



Guidance Document to the Import Health Standard for Biological Products (including samples)

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Part A. Introduction

Foreword

This guidance document has been issued to accompany the MAF Standard, Import Health Standard for Biological Products (including samples) - BIOPRODIC.ALL (the “standard”). It is not a legally binding document and, although it can be read independently of the standard, it should be read in conjunction with it to ensure that all matters relating to meeting the requirements of the standard are fully understood.

This standard revokes and replaces the following MAF standards:

- *Import Health Standard for the Importation of Raw Milk Samples for Evaluation and Destruction from New Caledonia - DAIRMSIC.NCA (27 July 1998)*
- *Import Health Standard for the Importation into New Zealand of Dairy Product Samples for Evaluation - DAISAMIC.ALL (11 May 2004)*
- *Import Health Standard for the Importation into New Zealand of Animal Fibre for Testing from All Countries - FIBTESIC.ALL (26 June 2001)*
- *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)*
- *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)*
- *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)*
- *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)*
- *Import Health Standard for the Importation of Meat Samples for Evaluation and Destruction into New Zealand from Fiji - MEASAMIC.FIJ (27 July 1998)*
- *Import Health Standard for the Importation into New Zealand of Meat and Meat Byproduct Samples for Evaluation from Specified Countries - MEASAMIC.SPE (21 October 2004)*
- *Import Health Standard for the Importation of Fresh Whole Eggs for Evaluation and Destruction into New Zealand from Fiji - POUEGGIC.FIJ (27 July 1998)*
- *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)*

Review and Amendment

This Guidance Document is subject to review and amendment at any time to ensure that it continues to meet its purpose.

All stakeholders are responsible for ensuring that the most recent version of the Guidance Document is used.

MAF Animal Imports contact details

For all matters relating to the standard and this Guidance Document, please contact:

Animal Imports Group

MAF Biosecurity New Zealand

PO Box 2526

WELLINGTON 6011

Fax: +64 4 894 0733

Email: animalimports@maf.govt.nz

Importer responsibilities

The costs to MAF in performing functions relating to the importation of biological products must be recovered in accordance with the Biosecurity Act 1993 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.

Part B. Scope

Eligibility

1. For the purposes of this standard, biological products (including animal product samples), means products imported for one of the following:
 - **Laboratory research, diagnostic and analytical purposes (including equipment calibration and validation).** Generally such use would be conducted in some type of “facility” because they mostly default to a laboratory-type environment, e.g. in crown research institutes, universities, private research institutions, diagnostic testing laboratories, veterinary laboratories etc.
 - **Animal product samples for evaluation and/or proficiency testing (e.g. meat, fibre, dairy, hides and skins samples).** 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.
 - **Environmental use;** this generally means that the biological product will end up in the environment and, therefore, require a biosecurity clearance. This includes a range of commercially manufactured and packaged products, e.g. effluent biodegraders, biofertilisers etc.
 - **Use in, or on, humans, animals and/or plants (e.g. medical, veterinary or horticultural use).** For use on animals and plants, there may be additional requirements under the Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act).

Exclusions

2. Biological products derived from humans are not subject to this import health standard and are eligible for biosecurity clearance.

NOTE: Any products containing infectious agents that can be transmitted between (or are shared by) animals and humans are not eligible for clearance. See section 3 below.

- Human beings are not considered to be organisms for the purposes of the Biosecurity Act 1993 and, therefore, are not risk goods in themselves.
- While there are products derived from, and associated with, human beings that are considered to be risk goods, these have been assessed by MAF to be of negligible risk or are considered to be adequately managed by the Ministry of Health and the Ministry of Labour under their respective legislative mandates. In addition, the majority of risks associated with such products are the same as those associated with human beings themselves.
- Consequently, these products do not need to be managed independently of other legislation that manages human movement into New Zealand.
- 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 import health standard for Biological Products (including samples) – BIOPRODIC.ALL.

3. The categories of biological products and/or risk goods **not** eligible for importation under this import health standard are:
- Goods that are, or contain, viable micro-organisms. This includes products that are imported with the intention of micro-organism enrichment (e.g. prions), isolation, and/or culture.

NOTE: Includes purposes where the microorganisms may, or may not be, rendered non-viable as part of the processing.

Such goods are subject to the import health standard MICROIC.ALL: [Import Health Standard for Micro-organisms from All Countries](#).

- 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.

NOTE: Includes purposes where the cultures/non-microbial cells may, or may not be, rendered non-viable as part of the processing.

Such goods are subject to the import health standard CELLCULIC.ALL: [Import health standard for Cell Cultures from All Countries](#).

4. Biological products that are eligible for, or meet the specific requirements of, another import health standard must be imported under that standard. This includes most biological products imported for purposes outside the scope in (1) above.

