Ministry for Primary Industries
Manatū Ahu Matua

Risk Management Proposal

Biological Products

BIOLOGIC.ALL

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New Zealand Government

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Contents

1 Purpose

(1) The purpose of this document is to:

a) Show how options for the management of risk organisms have been assessed.
b) Provide recommendations for import requirements.

2 Background

(1) Biological products are considered a risk commodity, with the potential to harbour exotic risk organisms. In December 2005, the Ministry of Agriculture and Forestry (MAF; superseded by the Ministry for Primary Industries (MPI)) completed an import risk analysis (IRA): *Non-viable Biological Products, Microorganisms and Other Viable Cells into New Zealand* (IRA 2005). The IRA 2005 was used to develop the *Import Health Standard (IHS) for Biological Products (Including Samples)* (2010).

(2) Part 1 of the IRA 2005 looked at non-viable products that have been derived from living organisms, or are identical to products derived from living organisms, and which are predominantly used by laboratories. Due to the number of products offered for sale by suppliers of biological products being too numerous, generic groups of products were considered within the IRA 2005.

(3) The following categories of biological products that are predominantly used in laboratories were included in the IRA 2005 analysis:

a) Amino acids
b) Antimicrobials (antibiotics)
c) Biological products derived from animal tissues
d) Culture media
e) Polynucleotides
f) Products derived from blood
g) Products derived from eggs
h) Products derived from microorganisms
i) Restriction enzymes
j) Small molecular weight fermentation products (including alcohols, organic acids and esters)
k) Test kits

(4) The scope of the IRA 2005 did not include the following categories of biological products as they fall under other legislation not the Biosecurity Act 1993:

a) Human medicines (Medicines Act 1981 – administered by the Ministry of Health)
b) Veterinary medicines (Agricultural Compounds and Veterinary Medicines Act 1997 (ACVM Act))
c) Food and food supplements (Food Act 2014)
d) Agricultural products (ACVM Act)

(5) The IHS for biological products contains generic import requirements. These requirements manage the biosecurity risk of importing biological products from all countries. Guidance will be issued by MPI and this will provide commodity specific guidance information.

(6) Import requirements for microorganisms and cell cultures and other live cells from plants and animals (covered in Parts 2 & 3 of the IRA 2005) fall within other import health standard(s).

(7) Under Article 3.3 of the World Organisation for Animal Health (OIE) Agreement on the Application of Sanitary and Phytosanitary Measures (the SPS Agreement), risk management measures which provide a level of protection greater than provided by international standards may be imposed only when they can be scientifically justified on the basis of a risk assessment.

(8) For a detailed analysis of potential hazards and their risks please refer to the supporting document, *Import Risk Analysis: Non-viable Biological Products, Microorganisms and Other Viable Cells into New Zealand* which contains the relevant risk assessment and an analysis of risk management options for each risk commodity group.

(9) The following biological products, predominantly used in laboratories, which were included in the preliminary hazards list were found to be of negligible concern and were not considered to be potential hazards requiring further investigation:

a) Amino acids
b) Antimicrobials (antibiotics)
c) Small molecular weight fermentation products

(10) The IRA 2005 concluded that risk management measures were justified for the following imported non-viable biological products:

a) Products derived from blood
b) Products derived from eggs
c) Products derived from microorganisms
d) Products derived from animal tissues

3 Objective

(1) The objective is to effectively manage biosecurity risks associated with the import of non-viable biological products, consistent with New Zealand's domestic legislation and international obligations.

4 Requirements for all importations of biological products

(1) This section covers the biological products considered in the IRA 2005, discusses the risk management options presented and makes a recommendation for inclusion in the IHS.

(2) The IRA 2005 has a section titled 'clearance to enter New Zealand'. It states that biological product importers must have a valid import permit which may document any specific restrictions that apply. The IHS for biological products currently does not have this requirement for all classes of product. In general import permits are only issued for products that require direction to a transitional facility, or if there are post arrival conditions, or if there is a Chief Technical Officer (CTO) direction that needs to be communicated. It is intended that this risk management proposal (RMP) reviews and identifies biological products which pose a negligible risk and may be cleared at the border without requiring an import permit.

