requirements of clause 1.8.2 and include all required attestations as indicated by the model certificate; and
e) The goods must be accompanied by a manufacturer's or supplier's declaration, where required by this IHS, that must comply with clause 1.8.3 and include the required declarations for the goods imported; and
f) The goods must be accompanied by an importer's declaration, where required by this IHS, that must comply with clause 1.8.4 and include the required declarations for the goods imported; and
g) The goods must be accompanied by a certificate of irradiation, where required by this IHS, that must comply with clause 1.8.5 and include the required declarations for the goods imported.

(2) Any goods that are not specifically described in Part 2, but where relevant information as indicated in sections 2.1.11, 2.2.7, or 2.3.8 has been provided to enable a product assessment to be undertaken and concluded to be managed effectively, must be accompanied by an import permit and meet the conditions of that permit before the goods are eligible to receive biosecurity clearance.

1.5 Requirements for moving goods to a transitional or containment facility

(1) Goods may only be moved to an approved transitional or containment facility if the goods are:

a) Described in Part 2 and meet the relevant requirements specified; and

b) Accompanied by an import permit and comply with the import permit conditions; and
c) Moved only to the transitional or containment facility named on the import permit; and

i) The facility approval is current at the time of import.

(2) Any goods that are not specifically described in section 2, but where relevant information as indicated in sections 2.1.11, 2.2.7, or 2.3.8 has been provided to enable a product assessment to be undertaken and concluded to be managed effectively in a transitional facility, must be accompanied by an import permit that directs the goods to an approved transitional facility, and meet the conditions of that permit before the goods are eligible to receive biosecurity direction.

1.6 Packaging and transport

(1) Packaging must be clean, secure, and free of any organic contaminants.

1.7 Import permit information

(1) An import permit under section 24D of the Act is required prior to importation, where indicated in Part 2 or Part 3 of this IHS.

(2) Import permits are issued subject to an assessment of the commodity being imported and its purpose and use in New Zealand.

a) Import permits may direct specific goods to receive clearance on arrival in New Zealand; or
b) Import permits may direct specific goods to be moved to a specific transitional or containment facility on arrival in New Zealand.

i) The transitional or containment facility must be approved at the time of import to an appropriate transitional facility standard, as determined by the specific goods being imported.

(3) Some commodities require a product assessment, as indicated in Part 2. These commodities must be accompanied by an import permit.

Guidance

- Apply for an import permit at MPI Online Import Permit
- For import permits that direct goods to a transitional facility, the application requires the name and address of the transitional/containment facility in New Zealand approved to the appropriate facility standard Facilities for Microorganisms and Cell Cultures: 2007a or Transitional Facilities for Biological Products to which the consignment is to proceed following import.
- Import permits may also direct goods to transitional facilities approved to Transitional Facilities for General Uncleared Risk Goods for holding only.
- Information requested from the importer for a product assessment may include:
  - Types of products of animal origin and the animal species it is derived from;
  - Scientific name of viable microorganism(s), if applicable;
  - Any relevant approvals, for example, HSNO approvals for new organisms, if applicable;
  - Country of origin of the product;
  - Details of processing steps used to produce the product;
  - The purpose and use of the product in New Zealand;
  - Any steps taken to ensure sterility or safety of the product; and
  - Any other relevant information.
- Ensure all relevant documentation is prepared prior to applying for an import permit.

1.8 Documentation that must accompany goods

(1) All documentation that is required by this clause 1.8 to accompany microorganisms, biological products derived from animals, and cell cultures must, unless otherwise stated:

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

(2) The consignment must arrive in New Zealand with the applicable documentation that is specified in Part 2 of this IHS, which meets the requirements of clauses 1.8.1 to 1.8.5 below.

1.8.1 Import permit

(1) An import permit (copy acceptable), as required by this IHS, will specify the number of consignments and period of validity.

1.8.2 Veterinary certificate

(1) A veterinary certificate from the exporting country's Competent Authority or Official Veterinarian, when required by this IHS, 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 and signature of the Competent Authority or Official Veterinarian.
e) Certification and endorsement by the Official Veterinarian that the general requirements outlined in *Part 1: Requirements* of this IHS have been met.
f) Certification and endorsement by the Official Veterinarian that the relevant requirements outlined in Part 2 of this IHS have been met.

(2) 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.

(3) 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.

1.8.3 Manufacturer's or supplier's declaration

(1) A declaration from the manufacturer or supplier (copy acceptable) must accompany the consignment, where indicated by this IHS. The declaration must:

a) Include statements that confirm compliance with the relevant requirements in Part 2 as required by the applicable commodity clauses.
b) Include product descriptors that match with official or commercial documents (e.g. bill of lading).
c) Be prepared by the manufacturer or supplier on official letterhead.
d) Be signed and dated within the last 12 months by the quality manager, supplying organisation's Head of Department, or equivalent.
e) Be endorsed by the government of the exporting country, if required by the relevant section of this IHS.

Guidance

- Commercially manufactured products require a declaration from the manufacturer, where indicated by this IHS.
- Non-commercially manufactured products require a declaration from the supplier, where indicated by this IHS.

- Specifying the section of the IHS the commodity is eligible for import under as part of the manufacturer's declaration may reduce the likelihood of delay clearing the product.

1.8.4 Importer's declaration

(1) A declaration from the importer (copy acceptable) must accompany the consignment, where indicated by this IHS. The declaration must:

a) Include statements that confirm compliance with the relevant requirements in Part 2 or Part 3 of this IHS as required by the relevant commodity clauses.
b) Be prepared by the importer.
c) Be signed and dated within the last 12 months by the approved operator of the importing facility or equivalent.

Guidance

- Specifying the section of the IHS the commodity is eligible for import under as part of the importer's declaration may reduce the likelihood of delay clearing the product.

1.8.5 Certificate of irradiation

(1) 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 clauses in Part 2 of this IHS.
b) Be prepared by the irradiation service provider on letterhead.
c) If hermetically sealed, include product identification codes that link the certificate to the sealed container containing the irradiated product.
d) Be issued by an official government department or a recognised institution.
e) Be signed and dated by the official government department or the quality manager (or equivalent) of the irradiation service provider or equivalent.

1.9 Transition period

(1) From the date of issue to 4 months after the date of issue the requirements of this import health standard for importing microorganisms may be met by complying with the requirements of the *Import Health Standard: Microorganisms from all countries, MICROIC.ALL* dated 31 January 2010 in force immediately before the replacement of the *Import Health Standard Microorganisms from all countries, MICROIC.ALL* dated 31 January 2010.

(2) From the date of issue to 4 months after the date of issue the requirements of this import health standard for importing biological products derived from animals may be met by complying with the requirements of the *Import Health Standard: Biological Products, BIOLOGIC.ALL* dated 14 March 2022 in force immediately before the replacement of the *Import Health Standard Biological Products* dated 14 March 2022.

(3) From the date of issue to 4 months after the date of issue the requirements of this import health standard for importing cell cultures and cell lines may be met by complying with the requirements of the *Import Health Standard: Cell cultures from all countries, CELLCULIC.ALL* dated 31 January 2010 in force immediately before the replacement of the *Import Health Standard Cell cultures from all countries, CELLCULIC.ALL* dated 31 January 2010.

Part 2: Specified requirements for biological products derived from animals

(1) This part specifies the requirements for biological products derived from animals, including products that are derived from microorganisms.

2.1 Products that do not contain live organisms for laboratory use

(1) **All products imported under section 2.1** of this IHS are required to be accompanied by an importer's declaration that complies with clause 1.8.4 of this IHS and confirms the commodity is:

a) For laboratory use only; and
b) Not for use in/on animals.

(2) If the importer is not the end user of the product the declaration must confirm the products are labelled prior to sale or distribution with the following:

a) For laboratory use only; and
b) Not for use in/on animals; and
c) Any other additional statements as required by the clauses for the commodity.

Guidance

- Products imported under section 2.1 are for laboratory use (see Schedule 2 for definition) and are not for *in vivo* research on animals or for manufacturing products that will be used on animals.
- Products that are eligible for import under this section but are imported for a different purpose, for example, non-laboratory use in the environment, or *in vivo* use on animals, may be eligible for import under section 2.2 for use in the environment or section 2.3 for use on animals.
- It is expected that products imported under this section are used for their indicated end use. Declarations from the importer are required for all products in this section to confirm the indicated end use. Declarations may be provided through APIPS.

2.1.1 Amino acids for laboratory use

(1) Amino acids may be imported from any country for laboratory use, provided the following requirements are met:

a) The amino acid must be commercially manufactured and packaged.
b) An importer's declaration as described in clause 2.1 must accompany the consignment.

