Ministry for Primary Industries
Manatū Ahu Matua

Guidance Document

Biological Products

BIOLOGIC.ALL

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New Zealand Government

Title

Guidance Document: Biological Products.

About this document

This guidance document contains information about acceptable ways of ensuring compliance with the requirements in *Import Health Standard (IHS): Biological Products*.

Any guidance on how to comply with the applicable requirements may not be the only way to achieve compliance. Stakeholders are encouraged to discuss departures from the approaches outlined in this guidance document with the Ministry for Primary Industries (MPI) to avoid expending resources on the development of alternative approaches which may later be considered unsuitable.

The term "must" is not typically used in guidance. In this particular document if the term "must" is used, it is used in the context of quoting or paraphrasing the requirements set out in the related *IHS: Biological Products.*

Related Requirements

Import Health Standard: Biological Products

Document history

Refer to Appendix 1.

Contact Details

For further information and questions about this guidance document, please contact:

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Disclaimer

This guidance does not constitute, and should not be regarded as, legal advice. While every effort has been made to ensure the information in this guidance is accurate, the Ministry for Primary Industries does not accept any responsibility or liability whatsoever for any error of fact, omission, interpretation or opinion that may be present, however it may have occurred.

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1 Purpose

(1) This guidance document has been issued to accompany *Import Health Standard: Biological Products*. This guidance document should be read in conjunction with that IHS.

(2) This document includes:

a) Model manufacturer's declarations.
b) The links to the model veterinary certificates for Australian- and/or New Zealand-origin fetal bovine serum, calf serum and bovine serum. These country-specific veterinary certificates represent what will be certified prior to exporting consignments of fetal bovine serum, calf serum and bovine serum from the country specified.

2 Background

(1) *IHS: Biological Products*, which this guidance document accompanies, contains generic import requirements. These are the rules to manage the biosecurity risk of importing biological products from all countries that can meet the requirements of the IHS and, in doing so, meet New Zealand's appropriate level of protection.

3 Definitions

(1) Refer to *Schedule 2* of *IHS: Biological Products.*

4 Importer Responsibilities

(1) The costs to MPI in performing functions relating to the importation of biological products will be recovered in accordance with the Biosecurity Act 1993 (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.

(2) Consignments that do not comply with the requirements of the IHS may be reshipped or destroyed using an MPI-approved destruction method.

5 Guidance

5.1 Equivalence

(1) MPI may accept an alternative method, system or process to that in this IHS to maintain at least the same level of protection assured by the measures in this IHS.

(2) 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.

(3) An import permit may be required where specific equivalence measures are approved by MPI. An import permit serves as evidence of equivalence decisions, which will be written as specific notes in the special conditions section of the permit.

(4) An import permit application form can be found at the following link: *Permit to Import Biological Products, Micro-organisms & Cell Cultures*.

(5) The importer should complete all information requested on the application form.

(6) Send completed applications to animal.imports@mpi.govt.nz.

5.2 Incorporation of material by reference

(1) Because some technical documents are too large or impractical to include in the IHS, they are incorporated by reference into the IHS. Incorporation by reference means that standards, guidelines or lists are incorporated into the IHS and they form part of the requirements.

(2) Where the IHS states that section 142O(1) of the Act does not apply, this means that importers need to refer to the most recent version of any standards, guidelines or lists that are incorporated by reference in the IHS.

5.3 Harmonised System (HS) codes

(1) The Harmonised System is an international product numbering classification developed by the World Customs Organization (WCO). The New Zealand Harmonised System is found here: Tariffs in New Zealand | Ministry of Business, Innovation & Employment (mbie.govt.nz)

(2) The most commonly used HS codes for imported biological products are:

HS Code	Commodity Description
05	Animal originated products; not elsewhere specified or included
3808	Insecticides, rodenticides, fungicides, herbicides, anti-sprouting products, plant growth regulators, disinfectants and the like, put up in forms or packings for retail sale or as preparations or articles
3821	Prepared culture media for the development or maintenance of micro-organisms (including viruses and the like) or of plant, human or animal cells
3822	Reagents; diagnostic or laboratory reagents on a backing and prepared diagnostic or laboratory reagents whether or not on a backing, other than those of heading no. 3002 or 3006; certified reference material

5.4 Exporting country systems and certification

5.4.1 Agreed country-specific veterinary certificates

(1) The country-specific veterinary certificates for bovine serum agreed between the Australian Competent Authority and MPI are included in the table below:

Country	Link to certificate	S27 CTO direction #	Date agreed	Date applicable for use
Australia	Tested, filtered and irradiated fetal bovine serum, calf serum and bovine serum			
Australia	Fetal bovine serum, calf serum and bovine serum for further processing			

(2) Country-specific veterinary certificates with equivalent measures will be recorded with a number relevant to a CTO direction issued under section 27(1)(d)(iii) of the Act, to enable border staff to clear the goods and record the number in the MPI database.

