Ministry for Primary Industries
Manatū Ahu Matua

Guidance Document

Biological Products (Including Samples)

BIOPRODIC.ALL

14 March 2014

A guidance document issued by the Ministry for Primary Industries

New Zealand Government

Title

Guidance Document: Biological Products (Including Samples)

About this document

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

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 (Including Samples).*

Related Requirements

Import Health Standard (IHS): Biological Products (Including Samples).

Change history

Refer to Appendix 1.

Contact Details

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

Ministry for Primary Industries
Standards Branch
Animal Imports
PO Box 2526
Wellington 6140
Email: animalimports@mpi.govt.nz

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 the *IHS: Biological Products (Including Samples)*. This guidance document should be read in conjunction with that standard.

2 Background

(1) The *IHS: Biological Products (Including Samples)* which this guidance document accompanies, is for the importation of non-viable products of biological origin (that is, the products are dead or not living). Products imported under the IHS are not to be used for microorganism enrichment, isolation or culture. Products containing viable cell lines, viable cell cultures or viable microorganisms are subject to other IHSs.

(2) The *IHS: Biological Products (Including Samples)* revokes and replaces the following IHSs:

a) Import Health Standard for the Importation of Raw Milk Samples for Evaluation and Destruction from New Caledonia - DAIRMSIC.NCA (27 July 1998)
b) Import Health Standard for the Importation into New Zealand of Dairy Product Samples for Evaluation - DAISAMIC.ALL (11 May 2004)
c) Import Health Standard for the Importation into New Zealand of Animal Fibre for Testing from All Countries - FIBTESIC.ALL (26 June 2001)
d) Import Health Standard for the Importation of Samples of Untanned Cattle/Sheep/Goat Hides and Skins of New Zealand Origin for Evaluation - HIDRESIC.ALL (15 January 1998)
e) Import Health Standard for the Importation into New Zealand of Samples of Untanned Cattle/Sheep/Goat/Deer Hides and Skins from Specified Countries - HIDSAMIC.SPE (28 June 2004)
f) Import Health Standard for the Importation of New Zealand Origin Tallow, Blood Meal, Fish Meal, Bone Meal Samples for Evaluation - INESAMIC.ALL (3 June 1998)
g) Import Health Standard for the Importation of Pig Meat and Poultry Meat Samples into New Zealand for Evaluation and Destruction from Australia - MEASAMIC.AUS (14 October 2002)
h) Import Health Standard for the Importation of Meat Samples for Evaluation and Destruction into New Zealand from Fiji - MEASAMIC.FIJ (27 July 1998)
i) Import Health Standard for the Importation into New Zealand of Meat and Meat By-product Samples for Evaluation from Specified Countries - MEASAMIC.SPE (21 October 2004)
j) Import Health Standard for the Importation of Fresh Whole Eggs for Evaluation and Destruction into New Zealand from Fiji - POUEGGIC.FIJ (27 July 1998)
k) Import Health Standard for the Importation of Frozen Salmon Offal Samples into New Zealand for Evaluation and Destruction from Australia - SALSAMIC.AUS (19 January 1998)

3 Definitions

(1) Refer to Definitions in Part A of the *IHS: Biological Products (Including Samples).*

4 Importer's responsibilities

(1) The costs to MPI in performing functions relating to the importation of biological products (including samples) will be recovered in accordance with the Biosecurity Act 1993 (the Act) and any regulations made under that Act. All costs involved with documentation, transport, storage and obtaining a biosecurity clearance must be covered by the importer or agent.

5 Guidance

5.1 Incorporation of material by reference

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

(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.

5.2 Inspection and verification

(1) On arrival, all documentation accompanying the consignment will 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.

5.3 Packaging

(1) It is the importer's responsibility to ensure that the exporter is informed of the transport requirements according to the International Air Transport Association (IATA) Dangerous Goods Regulations where necessary. These are available at http://www.iata.org/

(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.

5.4 Documentation

(1) Where required by the IHS an importer may apply to MPI for an import permit. Application forms can be found on our website at http://www.biosecurity.govt.nz/forms/permit-biologicals-microorganisms

(2) If applying for the inclusion of a product catalogue and/or product list, applications should be accompanied by a copy of the product catalogue and/or product list, and a Declaration of Potential Risk Goods. This form is available at: www.biosecurity.gov.nz/forms/assessment-biologicals-catalogues

(3) Completed applications should be submitted to the contact details listed in this guidance document.