2.1.2 Nucleic acids for laboratory use

(1) Nucleic acids may be imported from any country for laboratory use, provided the following requirements are met:

a) A manufacturer's or supplier's declaration is required. The declaration must comply with clause 1.8.3 of this IHS and confirm that the nucleic acid is:

i) Naked DNA or RNA that is not contained within a viral vector or microorganism; and
ii) Purified; and

b) An importer's declaration as described in clause 2.1 must accompany the consignment.

Guidance

- These requirements apply to amino acids and nucleic acids that are derived from animal cells. Synthetically produced amino acids and nucleic acids with no animal components are not risk goods and do not need to be imported under an IHS.
- Amino acids and nucleic acids derived from animal tissues for *in vivo* use in animals may be eligible for import under section 2.3.7 of this IHS.
- Amino acids and nucleic acids derived from animal tissues for human use may be eligible for import under the IHS for Specified Animal Products for Human Use, SPECHUMN.ALL.

Guidance for 2.1.2

- Nucleic acids are considered purified when they have been separated from their source cells by a process involving filtration or precipitation or a combination of these methods.
- The declaration required in a) may be prepared by the supplying institution if the nucleic acids are not commercially prepared.

2.1.3 Antibiotics and antimicrobials not for use in/on animals

(1) Antibiotics and antimicrobials may be imported from any country, provided the following requirements are met:

a) The antibiotics or antimicrobials must be commercially manufactured and packaged; and
b) An importer's declaration as described in clause 2.1 must accompany the consignment; and additionally state the products are:

i) Not for use in the production of products to be used on animals.

Guidance

- Antibiotics and antimicrobials for use in animals may be eligible for import under clause 2.3.4 of this IHS.

2.1.4 Viral vectors for laboratory use

(1) Vectors derived from viral sources may be imported from any country.

(2) If the viral vector is non-replicative, the vector may be imported provided the following requirements are met:

a) A manufacturer's declaration is required to accompany each consignment. The declaration must comply with clause 1.8.3 of this IHS and include the following information:

i) The specific vector being imported and its type (i.e. adenoviral, retroviral).
ii) Confirmation that the vector lacks the necessary genes to be able to replicate and specify the genes that have been deleted to render the vector non-replicative.

b) An importer's declaration as described in clause 2.1 must accompany the consignment.

(3) If the viral vector is able to replicate, the vector may be imported provided the following requirements are met:

a) An import permit is required that directs the vector to an appropriately approved transitional facility, subject to a product assessment as per clause 1.7 of this IHS that confirms the risk is effectively managed.
b) If the vector contains genetically modified material, a relevant HSNO approval is required that must be specified on the import permit, and the vector must be directed to an appropriately approved containment facility as per the HSNO approval.

Guidance

- Adenoviral vectors are considered non-replicative when they lack the E1A and E1B genes.
- Retroviral vectors are considered non-replicative when they lack the *gag, pol* and *env* genes.

2.1.4.1 Adeno-associated viral vectors for laboratory use

(1) Adeno-associated viral vectors may be imported from any country, provided the following requirements are met:

a) A manufacturer's declaration is required to accompany each consignment. The declaration must comply with clause 1.8.3 of this IHS and include the following information:

i) Confirmation that the vector is commercially manufactured and packaged; and

b) An importer's declaration as described in clause 2.1 must accompany the consignment.

Guidance

- Viral vectors include adenoviral, lentiviral, and retroviral vectors used for research. If they are able to replicate, EPA approval may be required.
- Confirmation from the EPA that the viral-derived vector is non-replicative may be required. For adenoviral and retroviral vectors, the EPA determination specifying the necessary genes that must be deleted can be found here.
- Adeno-associated viruses are replication-defective.
- Viral vectors for use on animals may be eligible for import under section 2.3.7 for in vivo research or 2.3.8 for veterinary use.

2.1.5 Laboratory test kits

(1) Test kits that do not contain live microorganisms may be imported from any country, provided the following requirements are met:

a) A manufacturer's declaration is required. The declaration must comply with clause 1.8.3 of this IHS and confirm that the test kit is:

i) Commercially manufactured and packaged; and
ii) Does not contain live microorganisms; and

b) An importer's declaration as described in clause 2.1 must accompany the consignment.

Guidance

- Test kits are products containing reagents and other items necessary to conduct an experimental or test procedure in a laboratory.
- Veterinary diagnostic kits may be eligible for import under section 2.3.5 of this IHS.
- Test kits used in non-laboratory settings may be eligible for import under section 2.3.5 of this IHS if they are for veterinary purposes, or section 2.2.7 of this IHS for environmental uses.
- Test kits containing viral vectors may be eligible for import under section 2.1.4 of this IHS.
- Test kits containing live microorganisms may be imported under section 3.1.2 of this IHS.
- Live microorganisms includes organisms that if dried, remain viable.

2.1.6 Culture media

(1) Culture media containing products derived from animals may be imported from any country, provided the following requirements are met:

a) Must be commercially manufactured and packaged; and

b) Either:

i) The packaging identifies the media as sterile; or
ii) A manufacturer's declaration is required. The declaration must comply with clause 1.8.3 of this IHS and confirm:

1) The media is sterilised to completely remove viable microorganisms or render them non-viable; and
2) The specific batch number(s) of the media being imported.

c) An importer's declaration as described in clause 2.1 must accompany the consignment, and additionally state the products are:

i) Not for use in the production of products to be used in/on animals.

(2) Dehydrated culture media, or non-sterile culture media components, may be imported from any country, provided all the following requirements are met:

a) A manufacturer's declaration is required. The declaration must comply with clause 1.8.3 of this IHS and confirm the commodity is:

i) Commercially manufactured and packaged; and
ii) Treated to completely remove viable microorganisms or render any microorganisms non-viable.

b) An importer's declaration as described in clause 2.1 must accompany the consignment, and additionally state the products are:

i) Not for use in the production of products to be used in/on animals.

Guidance

- Culture media for veterinary use such as in artificial reproduction, or for use in the bioproduction of veterinary vaccines may be imported under section 2.3.3 of this IHS.
- Pre-sterilised laboratory culture media for non-laboratory use may be imported under section 2.2.4 of this IHS.
- Dehydrated culture media components are intended to be sterilised prior to use.

2.1.7 Purified products derived from microorganisms for laboratory use

(1) Purified products from microorganisms may be imported from any country, provided the following requirements are met:

a) A manufacturer's declaration is required. The declaration must comply with clause 1.8.3 of this IHS and confirm the commodity is:

i) Commercially manufactured and packaged; and
ii) Purified or sterilised to remove viable microorganisms or render them non-viable; and

b) An importer's declaration as described in clause 2.1 must accompany the consignment, and additionally state the products are:

i) Not for use in the production of products to be used in/on animals.

Guidance

- Purified products produced from microorganisms for veterinary use or *in vivo* research may be imported under section 2.3 of this IHS.

2.1.8 Laboratory reagents and products produced from animal tissue other than blood

(1) Laboratory reagents and products produced from animal tissues, excluding blood, may be imported from any country, provided the following requirements are met:

a) A manufacturer's declaration is required. The declaration must comply with clause 1.8.3 of this IHS and confirm the commodity is:

i) Commercially manufactured and packaged; and
ii) Purified or sterilised to remove microorganisms or render them non-viable.

b) An importer's declaration as described in clause 2.1 must accompany the consignment, and additionally state the products are:

i) Not for use in the production of products to be used in/on animals.

(2) Non-commercially manufactured laboratory reagents and products produced from animal tissues, excluding blood, may be imported from any country, provided all the following requirements are met:

a) A declaration from the supplier is required. The declaration must comply with clause 1.8.3 of this IHS and confirm:

i) The species of animal tissue the product is derived from; and
ii) The product is not derived from blood; and
iii) The product has been treated to completely remove viable organisms or render them non-viable;

b) An importer's declaration as described in clause 2.1 must accompany the consignment, and additionally state the products are/will be:

i) Not for use in the production of products to be used in/on animals; and
ii) Appropriately destroyed after use by autoclaving or other laboratory-approved disposal method.

Guidance

- Products derived from blood may be imported under section 2.1.9.
- Laboratory reagents and products produced from animal tissue for use in animals may be eligible for import under section 2.3.
- Non-commercially manufactured products from microorganisms may be eligible for import under section 2.1.11.
- Non-commercially manufactured laboratory reagents and products produced from animal tissues excluding blood for *in vivo* use in animals may be eligible for import under section 2.3.7.