Example: *There are a number of import health standards for hides and skins. The purpose of importation for most of them relates to commercial processing, production and retail sale. This standard only applies to the importation of samples of these products for evaluation purposes.*

For a list of other import health standards refer to the MAF website: <http://www.biosecurity.govt.nz/ihs/search>

Part C. General Guidance

Documentation

5. Where required by the standard an importer may apply to MAF for an import permit. Application forms can be found on our website at <http://www.biosecurity.govt.nz/forms/imports-biologicals-microorganisms>
6. If applying for the inclusion of a product catalogue and/or listing, applications should be accompanied by a copy of the product catalogue and/or listing, and a Declaration of Potential Risk Goods. This form is available by contacting animalimports@maf.govt.nz
7. Completed applications should be submitted to the contact details listed under Part A of this document.

Inspection

8. Documentation in relation to a specific consignment of biological products must be inspected on arrival by an inspector. The inspector may also inspect the consignment, or part of the consignment to verify the documentation and/or check for compliance to the requirements of the import health standard.

Packaging

9. 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/>
10. 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.

Part D. Specific Guidance

Biological Products for Human Use

11. Biological products that are antibiotics, vaccines or surgical implants/products and intended to be used on or in humans, are eligible to receive biosecurity clearance provided that:
 - They are commercially manufactured;
 - The packaging identifies that the products are intended for human use; and
 - The packaging of surgical implants/products also identifies that the product(s) are sterile.

Milk and Milk Products

12. **Freedom from Foot & Mouth Disease.** To ensure that milk and milk products are free of foot and mouth disease (FMD), New Zealand will only allow such products to be imported from countries that are recognised by MAF as FMD-free.

Refer to the MAF list of FMD free countries/zones for the most up to date list of countries New Zealand recognises as free from foot and mouth disease virus, available at the following webpage:

<http://www.biosecurity.govt.nz/files/pests/foot-n-mouth/fmd-free-countries-and-zones.pdf>

13. Country of origin must be clearly identifiable on the sealed, and tamper-proof packaging.
14. **Tamper-proof packaging.** 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.

NOTE: For a full set of eligibility conditions, refer to the import health standard.

Animal Product (Trade) Samples for Evaluation

15. Animal products samples for evaluation 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 MAF Standard:
 - For fibre, or hides and skins samples, BNZ-STD-TFGEN – *Standard for General Transitional Facilities for Uncleared Risk Goods – ANNEX F: Animal Products* OR *ANNEX G: Holding of Biological Products*; OR
 - For all other products, 154.02.17 – *Transitional Facilities for Biological Products*.
16. Animal product samples are not eligible for clearance unless first treated to eliminate risk organisms as per relevant import health standard for that commodity.

17. 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:

EITHER

- i. exposure of the fibre to dry heat at 140°C for 3 hours; OR
 - ii. 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
 - iii. autoclaving of the fibre at 120°C for 10 minutes; OR
 - iv. gamma irradiation at a minimum dose of 50kGy (5Mrad) (i.e. either one treatment of 50 kGy, or two treatments of 25 kGy); OR
 - v. removal of all seeds and plant material from the fibre and then fumigation of the fibre with 10% formalin for 8 hours; OR
 - vi. other method as approved by the MAF Animal Imports Group
18. For clearance of hide and skin samples, after completion of evaluation, the hides and skins must complete the treatment requirements in the relevant import health standard for that commodity.

Processed Risk Goods for Use within a Transitional Facility

19. Biological products that have been subjected to some form of processing, but are still assessed by MAF 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 MAF Standard:

- o 154.02.17 – *Transitional Facilities for Biological Products*; OR
- o BNZ-STD-TFGEN – *Standard for General Transitional Facilities for Uncleared Goods Annex G: Holding of Biological Products*

NOTE: Products may only be opened and/or used in a 154.02.17 facility.

Unprocessed Risk Goods for Use within a Transitional Facility

20. Biological products that have not been processed, or assessed by MAF as not being adequately processed, will be deemed as higher risk. These products are only eligible for import into a PC2 accredited 154.02.17 *Transitional Facility for Biological Products* OR; a PC1 accredited 154.02.17 *Transitional Facility for Biological Products* with one of the following waste disposal methods:

EITHER:

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

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

21. In the case of bee products, the transitional facility must be insect proof, or have an active control programme to manage the risk of insect contamination.

Part E: Negligible-Risk Register

The following list contains biological products that have been assessed by MAF BNZ and considered as negligible risk. They are eligible for clearance without a permit to import.

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.”

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

Amino acids
Antimicrobials
Cellular dyes and stains
Chemical reagents and synthetic substances
Chitin
Collagen products (highly processed)
DNA (naked, i.e. not contained within a vector)
Enzymes
Fluorescent markers
Gelatine/Gelatin products
Heparin based products (including tubes)
Hormones
Plasmids (naked, i.e. not contained within a vector)
RNA (naked, i.e. not contained within a vector)