(3) The resulting IHS will require:

a) No import permit for commodities of negligible risk; or
b) An import permit issued for commodities assessed by MPI and concluded to be of negligible risk but where that product is not listed as negligible risk within the relevant IHS (a general import permit); or
c) An import permit issued for commodities assessed by MPI and concluded to pose a risk to New Zealand's biosecurity but for which the risk can be managed by directing the product to be held in and/or used in a transitional facility (a restricted import permit).

4.1 Culture media

(1) The IRA 2005 states that culture media should be classified according to the risk goods they are comprised of (for example, media containing whole serum, blood, or animal tissues that have not been sterilised should be assessed against the specific risk analysis for each risk ingredient).

(2) Commercially manufactured and packaged formulated media and media ingredients which do not contain whole blood or serum or animal ingredients will be free from infectious pathogens. Therefore, these products do not need to be kept in a transitional facility and are eligible for biosecurity clearance.

(3) As the release estimation in the IRA 2005 is negligible, risk management measures are not necessary for commercially manufactured and packaged pre-plated culture media. Sterile culture media products could be eligible for biosecurity clearance.

4.1.1 Recommendation

(1) Commercially manufactured and packaged non-sterile culture media may be imported from any country when accompanied by a signed and dated manufacturer's declaration (on manufacturer letterhead paper) confirming the product does not contain any ingredients of animal origin, including blood, whole serum, animal proteins or animal tissues.

(2) Commercially manufactured and packaged sterile culture media (including those that contain animal serum, blood and proteins) may be imported from any country when labelled for *in-vitro* use only and accompanied by a signed and dated manufacturer's declaration (on manufacturer letterhead paper) confirming the product has been sterilised.

(3) Culture media, from any country, which is not commercially manufactured and packaged 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).

(4) Culture media for use in the manufacture of veterinary medicines, animal feeds or agricultural compounds (as defined under the ACVM Act) requires a specific biosecurity assessment by MPI and, if MPI considers the risk can be effectively managed, must be accompanied by an import permit. This includes sterile products.

4.2 Polynucleotides

(1) The IRA 2005 states purified DNA or RNA not contained in a host is not a self-replicating organism. Those gene sequences that have been cloned into live host organisms (including viruses, phages and cell cultures) are considered living organisms and should be imported as per the microorganism import health requirements.

(2) As the IRA 2005 concludes the risk of purified DNA and purified RNA being contaminated with viable source organisms is negligible, risk management measures are not needed and such items could be eligible for biosecurity clearance without an import permit.

(3) Currently, these commodities fall on the negligible risk register in the current import health standard (2010).

4.2.1 Recommendation

(1) Purified DNA and purified RNA (naked) may be imported from any country.

4.3 Restriction enzymes

(1) The IRA 2005 discusses that restriction enzymes, also known as restriction endonucleases, are produced from cultures of microorganisms.

(2) Although the restriction enzymes are not biosecurity hazards, they could be contaminated with pathogenic organisms. However, the likelihood that reputable commercial companies would offer contaminated restriction enzymes is negligible.

(3) As the risk of restriction enzymes is estimated to be negligible in the IRA 2005, commercially manufactured and packaged restriction enzyme risk management measures are not necessary and could be eligible for biosecurity clearance.

4.3.1 Recommendation

(1) Commercially manufactured and packaged restriction enzymes may be imported from any country.

4.4 Biological products derived from animal tissues (excluding blood)

(1) The IRA 2005 states the range of products that could be classified as biological products derived from animal tissue is so great that it is not feasible to consider single risk products. Instead, the general

principles of the risk involved in importing the substances should be taken into consideration. This section excludes biological products derived from blood (refer to section 4.6 of this document).