2.1.9 Laboratory products derived from animal blood

2.1.9.1 Purified antibodies and antisera

(1) Purified antibodies and antisera derived from any species, including recombinant sources, may be imported from any country, provided the following requirements are met:

a) An importer's declaration as described in clause 2.1 must accompany the consignment, and additionally state the products are/will be:

i) Not for use in the production of products to be used in/on animals; and

b) One of the following options is required. Either:

i) The product must be commercially manufactured and packaged; and is purified and labelled as purified; or
ii) A manufacturer's declaration is required that complies with clause 1.8.3 of this IHS and confirms:

1) The product is commercially manufactured and packaged; and
2) The product is purified.

2.1.9.2 Unpurified antibodies and antisera derived from laboratory-raised guinea pigs, hamsters, mice, rabbits or rats

(1) Unpurified antibodies and antisera derived from laboratory-raised guinea pigs, hamsters, mice, rabbits, and rats may be imported from any country, provided the following requirements are met:

a) Must be commercially manufactured and packaged; and
b) An import permit is required, subject to a product assessment as per section 1.7 that confirms the risk is effectively managed; and
c) An importer's declaration as described in clause 2.1 must accompany the consignment, and additionally state the products are/will be:

i) Not for use in the production of products to be used in/on animals

Guidance

- Antibodies and antisera imported under section 2.1.9 are not for use in animals. Antibodies and antisera for use in animals may be eligible for import under section 2.3.
- Unpurified antibodies from other species not mentioned in section 2.1.9.2 may be eligible for import under section 2.1.11.

2.1.9.3 Inactivated panels containing antibodies, antigens, or serological fluids for diagnostic testing or quality assurance

(1) Inactivated panels containing antisera, antigens, or serological fluids from any species for diagnostic testing may be imported from any country, provided the following requirements are met:

a) An import permit is required, subject to a product assessment as per section 1.7 that confirms the risk is effectively managed.

i) The product assessment requires:

1) Information from the manufacturer specifying the species and source the panel material is derived from, and the inactivation method carried out on the panel material, and
2) A description of the use of the panel.

b) A manufacturer's declaration is required that complies with section 1.8.3 of the IHS and confirms:

i) The inactivation method, specifying inactivation parameters as appropriate; and
ii) The products are inactivated and contain no infectious particles; and

c) An importer's declaration as described in clause 2.1 must accompany the consignment, and additionally state the products are/will be:

i) Not for use in the production of products to be used in/on animals.

(2) If the requirements in (1) cannot be met, inactivated panels containing antisera, antigens, or serological fluids from any species for diagnostic testing may be imported for use in a transitional facility provided the following requirements are met:

a) An import permit is required, directing the panels to an appropriately approved transitional facility; and
b) The panels are destroyed after use; and
c) A manufacturer's declaration is required that complies with clause 1.8.3 of this IHS and confirms:

i) The panel material has been inactivated.

Guidance

- Panels containing live microorganisms may be imported under section 3.1.1, 3.1.3, or 3.1.4 of this IHS.

2.1.9.4 Other purified and/or sterilised products derived from blood for laboratory use

(1) Purified and/or sterilised products derived from blood, excluding serum products and bovine serum albumin (BSA), may be imported from any country provided the following requirements are met.

a) A manufacturer's declaration is required. The declaration must comply with clause 1.8.3 of this IHS and confirm that the commodity is:

i) Commercially manufactured and packaged; and
ii) Sterilised or purified to completely remove microorganisms or render any microorganisms non-viable; and

b) An importer's declaration as described in clause 2.1 must accompany the consignment, and additionally state the products are:

i) Not for use in the production of products to be used in/on animals

Guidance

- Purified and/or sterilised products derived from blood for use in/on animals may be eligible for import under section 2.3 of this IHS.

2.1.9.5 Dried animal samples on long-term DNA preservation cards for laboratory use

(1) Dried blood or other fluid samples stored on long-term DNA preservation cards may be imported from any country, provided the following requirements are met.

a) An import permit is required, subject to a product assessment as per section 1.7 that confirms the risk is effectively managed.

i) The product assessment requires:

1) Information on the type of samples and the animals they are collected from; and
2) Confirmation that the cards will be used for metabolic or nucleic acid analysis only; and
3) Confirmation that there are chemicals on the long-term DNA preservation card to inactivate risk organisms.

b) An importer's declaration as described in clause 2.1 must accompany the consignment.

Guidance

- Long-term DNA preservation cards include FTA cards and other similar products that are designed to preserve DNA in blood or other fluid samples for analysis.

2.1.9.6 Fetal bovine serum or bovine serum albumin for laboratory use

(1) Fetal bovine serum or bovine serum albumin for laboratory use may be imported from any country, provided the following requirements are met.

a) A manufacturer's declaration is required. The declaration must comply with clause 1.8.3 of this IHS and confirm that the fetal bovine serum or bovine serum albumin are:

i) Manufactured, packaged, stored, and transported using processes that comply with industry-accepted codes of good manufacturing practice, and using a quality system that complies with the current version of ISO 9001; and
ii) Commercially packaged; and
iii) Filtered with 0.22 µM filtration or equivalent; and
iv) Not packaged in containers larger than 100 mL in volume, with the total volume of the consignment not greater than 2 litres.

b) An importer's declaration as described in clause 2.1 must accompany the consignment, be provided by the facility where the fetal bovine serum or bovine serum albumin will be used in New Zealand, and additionally state the products are/will be:

i) Not for use in the production of products for use in/on animals; and
ii) For use within an accredited facility that operates under and maintains records of standard operating procedures (SOPs); and
iii) Destroyed after use by autoclaving or incineration according to the facility's standard operating procedure.

Guidance

- Section 2.1.9.6 applies to fetal bovine serum derived from unborn bovine fetuses and bovine serum albumin only.
- Other bovine serum products, bovine serum products in larger volumes, or for other uses may be imported under section 2.1.9.7 of this IHS for unprocessed bovine serum products for direction to a transitional facility; or section 2.2.3 for treated bovine serum products for clearance.

2.1.9.7 Unprocessed bovine serum products

(1) Bovine serum products for further processing may be imported from any country, provided the following requirements are met:

a) The product must be commercially manufactured, packaged, and sealed; and
b) An import permit is required, and the product must be moved to and used within the appropriately approved transitional facility named on the permit; and
c) A manufacturer's declaration is required. The declaration must comply with clause 1.8.3 of this IHS and confirm:

i) The specific bovine serum product being imported; and
ii) The product was manufactured, packaged, stored, and transported using processes that comply with industry-accepted codes of good manufacturing practice, and using a quality system that complies with the current version of ISO 9001; and
iii) Either:

1) Certify that product sourced from abattoirs was derived from animals which passed antemortem and postmortem inspection and were processed in premises under the supervision of the competent authority; or
2) Certify that 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

d) A veterinary certificate is required. The certificate must comply with clause 1.8.2 of this IHS and state that, after due enquiry, there is no reason to doubt the veracity of the manufacturer's declaration.
e) In addition, for bovine serum, newborn calf serum, calf serum and any other bovine blood products that are not derived from fetal blood, the veterinary certificate must attest that:

i) Either:

1) The blood and blood products were derived from bovines that were identified through an animal identification system and were born and kept in a country, zone or compartment posing a negligible risk of BSE according to WOAH.

ii) Or:

1) The blood and blood products were collected from bovines not subjected to a stunning process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, or to any other procedure that can contaminate the blood with nervous tissue prior to slaughter; and

2) The blood and blood products were collected and processed in a manner that ensures they are not contaminated with nervous tissue.

Guidance

- A model veterinary certificate that meets the requirements in 2.1.9.7 can be found in Schedule 3 of this IHS.

2.1.10 Microscope slides of fixed biological material without coverslips for laboratory use

(2) Microscope slides of animal tissue without coverslips may be imported from any country, provided the following requirements are met:

a) A manufacturer's or supplier's declaration is required. The declaration must comply with section 1.8.3 of this IHS and confirm:

i) The slides are for laboratory use; and
ii) The fixative solution is one of the following:

1) A minimum concentration of 10% liquid formalin; or
2) A minimum concentration of 4% formaldehyde; or
3) A minimum concentration of 4% paraformaldehyde; or
4) A minimum concentration of 70% alcohol; or
5) Glyoxal if equal to or less than 2mm thick; or
6) 2-4% glutaraldehyde **for tissues less than 2mm thick for electron microscope imaging or for larger samples by intravascular active perfusion;** or
7) A minimum concentration of 1% Lugol's solution **for zooplankton samples only;** or
8) Sodium acetate-acetic acid-formalin (SAF) with a minimum concentration of 2.5% formalin **for intestinal parasites and faecal specimens only.**

b) An importer's declaration as described in clause 2.1 must accompany the consignment.

