Import Health Standard
for
Biological Products (including samples)

Short name: Bioprodic.all

MAF Biosecurity New Zealand
Ministry of Agriculture and Forestry
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ISSUING AUTHORITY

This standard is issued under section 22 of the Biosecurity Act 1993 (the Act).

Dated at Wellington this day of 2011

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For Director General
(Issued under delegated authority)
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PART A. Introduction

Background

1. Under section 22 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 MAF 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, authorising will be issued for biological products that are eligible for biosecurity direction, when the requirements of this standard are met.

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 including animal product samples means products imported for one of the following:
   - 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).

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 the consignment:

Biological Product
Non-viable 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.

Raw Dairy Product
Includes all products manufactured from the milk and cream of animals that have not undergone further treatment (i.e. heat or chemical) to minimise biosecurity risk.

Sample
A small part intended as a representative of the whole
PART B. GENERAL REQUIREMENTS

Documentation

13. A permit to import is required for all biological products, with the exception of:
   o Milk and milk products that meet the criteria contained in Part C below, OR
   o 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 biological products are transported according to the requirements of 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 that are antibiotics, vaccines or surgical implants and/or 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 also identifies that the product(s) is sterile.

Milk and Milk Products
20. Milk and milk product samples must be packed in, and only contain ingredients sourced from, countries that are recognized by MAF as being free from foot and mouth disease at the time of milk collection. For a list of countries, see MAF recognised FMD free countries document. Note: Document under development

21. Milk and milk products must be packed by the manufacturer in tamper-proof packaging with the country of origin clearly stated on the packaging

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

23. Products that do not comply with the criteria specified in clauses 21 and 22 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 MAF to be goods with a negligible risk, OR
   - Are listed on the Negligible Risk Register. See Guidance Document.

Risk Goods for Use in a Transitional Facility
25. Biological products that are assessed by MAF to be risk goods may be eligible for a biosecurity authority to move to a MAF approved transitional facility provided they meet all conditions on the permit to import.

Samples of Biological Products
26. Animal product samples are not eligible for clearance unless first treated 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. Biological products that have not been sufficiently processed, or assessed by MAF as not being adequately processed, will be deemed as higher risk. Waste materials from these products must be disposed of in a MAF approved manner. See Guidance Document.

Bee Products
28. In the case of bee products, the laboratory must be insect proof, or have an active control programme to manage the risk of insect contamination.