(3) When a newly negotiated country-specific veterinary certificate replaces one that is currently in use, the application of new import conditions will apply according to the dates listed in the table above.

(4) When a new country-specific veterinary certificate is agreed on, there will be a four-month transition period to allow fetal bovine serum, calf serum and bovine serum to be prepared in accordance with the new conditions. During transition, both the old and the new import conditions are acceptable. After transition, the previous veterinary certificate for that country can no longer be used.

5.5 Eligibility

(1) Imported biological products (including fetal bovine serum, calf serum and bovine serum from Australia) fall into the four categories listed in the IHS. Further information about the four categories is included below.

5.5.1 Laboratory research, diagnostic and analytical purposes

(1) This includes equipment calibration and validation.

(2) Generally, such use would be conducted in a laboratory-type environment, including (but not limited to) Crown Research Institutes, universities, private research institutions, hospitals, diagnostic testing laboratories and veterinary laboratories.

5.5.2 Animal product samples for evaluation and/or proficiency testing

(1) While the size and volume of a sample can be arbitrary, it is recognised that samples are imported for purposes different from that of the whole. Importers should endeavour to keep the size, volume and quantity of samples to a minimum in order to ensure that the purposes of import are within the scope of the IHS and the scope of the transitional facility approval.

(2) Animal product samples for evaluation should meet all conditions on the import permit. The transitional facility listed on the import permit is to be approved at the time of import under one of the following MPI transitional facility standards (appropriate to commodity) or whichever facility standard replaces them:

a) For further processing, *Transitional Facilities for Animal Products, MPI-STD-ANIPRODS*; or
b) For testing and evaluation, *Transitional Facilities for Biological Products, 154.02.17.*

(3) As stated in the IHS, animal product samples may be eligible for clearance if treated in an MPI-approved facility as per the relevant IHS. The IHS search page can be found here: http://www.mpi.govt.nz/law-and-policy/requirements/import-health-standards/

5.5.3 Environmental use

(1) Environmental uses include a range of commercially manufactured and packaged products, for example, effluent biodegraders, biofertilisers.

(2) Also refer to the exclusion section of this guidance document (*Section 5*) relating to the importation of viable microorganisms.

(3) Biosecurity clearance is required before a biological product can be used in the environment.

5.5.4 Use in or on humans or animals

(1) Use of a biological product in or on humans or animals, for medical or veterinary use.

(2) Biological products intended to be used therapeutically on or in humans include, but are not limited to, antibiotics, medicines, inactivated vaccines, bioprosthetic devices and surgical implants/equipment.

(3) Additional requirements under the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act) may apply for use of biological products on animals and plants.

a) For information about agricultural compounds and veterinary medicines, refer to section 7.2 of this document and https://www.mpi.govt.nz/processing/agricultural-compounds-and-vet-medicines/.

5.6 Biological products derived from humans

(1) Any products containing infectious agents that can be transmitted between (or are shared by) animals and humans are not eligible for clearance. See exclusions section (*Section 6*).

(2) Non-viable biological products derived from humans are **not** subject to the IHS requirements and are eligible for biosecurity clearance. This is because:

a) Human beings are not considered to be organisms for the purposes of the Act and, therefore, are not risk goods in themselves.
b) While there are products derived from, and associated with, human beings that are considered as potential hazards under the Act, these have been assessed by MPI to be of negligible risk and can be considered not to be risk goods.

(3) Please note that there may be legislation managed by the New Zealand Ministry of Health and the Ministry of Business, Innovation & Employment that applies to these goods.

5.7 Packaging and transport

(1) Uncleared biological products should be transported in a secure and double contained manner to prevent spillage or contamination of the transporting vehicle, other cargo and/or the environment.

(2) Importers should ensure that packaging materials are not biosecurity risk goods in themselves. Materials should also be clean, dry and free from any contaminating material.

5.8 Import permit

(1) The import permit application form can be found on the MPI website at: *Permit to Import Biological Products, Micro-organisms & Cell Cultures.*

(2) The importer should complete all information requested on the application form.

(3) Send completed applications to animal.imports@mpi.govt.nz.

5.9 Inspection and verification

(1) On arrival, all documentation accompanying the consignment may be verified by an inspector. The inspector may also inspect the consignment, or a sample of the consignment, on arrival.