Guidance

- Microscope slides with coverslips and other preserved animal samples for use outside a laboratory may be imported under section 2.4 of this IHS.

2.1.11 Other biological products for laboratory use that do not contain viable organisms

(1) Biological products that fall within the scope of this IHS but are not listed in section 2.1 may be imported from any country, subject to a product assessment as per section 1.7.

a) The outcome of the product assessment determines the requirements. One of the following options will apply when the product is not for use in/on animals. Either:

i) An import permit and importer's declaration are required; or
ii) An import permit is required, and the product must be moved to and used within the appropriately approved transitional facility named on the permit; or
iii) The product is not eligible for import.

Guidance

- Section 1.8 has guidance on the type of information required for a product assessment.
- Section 2.1.11 is for products for laboratory use only, and not for products for use in/on animals nor in the production of products to be used in/on animals.
- Products for use in/on animals or in the production of products to be used in/on animals may be imported under section 2.3 of this IHS.
- Biological products that may be viable or contain viable microorganisms can be assessed under Part 3 of this IHS.

2.2 Biological products for any use, excluding human therapeutics and consumption

Guidance

- Commodities eligible for import under this section include biological products imported for a variety of uses, including but not limited to use in building materials, technical use excluding use on humans, or other non-laboratory uses.
- Products imported under this section are not restricted to laboratory use and therefore may be used on animals, unless specified. Additional ACVM requirements may apply.
- Products for veterinary use in/on animals are eligible for import under section 2.3 of this IHS.
- Products for human therapeutic use or human consumption may be eligible for import under the IHS for *Specified Animal Products for Human Consumption* SPECHUMN.ALL.

2.2.1 Dicalcium phosphate

(1) Dicalcium phosphate derived from degreased bones from any country may be imported, provided the following requirements are met:

a) The product must be accompanied by an official certificate stating it has no trace of protein or fat.

Guidance

- The model certificate template in Schedule 3 meets the certification requirement in section 2.2.1 and may be used for trade.
- Dicalcium phosphate that does not meet the requirements in section 2.2.1 of this IHS may be eligible for import under the IHS *Ruminant Meat and Ruminant Meat Products RUMNPROD.GEN*.

2.2.2 Highly processed collagen/protein products

(1) Commercially manufactured, highly processed collagen/protein products may be imported from any country.

Guidance

- Examples of highly processed collagen/protein products are keratin setting retarder for plaster-making, hydrolysed collagen, and other products containing animal proteins for use in the building trade (e.g. Durafoam protein).
- These requirements do not apply to highly processed collagen and protein products for human consumption. Those products may be eligible for import under the IHS for *Specified Animal Products for Human Consumption* SPECHUMN.ALL.

2.2.3 Treated bovine serum products

2.2.3.1 Tested, filtered, and irradiated bovine serum products from Australia

(1) Bovine serum products may be imported from Australia, provided the following requirements are met:

a) The product must be commercially manufactured, packaged, and sealed; and
b) A manufacturer's declaration is required. The declaration must comply with clause 1.8.3 of this IHS and confirm:

i) The product was manufactured, packaged, stored, and transported using processes that comply with industry-accepted codes of good manufacturing practice, and using a quality system that complies with the current version of ISO 9001; and

ii) The product has been subject to triple 0.1 micron membrane filtration, has been irradiated with a single or multiple radiation dose/s totalling 25 kGy, and the product has been tested and found free of mycoplasma, bovine virus diarrhoea, infectious bovine rhinotracheitis, bluetongue, and parainfluenza-3 using the methods described by relevant WOAH guidelines; and

iii) Either:

1) Certify that product sourced from animals that passed antemortem and postmortem inspection and were processed in premises under the supervision of the competent authority; or
2) Certify that the 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

c) A veterinary certificate is required. The certificate must comply with clause 1.8.2 of this IHS and state that, after due enquiry, there is no reason to doubt the veracity of the manufacturer's declaration.

d) For bovine serum, newborn calf serum, calf serum and any other bovine blood products that are not derived from fetal blood, the veterinary certificate must attest that:

i) Either:

1) The blood and blood products were derived from bovines that were identified through an animal identification system and were born and kept in a country, zone or compartment posing a negligible risk of BSE according to WOAH.

ii) Or:

1) The blood and blood products were collected from bovines not subjected to a stunning process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, or to any other procedure that can contaminate the blood with nervous tissue prior to slaughter; and
2) The blood and blood products were collected and processed in a manner that ensures they are not contaminated with nervous tissue.

2.2.3.2 Filtered and irradiated bovine serum products from any country

(1) Bovine serum products may be imported from any country, provided the following requirements are met:

a) The product must be commercially manufactured, packaged, and sealed; and

b) A manufacturer's declaration is required. The declaration must comply with clause 1.8.3 of this IHS and confirm:

i) The product was manufactured, packaged, stored, and transported using processes that comply with industry-accepted codes of good manufacturing practice, and using a quality system that complies with the current version of ISO 9001; and

ii) The product has been filtered to 0.22 micron (or smaller) and has been irradiated with a single or multiple radiation dose/s totalling 40 kGy; and

iii) Either:

1) Certify that product sourced from abattoirs was derived from animals that passed antemortem and postmortem inspection and were processed in premises under the supervision of the competent authority; or
2) Certify that 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

c) A veterinary certificate is required. The certificate must comply with clause 1.8.2 of this IHS and state that, after due enquiry, there is no reason to doubt the veracity of the manufacturer's declaration.

d) In addition, for bovine serum, newborn calf serum, calf serum and any other bovine blood products that are not derived from fetal blood, the veterinary certificate must attest that:

i) Either:

1) The blood and blood products were derived from bovines that were identified through an animal identification system and were bone and kept in a country, zone or compartment posing a negligible risk of BSE according to WOAH.

ii) Or:

1) The blood and blood products were collected from bovines not subjected to a stunning process with a device injecting compressed air or gas into the cranial cavity, or to a pithing process, or to any other procedure that can contaminate the blood with nervous tissue prior to slaughter; and
2) The blood and blood products were collected and processed in a manner that ensures they are not contaminated with nervous tissue.

Guidance

- Bovine serum products include fetal bovine serum, calf serum, bovine serum, and bovine serum albumin.
- Small volumes of bovine serum products for laboratory use may be eligible for import under section 2.1.9.6 of this IHS.
- Unprocessed bovine serum products for use in a transitional facility may be eligible for import under section 2.1.9.7 of this IHS.
- Bovine serum products included in media for use in/on animals or in veterinary vaccines may be eligible for import under section 2.3 of this IHS.
- A model veterinary certificate that meets the requirements under 2.2.3.1 for tested, filtered and irradiated bovine serum products from Australia can be found in Schedule 3 of this IHS.
- A model veterinary certificate that meets the requirements under 2.2.3.2 for bovine serum products from all countries can be found in Schedule 3 of this IHS.
- Sample certificates negotiated under this clause can be found in Schedule 3 of this IHS.

2.2.4 Sterilised culture media not restricted to laboratory use and not for use in/on animals

(1) Sterilised culture media containing products of animal origin may be imported from any country, provided the following requirements are met:

a) Must be commercially manufactured and packaged; and
b) A manufacturer's declaration is required. The declaration must comply with clause 1.8.3 of this IHS and confirm:

i) The media has been sterilised to completely remove viable microorganisms or render any microorganisms non-viable; and
ii) The batch number/s of the media being imported that link to batch numbers visible on the packaging of the media.

c) An importer's declaration is required. The declaration must comply with clause 1.8.4 of this IHS and confirm:

i) The media is not for use in the production of products destined for use in/on animals.

Guidance

- Non-sterile media for laboratory use may be imported under section 2.1.6 of this IHS.
- Non-sterile media for non-laboratory use, excluding use in/on animals, may be imported under section 2.2.7 of this IHS, subject to a product assessment.

- Non-sterile media for use in/on animals may be imported under section 2.3.7 of this IHS.

2.2.5 Emu oil from Australia

(1) Emu oil and products containing emu oil may be imported from Australia when accompanied by a government-endorsed manufacturer's declaration that certifies that the emu oil was subjected to a heat treatment process that is effective in raising the core temperature of the product to a minimum of 100°C for at least 1 minute during manufacturing.

Guidance

- The model certificate in Schedule 3 meets the certification requirements in clause 2.2.5 and may be used for trade.

2.2.6 Ovine and bovine concentrated bile and bile derivatives

(1) Ovine and bovine concentrated bile may be imported from any country provided the product is accompanied by an official certificate that states the product:

a) Has been collected from animals that have passed ante- and post-mortem inspection at premises with competent authority oversight; and
b) Has undergone heat treatment of 100°C for a minimum of 5 hours; and
c) Has been managed in a way that prevents contamination before dispatch from the processing premises; and
d) Is in packaging that is clean and free from visible signs of contamination.

