Import Health Standard

for

Biological Products (including samples)

Short name: BIOPRODIC.ALL

Ministry for Primary Industries
P.O Box 2526
Wellington 6140
New Zealand

ISSUING AUTHORITY

This standard is issued under section 24A of the Biosecurity Act 1993 (the Act).

Dated at Wellington this fifth day of November 2015.

Director-General Ministry for Primary Industries
(Issued under delegated authority)

IMPORTANT INFORMATION FOR IMPORTERS AND BORDER STAFF

Date: 03 November 2015

The following information relates to Chief Technical Officer (CTO) Direction CTO 2015 079 [B] which grants equivalence under clause 19:

Biological products intended to be used on or in humans such as, but not limited to; antibiotics, vaccines, and surgical implants/equipment, are eligible to receive biosecurity clearance provided that

- They are commercially manufactured **or manufactured in a GMP facility for non-commercially manufactured products**; and
- The packaging identifies that the products are intended for human use **or the import is accompanied by a signed and dated manufacturer's declaration stating the products are intended for human use, linking the batch numbers of the product to those being imported**; and
- The packaging of surgical implants also identifies that the product(s) is sterile.

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PART A. Introduction

Background

1. Under section 24A of the Act, this document is the Import Health Standard ("the standard") for Non-Viable Biological Products (including samples).

2. If this standard needs to be amended or revoked urgently, or the Director General considers that an amendment is minor, the amendment or revocation may be carried out without prior consultation.

3. A Guidance Document will be issued by MPI to accompany this Import Health Standard. The document will provide guidance information relevant to how the requirements may be met.

4. Pursuant to section 26 of the Biosecurity Act 1993, a **biosecurity clearance** will be issued for biological products that are eligible for biosecurity clearance, when the requirements of this standard are met.

5. Pursuant to section 25 of the Biosecurity Act 1993, a **biosecurity authority**, will be issued for biological products that are eligible to move to a transitional facility.

Scope

6. This standard specifies the requirements that must be met to effectively manage the risks associated with the importation of non-viable biological products (including animal product samples) into New Zealand.

7. For the purposes of this standard, biological products means products imported for one of the following purposes:

    - Laboratory research, diagnostic and analytical purposes (including equipment calibration and validation)
    - Animal product samples for evaluation and/or proficiency testing.
    - Environmental use; OR
    - Use in, or on, humans, animals and/or plants (e.g. medical, veterinary or horticultural use).

NOTE: See Guidance Document for eligibility and exclusions of biological products.

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

Outcomes

9. The desired outcome of this standard is that the biosecurity risks associated with biological products are effectively managed to eliminate any adverse effects these may have on New Zealand's natural and physical resources, the economy or human health and safety.

10. To achieve this outcome, biological products must be subject to risk assessment to identify those that require risk management and to exclude those considered to be of negligible risk.

11. Products imported under this standard must meet the general requirements contained in Part B of this standard and any specific requirements included in Part C that are applicable.

Definitions

12. The definitions below relate to the requirements for importing consignments under this import health standard:

Biological Product
Non-viable (not capable of living, replicating, reproducing or developing) products derived from living organisms, including samples of animal origin (Note: Biological products derived from humans are not subject to this import health standard).

Medicine
Has the same meaning as that defined in the Medicines Act 1981.

Milk and Milk Products
Includes all products manufactured from the milk of animals. For example; cream, cheese, yoghurt, butter, milk powder.

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

Sample
A small part intended as a representative of the whole

PART B. GENERAL REQUIREMENTS

Documentation

13. A permit to import is required for biological products, with the exception of:
    - Milk and milk products that meet the criteria contained in Part C below, OR
    - Biological products that are listed on the **Negligible Risk Register.** *See Guidance Document.*

14. A copy of the permit to import must accompany **each** consignment. This should be securely attached to the outside of the external packaging.

15. All unaccompanied products imported under this standard must be transported with information that identifies the origin of the product (i.e. country or zone), the destination in New Zealand, and adequately describes the nature of the product.

Inspection

16. 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 this standard.

Packaging and Transport

17. Packaging must be free of any contaminants, and must be appropriate given the nature of the goods to effectively contain any potential biosecurity risks during transport.

18. 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/

PART C. SPECIFIC REQUIREMENTS

Biological Products for Human Use

19. Biological products intended to be used on or in human such as, but not limited to; antibiotics, vaccines, and surgical implants/equipment, 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 also identifies that the product(s) is sterile.

Milk and Milk Products

Important information for importers

20 March 2017

CTO 2017 014[B] gives direction to replace the *MPI List of Foot & Mouth Disease (FMD) Free Countries* with the *OIE List of FMD Free Member Countries* for clearance of specified products.
http://www.oie.int/en/animal-health-in-the-world/official-disease-status/fmd/list-of-fmd-free-members/

For the purposes of this IHS, FMD free includes countries listed in these sections:

- *FMD free where vaccination is not practised;* and
- *FMD free where vaccination is practised.*

It does not include these sections:

- *FMD free zone where vaccination is not practised;* or
- *FMD free zone where vaccination is practised.*

20. Samples containing milk and milk products from Foot and Mouth Disease (FMD) free countries or zones (as per the MPI list of FMD free countries/zones) must:
    - individually weigh no more than 50kgs; AND
    - be in tamper-proof packaging; AND
    - be packed in; AND
    - be shipped from; AND
    - only contain ingredients sourced from an FMD-free country.

21. Milk and milk products must be packed by the manufacturer in sealed tamper-proof packaging with the country of origin clearly stated on the packaging, or documentation accompanying the sample(s).

22. Products that comply with the criteria specified in clauses 20 and 21 above will be eligible for **biosecurity clearance.**

23. Products that do not comply with the criteria specified in clauses 20 and 21 above will require a permit to import that specifies that the products are eligible for **biosecurity authority** to move to a transitional facility.

Negligible Risk Goods for Clearance

24. Other biological products may be eligible for **biosecurity clearance** provided that they:
    - Meet all conditions on the accompanying permit to import, OR
    - Have been assessed by MPI to be goods with a negligible risk, OR
    - Are listed on the **Negligible Risk Register.** *See Guidance Document.*

Risk Goods for Use within a Transitional Facility

25. Biological products (including samples) that are assessed by MPI to be risk goods may be eligible for a **biosecurity authority** to move to a MPI approved transitional facility provided they meet all conditions on the permit to import. See Guidance Document on requirements for processed and unprocessed risk goods.

26. Animal product samples may be eligible for clearance if treated in a MPI approved facility to eliminate risk organisms as per the relevant import health standard for that commodity. This option is only applicable to samples that meet the eligibility criteria of the relevant import health standard.

27. 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 D. EQUIVALENCE

28. The requirements for importation of biological products (including samples) are met if, in the opinion of the Director General, the measures taken for managing the risks associated with the importation of those consignments are equally effective at managing those risks as the requirements specified in (1) to (27) above. If an equivalence measure(s) is approved, MPI will issue a permit to import (under section 27(1)d(iii) of the Biosecurity Act).