(2) The source of the product, whether it is free from infectious pathogens, the extent of product purification and the sterilisation process should be assessed. The IRA 2005 lists the following sterilisation processes:

a) Filtration using membranes with pore sizes 0.2μm will remove microorganisms, with the exception of viruses and mycoplasma1.
b) Gamma irradiation will render viruses and other organisms non-viable but this method is rarely used on biological products offered for sale.
c) Appropriate time and temperature heat treatment will destroy organisms of concern but will also denature many biological products.
d) Chemical treatments are more commonly used to destroy viruses in blood products intended for medicinal human use. The assessed biological products catalogues did not make reference to this particular treatment.

(3) The laboratory-based catalogues used to help inform the IRA 2005 included, but in no means are limited to, the following categories of commodities extracted from biological products of animal origin:

a) Enzymes
b) Hormones
c) Crude tissue extracts
d) Monoclonal antibodies
e) Molecules extracted from tissues
f) Fatty acids
g) Actin and myosin
h) Cholic acid

(4) It was surmised that most of the products offered for sale in catalogues can be considered safe as they:

a) Are highly purified
b) Are produced from animals that do not have organisms which are a biosecurity risk
c) Are produced using harsh methods that will destroy all microorganisms.

(5) The IRA 2005 exposure assessment discussed the transmission of a pathogenic organism from a facility where the contaminated product is being used would only be possible if the product was:

a) Transferred from the transitional facility to a location outside the transitional facility where animals and / or plants are exposed to the biological product.
b) Injected into or administered to a live animal or used to infect plants outside the transitional facility where it is being held and then transmitted to ‘in contact' animals or plants (for example, embryo culture media containing serum that is implanted into a recipient animal).
c) Injected into or otherwise used in animals or plants in non-secure facilities and then transmitted in wastewater, urine, faeces, etc. or by aerosol to animals or plants outside the laboratory.

(6) If commercially manufactured and packaged products are being used in a laboratory’s appropriately approved transitional facility, the risk of contamination of animals, people or the environment is considered to be negligible. Because the commodities within the catalogues assessed are sold for laboratory use, it would be unlikely that they would contain harmful viable microorganisms. However, the risk is still deemed to be non-negligible.

(7) Biological products derived from animal tissue intended to be used in animals need to be imported on an import permit which restricts importation to a specific batch number(s). Additional requirements for the importation of such products would be needed. This includes, but is not necessarily limited to:

a) The health status of the donor animals and their herds and countries of origin
b) Manufacturing methods, auditing of the manufacture process in the country of origin
c) Contents of the compounded product

[1] https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3584481/

d) Specified tests for freedom from infectious agents with the testing carried out by an independent competent authority approved laboratory and not by the manufacturer or supplier.

4.4.1 Recommendation

(1) Commercially manufactured and packaged highly purified or sterilised laboratory reagents / products produced from animal tissues (excluding bloods, serum, and serum proteins) may be imported from any country if accompanied by a signed and dated manufacturer's declaration (on manufacturer letterhead paper). The manufacturer's declaration will need to confirm the laboratory reagents / products produced from animal tissues (excluding bloods, serum, and serum proteins) are commercially manufactured and packaged highly purified or sterilised.

(2) Catalogued and commercially manufactured and packaged products produced from animal products comprising of risk goods (excluding bloods, serum, and serum proteins) may be imported from any country when 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).

(3) Non-commercially manufactured and packaged biological products derived from animal tissue (excluding bloods, serum, and serum proteins) may be imported from any country when 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).

(4) Non-purified products derived from animal tissues (excluding bloods, serum and serum proteins) may be imported from any country when listed on an accompanying import permit which requires the product to be held and/or used in an appropriately approved transitional facility (as listed on the import permit).

(5) Biological products of animal origin derived from animal tissue intended to be used in animals may be imported from any country when accompanied by an import permit which directs the product into an appropriately approved transitional facility (as listed on the import permit). Use of such products in or on animals requires additional permission from the CTO.

4.5 Products derived from eggs

(1) The IRA 2005 excludes fertile hatching eggs from the scope. They are classified as living organisms and are covered by a separate risk analysis and import health standard.

(2) Biological products derived from eggs were considered as a potential hazard due to the range of infectious diseases that can affect both animals and humans.