(2) Bile derivatives from ovine and bovine animals may be imported from any country, provided the product is identified as a derivative that originates from bile.

Guidance

- The model certificate in Schedule 3 meets the certification requirements in clause 2.2.6 and may be used for trade.

2.2.7 Other animal products not specifically listed

(1) Other animal products that are not specifically listed in section 2.2 may be eligible for import from any country, provided the product is not eligible for import under another import health standard. The following requirements must be met:

a) An import permit is required, subject to a product assessment as per section 1.7 that confirms the risk is effectively managed.

i) Information to support the product assessment must be provided to MPI. This may include:

1) The nature of the product and animal species it is derived from; and
2) Country of origin of the product; and
3) Details of processing steps used to produce the product; and
4) The purpose/use of the product in New Zealand; and
5) Any steps taken to ensure sterility and/or safety of the product; and
6) Any other relevant information.

Guidance

- Products that are eligible for import under section 2.1 for laboratory use only may be imported under this section for non-laboratory use, subject to a product assessment.
- Products that are assessed and determined to pose an unacceptable risk to New Zealand's biosecurity are not eligible for import.

2.3 Biological products for animal, veterinary, or environmental use

2.3.1 Catgut suture

2.3.1.1 Catgut suture derived from bovine material

(1) Bovine origin catgut suture may be imported from any country, provided the following requirements are met:

a) Must be commercially manufactured and packaged; and
b) An import permit is required, subject to a product assessment as per section 1.7 that confirms the risk is effectively managed.

i) The product assessment requires the following information:

1) The manufacturer must confirm the suture is made of purified connective tissue derived from the serosal layer of bovine intestines from which the distal ileum has been discarded by the raw material supplier or during manufacturing; and
2) Details of the manufacturing process.

2.3.1.2 Catgut suture derived from ovine or caprine material

(1) Ovine or caprine origin catgut suture may be imported from any country, provided the following requirements are met.

a) Must be commercially manufactured and packaged; and
b) An import permit is required, subject to a product assessment as per section 1.7 that confirms the risk is effectively managed.

i) The product assessment requires the following information:

1) Assurance endorsed by the competent authority of the exporting country that the ovine or caprine materials were derived from animals born and raised in a scrapie free country, zone or establishment, according to the WOAH Terrestrial Code 14.8.3; and
2) Details of the manufacturing process.

2.3.2 Veterinary implants

(1) Veterinary implants may be imported from any country, provided the following requirements are met:

a) Must be sterile; and
b) Must not include any ruminant-derived materials; and
c) A manufacturer's declaration is required. The declaration must comply with clause 1.8.3 of this IHS and confirm:

i) The product is treated to completely remove viable microorganisms or render any microorganisms non-viable; and
ii) The product does not contain any material derived from ruminant animals.

(2) Veterinary implants that do not meet the requirements above may be eligible for import from any country, provided the following requirements are met:

a) An import permit is required, subject to a product assessment as per section 1.7 that confirms the risk is effectively managed.

i) The product assessment requires the following information:

1) The source of the animal-derived components and the health status of the animals the materials are derived from; and
2) The country of origin of the animal products and the country of export; and

3) The manufacturing process including sterilisation parameters and any other treatment; and
4) The intended recipient species and/or end use in New Zealand; and
5) Any other relevant factors.

Guidance

- Veterinary implants assessed under 2.3.2 and determined to pose an unacceptable biosecurity risk to New Zealand are not eligible for import.

2.3.3 Components for veterinary products

(1) Components for incorporation into products for veterinary use may be imported from any country, provided the following requirements are met:

a) The product must be commercially manufactured and packaged; and
b) An import permit is required, subject to a product assessment as per section 1.7 that confirms the risk is effectively managed.

i) The product assessment for veterinary product components requires the following information:

1) The source species of the animal product components and the health status of the donor animals; and
2) The country of origin of the donor animals; and
3) The country of export; and
4) The processing or treatment applied to the component prior to shipment; and
5) The intended use of the product; and
6) Any other relevant factors.

Guidance

- Veterinary product components assessed under clause 2.3.3 and determined to pose an unacceptable biosecurity risk to New Zealand are not eligible for import.

2.3.4 Agricultural compounds and veterinary medicines that require authorisation under the ACVM Act

(1) Agricultural compounds and veterinary medicines that are registered, provisionally registered, or subject to research or special circumstances approvals, authorised under the relevant sections of the ACVM Act may be imported from any country, provided the following requirements are met:

a) An ACVM authorisation is required, subject to a product assessment as per section 1.7 that confirms the risk is effectively managed.
b) Veterinary medicines authorised under section 21 (registration) of the ACVM Act must be in ACVM-approved packaging.

Guidance

- Further information regarding requirements of the ACVM Act for importing agricultural compounds can be found at: Importing agricultural chemicals ACVM.

2.3.5 Veterinary diagnostic kits

(1) Veterinary diagnostic kits that contain no viable microorganisms may be imported from any country, provided the following requirements are met:

a) A manufacturer's declaration is required that complies with clause 1.8.3 of this IHS and confirms:

i) The kit is commercially manufactured and packaged; and

ii) The kit contains no viable microorganisms; and
iii) The kit components derived from animals have been processed or purified to ensure no contaminating microorganisms are present; and
iv) The analytical procedure of the kit involves a sample taken from the subject animal and is not directly applied to a live animal.

Guidance

- Veterinary diagnostic kits may require a class determination under the ACVM Act. More information can be found at: Importing agricultural chemicals ACVM.
- Veterinary diagnostic kits that do not meet the requirements of section 2.3.5 may be eligible for import under section 2.3.7 of this IHS.

2.3.6 Bovine serum products for in vivo use in animals

(1) Bovine serum products for use in animals or contained in products that are used in animals may be imported from any country, provided the following requirements are met:

a) An import permit is required, subject to a product assessment as per section 1.7 that confirms the risk is effectively managed.

i) The product assessment for bovine serum products for in vivo use requires the following information:

1) The type of bovine serum product being imported; and
2) The health status of the donor animals; and
3) The country of origin of the donor animals; and
4) The country of export; and
5) Information about how the product is manufactured, including any quality control systems used by the facility; and
6) Evidence the product has been treated as described in section 2.2.3, or equivalent; and
7) The use of the products in New Zealand including the species of animals the product will be used on; and
8) Any other relevant information.

Guidance

- Bovine serum products assessed under clause 2.3.6 and determined to pose an unacceptable biosecurity risk to New Zealand are not eligible for import.

2.3.7 Biological products for in vivo use in laboratory animals

(1) Biological products derived from animals or microorganisms for in vivo use in/on animals that are not otherwise listed in section 2.3 may be imported from any country, provided the following requirements are met:

a) An import permit is required, subject to a product assessment as per section 1.7 that confirms the risk is effectively managed.

i) The product assessment for biological products for in vivo use requires the following information:

1) The species the product is derived from and the health status of the donor animals; and
2) The species the products will be used on; and

3) The type of animals the research will be carried out on and details about where they are housed; and
4) The product components, and processing and manufacturing information, including any disease testing or sterilisation procedures; and
5) Any other relevant information, which may include whether the facility holds a general approval for use of imported biological products on laboratory animals, and a description of how the product is covered by that approval.

(2) If the product assessment cannot confirm the risks are managed, the product may be eligible for direction to a transitional facility for use on animals within the facility, provided the following requirements are met:

a) An import permit is required, subject to a product assessment as per section 1.7 that confirms the risk is effectively managed by direction to the transitional facility named on the permit for use on animals within that facility.

Guidance

- Biological products assessed under clause 2.3.7 and deemed to pose an unacceptable biosecurity risk to New Zealand are not eligible for import.

2.3.8 Other biological products for veterinary or environmental use including ACVM-exempt commodities

(1) Other products derived from animals for veterinary or environmental use may be imported from any country, provided the following requirements are met.

a) Must be commercially manufactured and packaged; and
b) An import permit is required, subject to a product assessment as per section 1.7 that confirms the risk is effectively managed.

i) The product assessment for biological products for veterinary or environmental use requires the following information:

1) The species the product is derived from and the health status of the donor animals; and
2) Any manufacturing processes or treatments applied to the product; and
3) The end use and purpose of the product; and
4) Any other relevant factors.

Guidance

- BSE risk goods may only be assessed for import from countries with a negligible BSE risk status according to WOAH - Bovine spongiform encephalopathy aka BSE- WOAH.
- Products eligible for import under section 2.3.8 includes fertilisers including manure-derived, herbicides, and other products that are described in Column 1 of Schedule 2 of the Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011.
- ACVM-exempt products may require a class determination under the ACVM Act; contact ACVM for further guidance.
- Biological products assessed under section 2.3.8 and deemed to pose unacceptable biosecurity risk to New Zealand are not eligible for import.