(2) Inspectors are able to inspect and verify due to their authorised powers under the Act.

(3) These requirements are independent of the IHS requirements.

6 Exclusions

(1) The categories of biological products not eligible for importation under this IHS are:

a) Biological products which are eligible for movement and/or clearance under another IHS must be moved and/or cleared under that IHS.

i) For example: There are a number of IHSs relating to animal products, such as milk and milk products, egg products, and bee products.
ii) For a list of other IHSs, refer to the MPI website: http://www.mpi.govt.nz/importing/overview/import-health-standards/
iii) Products that do not comply with the clearance requirements of another IHS must be accompanied by an import permit which requires the product to be held and/or used in an appropriately approved transitional facility (as listed on the import permit).

b) Biological products that are microorganisms; or biological products that contain viable microorganisms which are imported with the intention of isolating or culturing microorganisms from the samples, or used for microorganism enrichment. Examples include, but are not limited to, viruses, bacteria, prions and protozoa.

i) This includes for purposes where the microorganisms may, or may not be, rendered non-viable as part of the processing.
ii) Such products are subject to the *Import Health Standard: Microorganisms from All Countries, MICROIC.ALL* (or any IHS which replaces that standard).

c) Biological products that are, or contain, viable cell cultures/non-microbial cells where, for example, products are imported with the intention of cell isolation and/or culture.

i) This includes for purposes where the cultures/non-microbial cells may, or may not be, rendered non-viable as part of the processing.
ii) Such products are subject to the *Import Health Standard: Cell Cultures from All Countries, CELLCULIC.ALL* (or any IHS which replaces that standard).

d) Chemically synthesised compounds do not meet the definition of a biological product and are exempt from this IHS.
e) Biological products derived from plants are not eligible for import under this IHS.

7 Specified Requirements for Biological Products

(1) Products, including those for therapeutic use on or in humans, that contain honey must also comply with the requirements of the *Import Health Standard for Specified Processed Bee Products, BEEPROIC.ALL* (or any IHS which replaces that standard).

7.1 Biological products that can be cleared on entry to New Zealand

(1) MPI has assessed the biosecurity risks associated with the biological products described in *Schedule 4* and concluded that they are managed effectively by the requirements of this IHS.

(2) If a biological product falls within *Schedule 4* of the IHS and no import permit is required under that Schedule, it is recommended that the accompanying documentation includes the declaration "Goods are included in section/subsection [insert relevant section/subsection here] category under *Schedule 4* of the *IHS: Biological Products*."

(3) If the commodity being imported is eligible for import under another IHS, it must be imported under that IHS.

(4) Importers of test kits that test for a notifiable organism or a reportable organism should be aware there is a legal requirement to report a positive result immediately to MPI on **0800 80 99 66**.

a) A positive test result for a notifiable organism may be a false positive and is considered only 'suspicious' until confirmed at the MPI Animal Health Laboratory (AHL).
b) When supplying test kits for exotic diseases to a third party, this party must be informed of the conditions listed above.

(5) The use of a kit to create a genetically modified microorganism (GMO) requires HSNO Act approval. Under the HSNO Act, anyone wanting to import or create a GMO must have approval from the EPA and strict criteria must be met regarding the organisms' management and containment.

7.2 Biosecurity requirements for agricultural compounds and veterinary medicines

(1) Information regarding biosecurity assessments for ACVM Act imports can be found on the MPI website here: http://www.mpi.govt.nz/importing/biological-products-and-organisms/biological-products/steps-to-importing/biosecurity-assessments-for-acvm-imports/

(2) Veterinary medicines that contain ingredients of biological origin other than those included in the Negligible Risk Ingredient Schedule of the *Biosecurity Approval of Imported Agricultural Compounds and Veterinary Medicines: ACVM Guidance* must have a biosecurity assessment as part of the ACVM Act authorisation process. This assessment is managed by the Animal Imports team.

(3) Where applicable, a biosecurity approval letter will be issued for the veterinary medicine. The purpose of the biosecurity approval letter is not for biosecurity clearance of the veterinary medicine at the border but to inform the applicant of their obligations under the Biosecurity Act with respect to conditions of the biosecurity approval, i.e. requirements for biosecurity reassessment.

(4) Biosecurity reassessment for the veterinary medicine will be required if one or more of the following occurs:

a) There is a change in the formulation, source and/or manufacturing process of any biological ingredient, other than those listed in the Negligible Risk Ingredient Schedule.
b) There is an extension of use to include additional target species.
c) Five years have elapsed since the date of issue of the biosecurity approval letter.