(3) The IRA 2005 reviewed laboratory-based manufacturer catalogues and found a range of biological products derived from eggs. Examples include:

a) Lecithin
b) Choline
c) Antibiotics produced in eggs
d) Egg yolk emulsions
e) Egg yolks
f) Egg white
g) Cystatin
h) Avidin
i) Conalbumin
j) Lysozyme
k) Egg white powder
l) Proteins derived from egg whites

(4) Products derived from egg and sold for use in culture media (such as egg yolk emulsions) are covered in section 4.1 of this document. They will be sterile and will be resterilised before use in media and again after use before disposal.

(5) Since there are a large number of products derived from egg and the production methods are not specified, the risk is assessed to be non-negligible.

(6) Additionally, the importation of products intended to be used in birds requires an import permit for each batch imported as well as any quality control requirements (the testing should be carried out by an independent competent authority approved laboratory and not by the manufacturer or supplier). CTO approval would also be required to use the product(s) in animals in a transitional or containment facility setting. Information regarding the health status of donor animals and their flocks, country of origin, manufacturing methods (including auditing the manufacturing process in the country of origin), composition of the compounded product and tests for freedom from infectious agents would need to be provided at a minimum.

4.5.1 Recommendation

(1) Commercially manufactured and packaged highly purified, sterilised or chemically synthesised laboratory reagents or products produced from egg may be imported from any country. This would include most catalogue products. The shipment is to be accompanied by a signed and dated manufacturer's declaration (on manufacturer letterhead paper) confirming this.

(2) Non-purified products derived from egg 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).

4.6 Products derived from blood

(1) The IRA 2005 states that all blood products are derived from a common source – therefore, the risks involved in importing non-purified and purified blood products is similar. The health status and species of the donor animals will impact on the likelihood the product is contaminated with harmful microorganisms (for example, bovine viral diarrhoea type 2 has been isolated from imported foetal calf serum).

(2) Blood products include:

a) Serum
b) Antisera
c) Plasma
d) Hormones
e) Albumins
f) Globulins
g) Antibodies
h) Proteins derived from blood

Antisera from laboratory animals

(3) The IRA 2005 discusses antisera from laboratory animals (such as mice and rabbits) has a negligible biosecurity risk as the rabbit and mouse viruses are not considered to be of importance to New Zealand. The use in and/or on laboratory animals must be in accordance with the transitional facility standard and requires CTO approval.

(4) After further consideration by MPI in 2019, the biosecurity risk of importing commercially manufactured blood products from laboratory animals (rabbits, hamsters, guinea pigs, mice, and rats) into New Zealand for laboratory use was reassessed. It was concluded that certain hazards may enter New Zealand via imported blood products from laboratory animals, deeming the risk of these products to be non-negligible.

Products purified from blood

(5) Products purified from blood such as plasma proteins (albumin and globulin), hormones and affinity purified antibodies are less likely to be contaminated with microorganisms than non-purified serum and plasma.

Products derived from blood and intended to be used in and/or on animals

(6) Some animal products may be imported with the intention of using them in the manufacture or formulation of products that will directly be used in animals – for example, in the manufacture of embryo media. This involves a higher risk and needs to be assessed according to the individual components within the media.

(7) The IRA 2005 release assessment concludes without adequate manufacturer guarantees regarding the freedom of blood products from contaminating microorganisms (including viruses), the risk likelihood is non-negligible.

(8) Where the origin and manufacturing procedures are unknown, the likelihood that blood products may carry infectious pathogens cannot be adequately assessed.

(9) Risk goods could be held and/or used in an appropriately approved transitional facility with a special condition noting that these products must be kept in a transitional facility and are not permitted to be injected or used in animals unless special clearance has been obtained from the CTO.