2.4 Preserved animal specimens

2.4.1 Preserved animal specimens

(1) Preserved animal specimens (including whole animals) may be imported from any country, provided the following requirements are met:

a) A manufacturer's declaration is required. The declaration must comply with clause 1.8.3 of this IHS and confirm:

i) That the commodity is preserved with one of the following methods:

1) A minimum concentration of 10% formalin; or
2) A minimum concentration of 70% alcohol; or
3) A minimum concentration of 4% formaldehyde; or
4) A minimum concentration of 4% paraformaldehyde; or
5) A minimum concentration of 1% Lugol's solution, **for zooplankton samples only;** or
6) Sodium acetate-acetic acid-formalin (SAF) with a minimum concentration of 2.5% formalin, **for intestinal parasites and faecal specimens only.**

(2) Preserved specimens of animal tissues may be imported from any country, provided the following requirements are met:

a) A manufacturer's declaration is required. The declaration must comply with clause 1.8.3 of this IHS and confirm:

i) That the commodity is preserved with one of the following methods:

1) Fixed in 2% to 4% glutaraldehyde for samples less than 2 mm thick; or
2) Fixed in 2% to 4% glutaraldehyde for larger samples by intravascular active perfusion; or
3) Fixed in glyoxal if less than or equal to 2 mm thick.

(3) Preserved marine or freshwater molluscs may be imported from any country, provided the following requirements are met:

a) The mollusc is fixed in formalin.

Guidance

- Section 2.4.1(1) applies to preserved parasites and animal faecal specimens as well as whole animals and samples of animal tissue.
- Samples of animal tissues may be preserved using any of the methods specified in 2.4.1(1) or 2.4.1(2).

2.4.2 Irradiated whole animals

(1) Irradiated whole animals may be imported from any country, provided the following requirements are met:

a) A certificate of irradiation is required that complies with clause 1.8.5 of this IHS and confirms that the whole animal has been:

i) Subjected to a minimum radiation dose of 50 kGy; and
ii) Contained in a hermetically sealed container that is linked to the certificate of irradiation.

2.4.3 Microscope slides of fixed biological materials, including animal tissue

(1) Microscope slides of animal tissue may be imported from any country, provided the following requirements are met:

a) The animal tissue must be fixed onto glass microscope slides; and

b) The animal tissue must be under glass coverslips.

Guidance

- Section 2.4.3 applies to microscope slides of animal tissue as well as bacteria and protozoa.
- Microscope slides of fixed biological materials without coverslips for laboratory use may be imported under section 2.1.10 of this IHS.

2.4.4 Dried or preserved invertebrates including commercially prepared insects

(1) Dried or preserved invertebrates may be imported from any country, provided the following requirements are met:

a) A manufacturer's declaration is required. The declaration must comply with section 1.8.3 of this IHS and confirm:

i) The commodity is free of visible and viable pests; or
ii) The commodity has been treated pre-export by fumigation with methyl bromide.

b) Dried and preserved invertebrates that do not meet the requirements in (a) may be imported from any country, provided they are treated by fumigation with methyl bromide at the port of entry at the importer's expense.

(2) Commercially prepared insects in glass display cases may be imported from any country, provided the following requirements are met:

a) The packaging or associated documentation must confirm that the commodity is commercially prepared and is an insect; or
b) If the requirements in (a) cannot be met, a manufacturer's declaration is required. The declaration must comply with section 1.8.3 of this IHS and confirm:

i) The commodity is commercially prepared and is an insect.

(3) Invertebrates that are embedded in amber, resin, or similar solid coating may be imported from any country, provided the following requirements are met:

a) The packaging or associated documentation must confirm that the commodity is an invertebrate and is embedded in amber, resin, or similar solid coating; or
b) If the requirements in (a) cannot be met, a manufacturer's declaration is required. The declaration must comply with section 1.8.3 of this IHS and confirm:

i) The commodity is an invertebrate and is embedded in amber, resin, or similar solid coating.

Guidance

- Importers are advised that there are limited treatment facilities operating, which may mean that there are no treatment options for non-compliant goods.

2.4.5 Specified items of animal origin

(1) Commercially manufactured specified items of animal origin listed below may be imported from any country.

a) Animal skin/hide glue (see Schedule 2 for definition)
b) Game trophies from the EU that are accompanied by a veterinary certificate.
c) Goldbeater's skin.
d) Ornamental products (see Schedule 2 for definition).
e) Parchment or vellum.

(2) Specified items of animal origin that are listed below may be imported from any country, provided they are clean, free from visible contamination (see definition in Schedule 2), and meet any additional requirements below:

a) Antlers, beaks, bones, claws, hooves, horns, skulls, teeth, and tusks (either mounted or unmounted).
b) Coral that is non-viable and dry.
c) Egg shell ornaments, including blown eggs.
d) Finished game trophies (see Schedule 2 for definition).
e) Fly-tying material containing animal skin and/or hair that is dyed.
f) Shells (terrestrial and marine) and marine ornaments that are dry.
g) Rawhide articles and handicrafts.

Guidance for 2.4.5

- Importers are reminded of their obligation to meet applicable CITES requirements.
- Non-compliant items may be treated on arrival in accordance with MPI *Approved Biosecurity Treatments MPI-STD-ABTRT*.
- Importers are advised that there are limited treatment facilities operating, which may mean that there are no treatment options for non-compliant goods.

Guidance for 2.4.5(1)b)

- The agreed certificate in Schedule 3 may be used for trade.
- Personal consignments of game trophies may be imported under the IHS *Personal Consignments of Animal Products PERSONAL.ALL*.
- Commercial consignments of hides and skins are not eligible for import under this IHS and may be imported under the IHS *Hides and Skins HIDESKIN.ALL*.

Guidance for 2.4.5(2)a)

- This clause may apply to curios, buttons, jewellery, paper knives, and ornamental carapace of turtles/tortoises.

Guidance for 2.4.5(2)b)

- Live coral is not eligible for import under this IHS and may be imported under the IHS *Ornamental Fish and Marine Invertebrates ORNAMARI.ALL*.

Guidance for 2.4.5(2)d)

- This clause may apply to small birds, long-tailed animals, bear skins with paws and claws attached, and bison skins with muzzles.

Guidance for 2.4.5(2)f)

- If the shape of the shell includes inner parts not visible for inspection to determine that it is dry, the item may be treated, reshipped, or destroyed.

Guidance for 2.4.5(2)g)

- This clause may apply to artworks, traditional drums, hunting shields, cultural heritage items, or items of cultural value that are used for performance or decorative purposes.
- If the complete surface area of the rawhide is not visible for inspection, the item may be treated, reshipped, or destroyed.

Part 3: Specified requirements for microorganisms, products containing microorganisms, and cell lines

3.1 Cultures and products containing microorganisms

Guidance

- The requirements for importing microorganisms depend on their risk, as determined by whether they are new organisms, unwanted organisms, or regulated organisms.
- The EPA maintains a list of microorganisms deemed present in New Zealand under the HSNO Act, following a statutory declaration or non-statutory advice request. The list can be found here under "Databases of organisms present in New Zealand".
- The list of unwanted and regulated organisms can be found by checking the Pests of concern list on the Official New Zealand Pest Register.
- Microorganisms assessed to pose unacceptable biosecurity risk to New Zealand are not eligible for import.

3.1.1 Microorganisms that are not new, or unwanted, or regulated organisms

(1) Microorganisms may be imported from any country for laboratory use only, provided that the following requirements are met.

a) A declaration from the supplier is required. This declaration must comply with section 1.8.3 of this IHS and confirm:

i) The species of microorganism/s being imported (full scientific name); and
ii) The microorganism/s is/are not genetically modified; and

b) An importer's declaration is required. This declaration must comply with section 1.8.4 of this IHS and confirm:

i) The species of microorganism/s being imported (full scientific name); and
ii) The microorganism/s is/are not an unwanted organism (as per the Official New Zealand Pest Register); and
iii) The microorganism/s is/are not a regulated organism; and
iv) The microorganism/s is/are not new as determined by the Environmental Protection Authority (EPA) under the Hazardous Substances and New Organisms (HSNO) Act and indicated in their database HSNO application register | EPA; and
v) Either:

1) The species is/are on the EPA's list of microorganisms present in New Zealand; or
2) Provide evidence that MPI or the EPA has confirmed the organism/s is/are likely present in New Zealand.

vi) The microorganism/s is/are for laboratory use only.
vii) The microorganism/s are for use by [importer].