(5) Veterinary medicines (other than blood plasma products) authorised via registration (s21), provisional registration (s27), research approval (s8C), and special circumstances approval (s8C) pathways of the ACVM Act do not require an import permit.

(6) Agricultural compounds described in Column 1 of Schedule 2 of the Agricultural Compounds and Veterinary Medicines (Exemptions and Prohibited Substances) Regulations 2011 and are used in or on animals and that contain ingredients of animal origin must either meet the scope or intended purpose and requirements of an IHS or undergo a biosecurity assessment to determine if an import permit might be issued. Import application forms can be found under specific commodity type here: https://www.mpi.govt.nz/importing/

7.3 Biosecurity risk assessment

(1) The range of risk goods that are included within the definition of biological products is wide and diverse, as are the activities that may be undertaken with them. This means it is not possible to prescribe in this IHS how the biosecurity risks that may be associated with all such biological products and associated activities should be managed.

(2) Where an importer applies to import a biological product not described in *Schedule 3, 4* or *5* of the IHS, and there is no prior MPI risk assessment for that biological product, a specific risk assessment must be undertaken by MPI.

a) The application and the specific risk assessment will need to be consulted on with "any other persons the officer considers to be representative of the classes of persons having an interest in

it" as required by section 23(3)(b) of the Biosecurity Act 1993. This consultation can be targeted, and any commercially sensitive information will not be made available unless express permission has been given by the manufacturer of the biological product.

b) The importer will be notified if consultation is required and of estimated timeframes.

(3) An essential part of allowing the importation of biological products is ensuring that any biosecurity risks that such products may present are identified, can be effectively managed and do not compromise the ability to maintain compliance with the Act, New Zealand's international obligations, this IHS or any associated facility standard. This is to ensure animal, human and environmental elements are not exposed to risk organisms which may be contained within animal bodies, organs, tissues, cells, samples, blood, body fluids or waste material.

(4) A biosecurity risk assessment undertaken by MPI will include, but is not limited to, consideration of the following (where appropriate to the biological product):

a) The animal species the biological product is derived from.
b) The country the biological product is derived from and the presence or absence of risk organisms in that country that may present a biosecurity risk to New Zealand.
c) The type of biological product.
d) The type of processing that may have been applied to the biological product that may mitigate the presence of microorganisms.
e) Intentional or unintentional exposure to animals, humans, and the environment.
f) Why and how the biological product is proposed to be used (including, but not limited to, further processing, analysis, media preparation, assays, use in or on animals) and the potential exposure routes.
g) Frequency of exposure to people and/or animals.
h) Details of any human or animal diseases or environmental damage (biosecurity and biosafety factors) that may be associated with exposure to, or release of, biological agents or hazards.
i) Measures to mitigate each risk to the lowest level that is reasonably practicable (necessary control measures).

7.4 Biological products for use within a transitional facility

(1) Biological products that have an unknown health status, or are known to be infected, or have a risk of harbouring unwanted or exotic organisms, are a risk to New Zealand's biosecurity. Such biological products may not be eligible for movement or clearance, subject to a risk assessment of that product and depending on whether or not a transitional facility has been approved for that type of product.

(2) As a general guide, biological products to be used within an appropriately approved transitional facility include, but are not limited to:

a) Animal tissues or product samples.
b) Blood and serum products.
c) Semen.
d) Faeces and urine.

(3) The exception to this is if the products are covered by another IHS. If this is the case, the biological products would be subject to the conditions within that specific IHS.

(4) If the risk goods are arriving via the passenger route, the goods will need to be couriered from the port of first arrival to the transitional facility named on the import permit if:

a) The passenger is not going directly to the transitional facility named on the import permit; or
b) The passenger is not named on the import permit, or does not have a letter from the operator of the transitional facility or the import permit holder authorising the use of the import permit.

(5) The transitional facility is to be appropriately approved under a transitional facility standard relevant to the commodity. The transitional facilities will most likely be approved under one of the following facility standards (or any facility standard that replaces these standards):

a) *Transitional Facilities for Biological Products, 154.02.17*
b) *Transitional Facilities for General Uncleared Risk Goods, TFGEN* (approved to allow holding of (not opening/using) biological products only)
c) *Transitional Facilities for Animal Products, MPI-STD-ANIPRODS*

7.4.1 Commercially manufactured and packaged risk goods

(1) Commercially manufactured and packaged products comprised of animal products that are risk goods that do not meet the requirements of *Schedules 3* and/or *4* of this IHS must be accompanied by a relevant import permit that requires the product to be moved to an appropriately approved transitional facility (as listed on the import permit).