(10) Biological products derived from blood that are intended to be used in animals need to be imported on an import permit which restricts importation to a specific batch number. Additional risk assessment undertaken before the importation of such products would be needed. Additional information required to undertake this assessment may include, but is not necessarily limited to:

a) the health status of the donor animals and their herds and countries of origin,
b) manufacturing methods, auditing of the manufacture process in the country of origin,
c) contents of the compounded product,
d) specified tests for freedom from infectious agents with the testing carried out by an independent, competent authority approved laboratory and not by the manufacturer or supplier

4.6.1 Recommendation

(1) Commercially manufactured and packaged highly purified or sterilised products for laboratory use that are derived from blood (including antibodies, antisera, globulins, hormones) may be imported from any country. The shipment is to be accompanied by a signed and dated manufacturer's declaration (on manufacturer letterhead paper). The manufacturer's declaration will need to confirm the products for laboratory use are derived from blood (including antibodies, antisera, globulins, hormones) and are commercially manufactured and packaged highly purified or sterilised products.

(2) Commercially manufactured and packaged antisera and antibodies from laboratory-raised animals (guinea pigs, hamsters, mice, rabbits, rats) for laboratory use may be imported from any country. A specific biosecurity risk assessment must be undertaken by MPI and, if the biosecurity risk assessment concludes the risk is effectively managed, a general import permit is required. Otherwise, the products will require an import permit that requires direction to an appropriately approved transitional facility.

(3) Commercially manufactured and packaged products for laboratory use (excluding test kits) that comprise of risk goods (including, but not limited to, bovine serum albumin and foetal calf serum) may be imported from any country as long as they are 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).

(4) Non-purified products derived from blood may be imported from any country as long as they are 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.

(5) Products derived from blood or serum and intended for use as veterinary medicines will need to be assessed as per ACVMs in the IHS, and special conditions may be imposed.

(6) Biological products derived from blood intended to be used in animals may be imported from any country as long as they are 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). Use of such products in or on animals requires additional permission from the CTO.

4.7 Test kits

(1) The IRA 2005 acknowledges there are a very large number of test kits available for the diagnosis of animal and plant diseases and other analytical procedures. Test kits will be generally used in a laboratory environment but certain types of kits may also be used in the field.

(2) Commercially manufactured and packaged test kits can be regarded as safe as long as they do not contain live organisms. Therefore, these do not need to be restricted goods. Commercially manufactured and packaged test kits that contain live organisms should be assessed according to the most appropriate import health standard.

(3) As the risk of test kits that do not contain viable microorganisms is estimated to be negligible in the IRA 2005, commercially manufactured and packaged test kits that do not contain live organisms could be supplied without requiring the test kits to be imported into, and used in, an appropriately approved transitional facility.

4.7.1 Recommendation

(1) Commercially manufactured and packaged test kits intended for laboratory use and that do not contain live organisms may be imported from any country.

(2) Commercially manufactured and packaged test kits that contain live organisms should be assessed according to the most appropriate import health standard.

4.8 Amino acids

(1) The IRA 2005 considers that the purification processes for amino acids will produce purified low molecular weight products which are free from contaminating viable microorganisms. The IRA 2005 concludes the risk of commercially manufactured and packaged amino acids is negligible with no necessary risk management measures required. Therefore, commercially manufactured and packaged amino acids could be eligible for biosecurity clearance.

(2) It should be noted the IRA 2005 does not consider crude mixtures of amino acids and small peptides produced by hydrolysis of proteins to be classified as amino acids. Such products are described as peptones or hydrolysates and should be assessed as per the section on culture media (section 6.4 of IRA).

(3) These commodities fall on the negligible risk register in the current import health standard (2010).

4.8.1 Recommendation

(1) Commercially manufactured and packaged amino acids intended for laboratory use may be imported from any country.

4.9 Products derived from microorganisms

(1) The IRA 2005 states a large number of enzymes and other biological products (mainly proteins) are offered for sale to laboratories (products extracted directly from the tissues of animals (including blood) and eggs have been discussed in the relevant sections). Most other products are derived from microorganisms, with the majority of these being proteins. Products derived from microorganisms also includes some long chain fatty acids, starch, sugars and alcohol.

(2) Since the medium the microorganisms grow on is sterile, the only organisms that could contaminate the end-product are the donor organism(s).

(3) The risk in the IRA 2005 is estimated to be negligible for the presence of viable contaminating microorganisms in purified products. Therefore, the implementation of risk management measures is not justified. Products derived from microorganisms could be eligible for biosecurity clearance.