(2) Microorganisms that are not new organisms, are not regulated organisms, and are not unwanted organisms, or products containing such organisms for use outside of the laboratory may be imported from any country, provided the following requirements are met:

a) An import permit is required, subject to a product assessment as per section 1.7 that confirms the biosecurity risk is effectively managed.

i) Information to support the product assessment must be provided to MPI. This may include:

1) The name of the product and manufacturer; and
2) A description of all ingredients or components of the product; and

3) The full scientific name of all viable microorganisms in the product; and
4) Details of the manufacturing, processing, and any treatments applied to ingredients or the final product; and
5) Evidence that the product meets acceptable levels of microbial contaminants.

Guidance for 3.1.1(1)

- The list of microorganisms present in New Zealand maintained by the EPA can be found here under "Databases of organisms present in New Zealand".
- If the microorganisms are contained within plant material imported for research, the supplier's declaration may be supplied as part of the permit application for the plant material under the IHS for *Research Samples (excluding animal samples)* RESEARCH.IHS.
- If the importer is not the end user of the microorganisms, the requirements in 3.1.1(2) apply.

Guidance for 3.1.1(2)

- Products containing microorganisms that meet the requirements may be imported under 3.1.1(2).
- Information about the acceptable levels of microbial contaminants and the product analysis evidence required can be found on the APIPS permit application for these products.
- If the microorganisms are contained within plant material imported for research, the supplier's declaration may be provided as part of the permit application for plant material under the IHS for *Research Samples (excluding animal samples)* RESEARCH.IHS.
- Probiotic foods containing viable microorganisms for human or animal consumption are eligible for import under the relevant IHS: SPECHUMN.ALL for human foods containing probiotic organisms, and ANIFOOD.ALL for animal foods containing probiotic organisms.

3.1.2 Test kits containing microorganisms that are not new, and not unwanted, and not regulated organisms

(1) Test kits containing microorganisms may be imported from any country for laboratory use only, provided that the following requirements are met:

a) A manufacturer's declaration is required. The declaration must comply with clause 1.8.3 of this IHS and confirm:

i) The commodity is commercially manufactured and packaged; and
ii) The species of microorganism (full scientific name) is included in the kit as a pure culture; and
iii) The microorganism is not genetically modified; and
iv) Either:

b) An importer's declaration is required. The declaration must comply with clause 1.8.4 of this IHS and confirm:

i) The species of microorganism included in the kit (full scientific name) and
ii) The microorganism included in the kit is not an unwanted organism (as per the Official New Zealand Pest Register); and
iii) Either:

1) The species is/are on the EPA's list of microorganisms present in New Zealand; or
2) Provide evidence that MPI or the EPA has confirmed the organism/s is/are likely present in New Zealand; and

iv) The test kit is for laboratory use only; and
v) The test kit is not for use in/on animals.

Guidance

- The list of microorganisms present in New Zealand maintained by the EPA can be found here under "Databases of organisms present in New Zealand".
- If the test kit contains materials derived from plants, it must also meet the requirements of the IHS for *Research Samples (excluding animal samples)* RESEARCH.IHS.

3.1.3 Microorganisms that are not new organisms and are unwanted or regulated organisms

(1) Unwanted and/or regulated microorganisms may be imported from any country for research purposes, provided the following requirements are met:

a) Either:

i) The microorganism is on the EPA's list of microorganisms present in New Zealand; or
ii) MPI or the EPA have confirmed the microorganism is likely present in New Zealand; and

b) An import permit is required to direct the commodity to an appropriately approved transitional facility, subject to a product assessment as per section 1.7 that confirms the biosecurity risk is effectively managed.

c) At the conclusion of the research, all materials must be disposed of according to the facility procedures to ensure the organism is not released into the environment.

(2) Panels for quality assurance or laboratory accreditation purposes containing microorganisms that are not new organisms and are unwanted organisms may be imported from any country, provided the following requirements are met:

a) An importer's declaration is required. This declaration must be provided by the facility in New Zealand where the panel will be used, comply with clause 1.8.4 of this IHS, and confirm:

i) The panels may contain unwanted organisms that are commercially manufactured, and the use of the panels is limited to quality assurance; and
ii) Either:

1) The panels will only be used in a laboratory that holds a current accreditation to carry out diagnostic testing; or
2) The panels will only be used in a laboratory that is undertaking proficiency testing to gain accreditation; and

iii) The individuals who will use the panel are trained professionals, or operate with oversight of a trained professional, and there will be adherence to laboratory processes and procedures related to infectious organisms; and
iv) Laboratory processes and procedures for the handling, storage, and destruction of microorganisms are dictated by a quality assurance manual; and
v) The laboratory undergoes annual, external inspections or audits; and
vi) Either:

1) Any unwanted organisms identified in quality assurance panels will be destroyed immediately following identification in accordance with approved processes and procedures; or
2) The laboratory is in possession of an appropriate permission under section 52 and/or 53 of the Biosecurity Act 1993.

Guidance

- If the microorganism will be communicated or propagated, a relevant permission under s52/53 of the Biosecurity Act 1993 may be required.

3.1.4 Microorganisms that are new organisms

(1) Microorganisms that are new organisms may be imported from any country, provided the following requirements are met:

a) An import permit is required to direct the commodity to an appropriately approved containment facility, subject to a product assessment as per section 1.7 of this IHS that confirms the biosecurity risk is effectively managed; and
b) The relevant HSNO approval for importing the new organisms must be provided and mentioned on the import permit; and
c) All the relevant controls and purpose of the HSNO Act approval are met.

(2) Panels containing microorganisms that are new organisms of risk group 1 or risk group 2 that are part of a panel for quality assurance or laboratory accreditation purposes may be imported from any country, provided the following requirements are met:

a) An importer's declaration is required. The declaration must comply with section 1.8.4 of this IHS and confirm that the conditions of the HSNO approval are satisfied:

i) The quality assurance panels may contain new organisms of risk group 1 or risk group 2 as defined in AS/NZS 2243.3:2022 Microbiological Safety and Containment standard; and
ii) Either:

1) The facility importing the panel is accredited to ISO 17025 or ISO 15189; or
2) The facility importing the panel is registered with IANZ and gaining accreditation to those standards and the panel will only be used in [facility name]; and

iii) Either:

1) The panels are being imported under HSNO approval NOR100207 for risk group 1 organisms; and / or
2) The panels are being imported under HSNO approval NOR100206 for risk group 2 organisms; and

iv) The HSNO approval is current; and
v) The relevant conditions of the HSNO approval will be complied with, specifically regarding safe handling, requirements for laboratory staff, and use and disposal of the proficiency panel material.
vi) The panel does not contain any organisms New Zealand claims freedom from listed in Schedule 7 of Specified Approvals for Animal Import Health Standards (MPI-STD-SAA).

b) If the proficiency panel contains unwanted organisms, the importer's declaration must also confirm:

i) The laboratory importing the panel undergoes annual, external inspections and/or audits; and
ii) Either:

1) Any unwanted organisms identified in the quality assurance panels will be destroyed immediately following identification in accordance with approved processes and procedures; or
2) The laboratory is in possession of appropriate permissions under section 52 and/or 53 of the Biosecurity Act 1993.

Guidance

- Proficiency panels containing new organisms that are risk group 3 organisms may be imported under (1) to MPI-approved containment facilities operating to PC3.
- Proficiency panels containing new organisms that are risk group 1 or 2 organisms may be imported under (1) to MPI-approved containment facilities operating to PC2.

3.2 Animal samples that may contain unidentified microorganisms

3.2.1 Samples from animals with unknown health status

(1) Animal tissue or fluid samples, or entire organisms of unknown health status may be imported for analysis, provided the following requirements are met:

a) An import permit is required to direct the commodity to an appropriately approved transitional facility, subject to a product assessment as per section 1.7 of this IHS that confirms the biosecurity risk is effectively managed.
b) Invertebrate samples must be directed to a facility that is invertebrate vector-proof as per the facility's MPI-approved quality management system or operating manual.

Guidance

- Analysis can include testing where the animal sample is destroyed or testing that involves propagation.
- Diagnostic samples may be imported under section 3.2.1.
- If a new organism is identified, the importer must immediately notify the EPA.
- If an unwanted organism is identified, the importer must immediately notify MPI and either destroy the sample in accordance with the operating procedures of the transitional facility where the analysis occurs or follow the instruction of a warranted MPI officer.
- A section 52/53 permission is required to communicate and/or propagate an unwanted organism identified in a sample.
- A HSNO approval may be required to store and/or propagate a new organism identified in a sample. Contact the EPA for further information.
- CITES requirements may apply to animal tissue samples. Species with CITES requirements are listed at the checklist of CITES species. For further information about CITES requirements, contact the Department of Conservation.