6 General requirements

6.1 Eligibility

(1) Imported biological products (including samples) fall into the four categories listed in the IHS. Further information about the four categories is included below.

6.1.1 Laboratory research, diagnostic and analytical purposes

(1) This includes equipment calibration and validation.

(2) Generally such use would be conducted in some type of 'facility' because they mostly default to a laboratory-type environment, for example; in crown research institutes, universities, private research institutions, diagnostic testing laboratories, veterinary laboratories, etc.

6.1.2 Animal product samples for evaluation and/or proficiency testing

(1) Product samples include meat, fibre, dairy, hides and skins.

(2) While the size and volume of a sample can be arbitrary, it is recognised that samples, as being a small part representative of the whole, 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 standard.

6.1.3 Environmental use

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

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

(3) A biosecurity clearance is required when a biological product will be used in the environment.

6.1.4 Use in, or on humans, animals or plants

(1) This includes medical, veterinary or horticultural use.

(2) Additional requirements under the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act) may be needed for use on animals and plants.

a) For information about ACVM please refer to: http://www.foodsafety.govt.nz/industry/acvm/

6.2 Products of human origin

(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.

(2) Biological products derived from humans are not subject to the IHS requirements and are eligible for biosecurity clearance.

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 Ministry of Health and the Ministry of Business, Innovation & Employment that applies to these goods.

(4) If clearance of human derived products is sought, it is recommended that the accompanying documentation declares the products as being of human origin, and communicates that clearance is sought under clause 8 of the *IHS: Biological Products (Including Samples).*

6.3 Exclusions

(1) The categories of biological products and/or risk goods not eligible for importation under the IHS are:

a) Goods that are, or contain, viable micro-organisms. This includes products that are imported with the intention of isolating or culturing microorganisms from the samples, or used for microorganism enrichment, for example; viruses, bacteria, prions, protozoa etc.
b) Includes purposes where the microorganisms may, or may not be, rendered non-viable as part of the processing.
c) Such goods are subject to the Import Health Standard: Micro-organisms from All Countries (MICROIC.ALL).

(2) Goods that are, or contain, viable cell cultures/non-microbial cells. This includes products that are imported with the intention of cell isolation and/or culture.

a) Includes purposes where the cultures/non-microbial cells may, or may not be, rendered non-viable as part of the processing.
b) Such goods are subject to the Import health standard: Cell Cultures from All Countries (CELLCULIC.ALL).

(3) Biological products that are eligible for, or meet the specific requirements of, another IHS must be imported under that standard. This includes most biological products imported for purposes other than eligible products.

a) Example: There are a number of IHSs for hides and skins. The purpose of importation for most of them relates to commercial processing, production and retail sale. The *IHS: Biological Products (Including Samples)* only applies to the importation of samples of these products for evaluation purposes.
b) For a list of other IHSs refer to the MPI website: http://www.biosecurity.govt.nz/ihs/search

7 Specified requirements for identified risk organisms

7.1 Biological products for human use

(1) Where these goods meet the requirements of the IHS, these goods are eligible for import without a permit to import.

7.2 Milk and milk products eligible for clearance

7.2.1 Foot and mouth disease (FMD)

(1) Milk and milk products imported from countries or zones that are recognised by MPI as FMD-free will be eligible for clearance as long as they meet the eligibility criteria described in the IHS.

(2) Refer to the MPI list of FMD free countries or zones for the most up to date list of countries New Zealand recognises as free from FMD virus, available at the following webpage: http://www.biosecurity.govt.nz/files/pests/foot-n-mouth/fmd-free-countries-and-zones.pdf

7.2.2 Tamper proof packaging

(3) The intent of this requirement is to ensure that milk and milk products are packaged in such a way as to limit the possibility of them being interfered with or inadvertently opened during transport. This will reduce the likelihood of biosecurity risks being introduced following the products being packaged.

(4) For a full set of eligibility conditions, refer to the IHS.