(2) This includes, but is not limited to, products comprised of blood, serum and/or serum proteins such as bovine serum albumin (BSA) and fetal calf serum (FCS). It excludes test kits for laboratory use that do not contain viable microorganisms.

7.4.2 Non-commercially manufactured and/or packaged, unsterilised/unpurified laboratory products

(1) Non-commercially manufactured and/or packaged laboratory unsterilised/unpurified products may not have been treated to sufficiently inactivate or remove potential contaminating microorganisms and are required to be moved to an appropriately approved transitional facility (as listed on the import permit).

(2) Examples may include, but are not limited to:

a) Culture media.
b) Egg products.

7.4.3 Samples from clinically healthy animals for analytical testing

(1) Samples from clinically healthy animals for analytical testing, that do not meet another IHS, fall under *Schedule 5* of the IHS and must be accompanied by a restricted import permit which requires the product to be moved to an appropriately approved transitional facility (as listed on the import permit).

(2) The species of animal, the country of origin, the sample type and details of the tests to be undertaken need to be provided.

(3) Examples of samples from clinically healthy animals for analytical testing that must be held and used in a transitional facility include, but are not limited to:

a) Blood and milk samples (note: samples intended for microorganism enrichment, isolation and/or culture must be imported under *Import Health Standard for Microorganisms* or whichever IHS replaces it).
b) Samples for trace element testing, nutritional analysis, and chemical analysis.

(4) Samples collected from clinically unhealthy animals or animals suspected of being at high risk of an exotic disease are not considered an acceptable risk for most New Zealand transitional facilities.

7.5 Model manufacturer's declaration

(1) Commercially manufactured and packaged:

a) Amino acids.
b) Antibiotics / antimicrobials.
c) Test kits that do not contain viable microorganisms.
d) Products derived from microorganisms.
e) Restriction enzymes.

<table>
<tr><th colspan="2">Company Letterhead</th></tr>
<tr><td colspan="2">1. Importer name:
Address:</td></tr>
<tr><td>2. Country of destination: New Zealand</td><td>3. Country of origin:</td></tr>
<tr><td colspan="2">4. Description of commodity:</td></tr>
<tr><td>5. Invoice number:</td><td>6. Nature of packaging:</td></tr>
<tr><td>7. Number of packages:</td><td></td></tr>
<tr><td colspan="2">8. Number of container(s):</td></tr>
<tr><td colspan="2">I, _____, the Quality Manager (or equivalent) of the manufacturing premises, declare that:

(1) The commodities in this consignment are (strikethrough or delete non-applicable categories):
(a) Amino acids;
(b) Antibiotics / antimicrobials;
(c) Test kits that do not contain viable microorganisms;
(d) Products derived from microorganisms;
(e) Restriction enzymes

(2) All the commodities in this consignment are:
(a) Commercially manufactured and packaged;
(b) In new, clean, and secure packaging; and
(c) For in-vitro laboratory use</td></tr>
<tr><td colspan="2">Name of quality manager of the manufacturer or equivalent:

Position:

Signature: Date:</td></tr>
</table>

(2) Commercially manufactured and packaged:

a) Unsterilised laboratory culture media that contains no ingredients of animal origin.
b) Sterilised laboratory culture media.
c) Highly purified/sterilised laboratory reagents or products derived from egg.

Company Letterhead	
1. Importer name: Address:	
2. Country of destination: New Zealand	3. Country of origin:
4. Description of commodity:	
5. Invoice number:	6. Nature of packaging:
7. Number of packages:	
8. Number of container(s):	
I, _____, the Quality Manager (or equivalent) of the manufacturing premises, declare that: (1) The commodities in this consignment are *(strikethrough or delete non-applicable categories)*: (a) unsterilised laboratory culture media that contains no ingredients of animal origin; and/or (b) sterilised laboratory culture media; and/or (c) highly purified / sterilised laboratory reagents or products derived from egg. (2) The commodities in this consignment have been commercially manufactured and packaged; the packaging is new, clean, and secure; and the commodities *(strikethrough or delete non-applicable categories)*: (a) have been sterilised to completely remove viable microorganisms or render any microorganisms non-viable.; or (b) do not contain any ingredients of animal origin, including blood, whole serum, animal proteins or animal tissues. (3) The commodities in this consignment are not for use in the production of products destined for use in or on animals as veterinary medicines.	
Name of quality manager of the manufacturer or equivalent: Position: Signature: Date:	

Appendix 1 – Document History

Date First Issued	Title	Shortcode
17 December 2021	Guidance Document: Biological Products	GD BIOLOGIC.ALL
Date of Issued Amendments	**Title**	**Shortcode**