3.3 Cell lines

Guidance

- Cell lines assessed by MPI and deemed to pose unacceptable biosecurity risk to New Zealand are not eligible for import.
- Non-genetically modified cell lines derived from humans are exempt from this IHS and can be given clearance.
- Cell lines derived from the tissues of unwanted organisms are unwanted organisms, unless determined otherwise by a CTO.
- Cell lines derived from the tissues of new organisms are new organisms unless a HSNO Act determination from the EPA is provided stating these cell lines are not new organisms.
- Cell lines and tissue cultures derived from plants are not eligible for import under this IHS, and may be imported under the IHS Plants for Planting.

3.3.1 Cell lines derived from organisms present in New Zealand

(1) Cell lines derived from organisms present in New Zealand may be imported from any country, provided the following requirements are met:

a) An import permit is required, subject to a product assessment as per section 1.7 of this IHS that confirms the biosecurity risk is effectively managed.
b) The consignment must be directed to and used within an appropriately approved transitional facility named on the permit.

Guidance

- Cell lines derived from unwanted organisms that are considered unwanted organisms may require a permission under s52/53 of the Biosecurity Act 1993.

3.3.2 Cell lines derived from new organisms

(1) Cell lines derived from new organisms may be imported from any country, provided the following requirements are met:

a) An import permit is required to direct the commodity to an appropriately approved containment facility, subject to a product assessment as per section 1.7 of this IHS that confirms the biosecurity risk is effectively managed; and
b) The import permit must list the specific HSNO approval number for importing, holding, and using the cell cultures; and
c) All the controls and the purpose of the HSNO approval are met; and

Guidance

- Cell lines derived from cells that have been genetically modified, including genetically modified human cells, are considered new organisms under the HSNO Act. The import requirements in 3.3.2 apply.

Schedule 1 – Document history

The information contained in this schedule is for guidance and is not part of the statutory requirements

Date First Issued	Title	Shortcode
Date	Import Health Standard: Microorganisms, biological products derived from animals, and cell cultures	MOBIOCELL.ALL
Date of Amendment	**Details of amendments**	**Shortcode**
Date		

Schedule 2 – Definitions

ACVM Act
Agricultural Compounds and Veterinary Medicines Act 1997.

Agricultural compound
As defined in the Agricultural Compounds and Medicines Act 1997.

Animal hide/skin glue
As defined in the Agricultural Compounds and Medicines Act 1997.

Appropriately approved transitional facility
An MPI-approved transitional facility that has been approved to hold and contain specific uncleared biological products, and where specific uncleared biological products must be used.

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

Commercially manufactured and packaged
A product that has been 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 the World Organisation of Animal Health 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 Code in the whole territory.

Environmental use
Use [of imported commodities] in a way that involves direct or indirect contact with the natural environment, for example, fertilisers or items used in the building industry.

Finished game trophy
An animal, or part of an animal, of any species that has undergone a complete taxidermy process, being cleaned and processed by a taxidermist, including tanning of the skin, resulting in the animal or animal part being preserved at ambient temperatures. Finished game trophies include stuffed animals, mounted animals, and heads of animals (with or without antlers/horns).

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

Hermetically sealed
A type of sealing that makes a given object airtight to maintain a contaminant-free environment.

Import permit
A permit issued by the Director-General of MPI or their delegate, pursuant to Section 24D(2) of the Act. Import permits may specify the transitional or containment facility where goods are held and/or used; or indicate that a product assessment has been carried out by MPI and concluded to be managed effectively.

In vitro
A process or reaction conducted outside a living organism, i.e. in a culture dish or test tube.

In vivo
A process or reaction carried out inside a living organism.

Laboratory use
Use [of imported commodities] within a laboratory as part of a clearly defined research or analytical process. A laboratory is defined as a place within a scientific institution, school, or university that is built for the purpose of carrying out laboratory procedures separate from the environment that is accredited and operates under and

maintains records of standard operating procedures (SOPs) and is subject to regular auditing by / approval from an independent body.

Microorganism
A microscopic organism including bacteria, viruses, fungi, bacteriophages, unicellular algae, spores, and prions.

MPI
Ministry for Primary Industries, New Zealand.

New organism
As defined in the Hazardous Substances and New Organisms (HSNO) Act 1996.

Non-viable
Incapable of living, growing, developing or functioning.

Official Veterinarian
A veterinarian authorised by the Competent Authority of a 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 World Organisation for Animal Health Terrestrial Animal Code Chapter for certification procedures.

Ornamental products of animal origin
Non-viable products made of animals, or the parts of animals, that are generally used for decorative or display purposes.

Purified
Subjected to a procedure designed to separate a target material from its source cells, typically involving precipitation or filtration.

Quality Management System (QMS)
Documented policies and procedures carried out to meet the requirements of an MPI-approved transitional facility, an MPI-approved containment facility, or other facility with a QMS system accredited to an independent body. For manufacturers see Good Manufacturing Practice.

Quality Manager
A person employed by the company manufacturing the commodity in question and whose role is to ensure that the animal product manufactured by the company meets its minimum standard of quality.

Sample
A small part intended as a representative of the whole. For the purposes of this IHS, an animal sample may consist of the entire animal.

Sterilised
Subjected to a procedure to remove contaminating microorganisms from the product or render the microorganisms non-viable.

Test kit
A product containing reagents and other items necessary to conduct a laboratory test procedure or to measure a quantity of a specific factor.

Vector
An insect or any living carrier that transports an infectious agent from an infected individual to a susceptible individual or its food or immediate surroundings. The organism may or may not pass through a development cycle within the vector.

Vector-proof facility
A facility which provides maximum protection from invertebrate vectors. This should be a building, ideally a compartment within a building, with risk management strategies to protect animals and the facility from vectors.

Veterinary biological implant
Biological tissue harvested from a donor animal for insertion or grafting into a recipient animal.

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

Veterinary medicine
As defined in Section 2 of the Agricultural Compounds and Veterinary Medicines Act 1997, a veterinary medicine means any substance, mixture of substances, or biological compound used or intended for use in the direct management of an animal.

Veterinary use
Use [of imported commodities] in research or as part of procedures that involve the commodity being applied, injected, or otherwise used on an animal; including production of embryos used in IVF.

WOAH
The World Organisation for Animal Health.

Schedule 3 – Model and sample certificates

Unprocessed bovine serum products for further processing from all countries

(1) The model certificate template for unprocessed bovine serum products for further processing from all countries is available at the link.

(2) Before trade can begin, a veterinary certificate (using the model) must be negotiated and agreed between MPI and the Competent Authority of the exporting country.

(3) Links to samples of negotiated certificates will be listed below:

Specified animal products

(1) The model certificate template for specified animal products is available at the link.

(2) The model certificate **does not require MPI recognition** of the exporting country's systems and certification for trade of dicalcium phosphate and ovine and bovine concentrated bile. **Delete clauses which are not applicable.**

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

(1) The model certificate template for tested, filtered and irradiated fetal bovine serum, calf serum, and bovine serum from Australia is available at the link.

(2) Before trade can begin, a certificate (using the model) must be negotiated and agreed between MPI and the Competent Authority of Australia.

(3) Links to samples of negotiated certificates will be listed below:

Filtered and irradiated fetal bovine serum, calf serum, and bovine serum from all countries

(1) The model certificate template for filtered and irradiated fetal bovine serum, calf serum, and bovine serum from all countries is available at the link.

(2) Before trade can begin, a veterinary certificate (using the model) must be negotiated and agreed between MPI and the Competent Authority of the exporting country.

(3) Links to samples of negotiated certificates will be listed below:

Game trophies from the EU

(1) The agreed veterinary certificate for game trophies from the EU is available at the link.

Explanatory Note

This note is not part of the Import Health Standard but is intended to indicate its general effect.

Information about publication of standard

This standard is published on the MPI website at Secondary legislation | NZ Government.

This is secondary legislation issued under the authority of the Legislation Act 2019.

Title	Import Health Standard: Microorganisms, biological products derived from animals, and cell lines [Date of Signing]
Principal or amendment	Principal
Consolidated version	No
Empowering Act and provision(s)	Biosecurity Act 1993 section 24A
Replacement empowering Act and provision(s)	Not applicable
Maker name	Ministry for Primary Industries
Administering agency	Ministry for Primary Industries
Date made	[Date of Signing]
Publication date	[Date of Signing]
Notification date	Not applicable
Commencement date	[Effective Date]
End date	Not applicable
Consolidation as at date	Not applicable
Related instruments	Not applicable