7.3 Animal product (trade) samples for evaluation

(1) Animal product samples for evaluation must meet all conditions on the permit to import. The transitional facility listed on the permit to import must be approved at the time of import to one of the following MPI Transitional Facility Standards:

a) For fibre, or hides and skins samples, MPI-STD-TFGEN – Standard for General Transitional Facilities for Uncleared Risk Goods – ANNEX F: Animal Products OR ANNEX G: Holding of Biological Products; or
b) For all other products, 154.02.17 – Transitional Facilities for Biological Products.

(2) As stated in the IHS, animal product samples may be eligible for clearance if treated in a MPI approved facility as per the relevant IHS. The IHS search page can be found here: http://www.biosecurity.govt.nz/ihs/search

(3) For clearance of fibre samples (e.g. wool, mohair, cashmere, alpaca fibre), after completion of evaluation, the fibre must be treated by one of the following methods:

a) Exposure of the fibre to dry heat at 140°C for 3 hours; or
b) Immersion of the fibre in water heated and maintained at a temperature of 95°C for 25 minutes or at a temperature of 100°C for 15 minutes; or
c) Autoclaving of the fibre at 120°C for 10 minutes; or
d) Gamma irradiation at a minimum dose of 50kGy (5Mrad) (i.e. either one treatment of 50 kGy, or two treatments of 25 kGy); or
e) Removal of all seeds and plant material from the fibre and then fumigation of the fibre with 10% formalin for 8 hours; or
f) Other method as approved by MPI.

7.4 Processed risk goods for use within a transitional facility

(1) Biological products that have been subjected to some form of processing, but are still assessed by MPI to be risk goods, must meet all conditions on the permit to import and the transitional facility listed on the permit to import is approved at the time of import to either MPI Standard:

a) 154.02.17 – Transitional Facilities for Biological Products; or
b) MPI-STD-TFGEN – Standard for General Transitional Facilities for Uncleared Goods Annex G: Holding of Biological Products

(2) Products may only be opened and/or used in a transitional facility approved to MPI standard 154.02.17.

7.5 Unprocessed risk goods for use within a transitional facility

(1) Biological products that have not been processed, or assessed by MPI as not being adequately processed, will be deemed as higher risk. These products are only eligible for import into

a) A PC2 accredited 154.02.17 Transitional Facility for Biological Products or;
b) A PC1 accredited 154.02.17 Transitional Facility for Biological Products with one of the following waste disposal methods:

i) Pressure steam sterilisation; or
ii) Chemical disinfection; or
iii) High temperature, high efficiency regional council-approved incineration; or
iv) MPI approved biohazard waste disposal supplier; or
v) Other process as agreed by MPI, and approved in writing.

(2) Examples of such products include, but are not limited to: egg, poultry, blood, semen, bee products, freshwater fish, and faeces.

7.6 Negligible risk register

(1) The following list contains biological products that have been assessed by MPI and considered non risk goods. They are eligible for clearance without a permit to import:

a) Amino acids
b) Antimicrobials
c) Cellular dyes and stains
d) Chemical reagents and synthetic substances
e) Chitin
f) Collagen products (highly processed)
g) DNA (naked, i.e. not contained within a vector)
h) Enzymes
i) Fluorescent markers
j) Gelatine/Gelatin products
k) Heparin based products (including tubes)
l) Hormones
m) Plasmids (naked, i.e. not contained within a vector)
n) RNA (naked, i.e. not contained within a vector)

(2) If clearance is sought using the Negligible Risk Register, it is recommended that the accompanying documentation includes the declaration; "Goods are included in the [insert item here] category on the Negligible Risk Register in the guidance document of BIOPRODIC.ALL."

(3) All items must be commercially manufactured and packaged, with the exception of DNA/RNA (including plasmids).

Appendix 1 – Change History

Previous Version Date	Current Version Date	Section Changed	Change(s) Description
03 June 2011	14 March 2014	Various	Replaced references to Ministry of Agriculture and Forestry (MAF) and Biosecurity New Zealand (MAFBNZ; BNZ) with Ministry for Primary Industries (MPI)
		Exclusions	Clarify that 'negligible risk goods' are considered 'not risk goods'. Update reference to Department of Labour with Ministry of Business, Innovation and Employment.
		Milk and Milk Products	Amendment to reflect conditions of the IHS