4.9.1 Recommendation

(1) Commercially manufactured and packaged purified products derived from microorganisms and intended for laboratory use may be imported from any country.

4.10 Small molecular weight fermentation products

(1) The IRA 2005 states small molecular weight fermentation products include alcohols, organic acids and esters and concludes the likelihood small molecular weight products sold as highly purified products for laboratory use would contain contaminating unwanted organisms is negligible.

(2) For the purpose of the IRA 2005, highly purified small molecular weight fermentation products are not considered to be potential risk goods for this analysis and could be eligible for biosecurity clearance.

4.10.1 Recommendation

(1) Commercially manufactured and packaged highly purified small molecular weight fermentation products for laboratory use may be imported from any country.

4.11 Antimicrobials/antibiotics

(1) The IRA 2005 considers all antibiotics derived from non-pathogenic microorganisms or those which are synthesised or semi-synthesised products. The IRA 2005 also states antibiotics produced from microorganisms are always purified.

(2) The IRA 2005 concludes the risk of antimicrobials/antibiotics as being negligible with no necessary risk management measures required. Antibiotics could be eligible for biosecurity clearance.

(3) Currently, these commodities fall on the negligible risk register in the current import health standard (2010).

4.11.1 Recommendation

(1) Commercially manufactured and packaged antimicrobials/antibiotics for laboratory use may be imported from any country.

(2) Antimicrobials/antibiotics intended for use as veterinary medicines will need to be assessed as per ACVMs in the IHS, and special conditions may be imposed.

5 Products covered by other IHSs that have been integrated into revised biological products IHS

5.1 Nonviable animal specimens from all countries

(1) Certain clauses from the *Import Health Standard for Non-viable Animal Specimens from All Countries, INESPEIC.ALL* have been incorporated into the revised biological products IHS.

(2) In addition to the current requirements of *INESPEIC.ALL*, the following have been incorporated:

a) The minimum percentage of fixative has been included (where relevant). These have been bolded in this RMP; and
b) The requirement of a declaration of the percentage of fixative has been included (where relevant). The declaration will be either stated on the label of the container containing the preserved specimen(s) or stated on a paper declaration accompanying the preserved specimen(s).
c) Specimens of animal tissue equal to, or less than, 2mm thick fixed in glyoxal.

(3) The following categories are eligible for biosecurity clearance (no import permit is required):

a) Whole animal specimens that have been preserved with **a minimum of 10%** liquid formalin or **70%** alcohol.
b) Whole animal specimens accompanied by a certificate of irradiation issued by an official government department or a recognised institution stating that the whole animal specimens have been subjected to a minimum dose of 5 mrad (50kGy) and that the whole animal specimens have been sealed in a hermetically sealed container and identified in a manner which can be referenced to the certificate of irradiation.
c) Specimens of animal tissues and animal faeces preserved in **a minimum of 10%** liquid formalin or **70%** alcohol.
d) Specimens of animal tissue less than 2mm thick fixed in 2 to 4% glutaraldehyde for electron microscope imaging, OR larger samples fixed in 2 to 4% glutaraldehyde by intravascular active perfusion.
e) Microscope slides of animal tissue, bacteria and protozoa fixed onto glass microscope slides under glass coverslips.
f) Specimens of animal tissue equal to, or less than, 2mm thick fixed in glyoxal.

(4) The clauses from *INESPEIC.ALL* that have not been proposed for incorporation are intended to be included as part of the revision scheduled for the *Import Health Standard: Ornamental Products of Animal Origin, INETROIC.ALL* and within the *IHS: Personal Consignments of Animal Products*, *PERSONAL.ALL*.

5.2 Specified animal products and biologicals

(1) Certain clauses of the *Import Health Standard for Specified Animal Products and Biologicals, INEPROIC.ALL* have been incorporated into the revised biological products IHS.

(2) Under *INEPROIC.ALL*, the following categories are eligible for biosecurity clearance (no import permit is required):

a) [*INEPROIC.ALL*, clause 6.6] Commercially manufactured antibiotics, medicines and vaccines intended for human use from any country may be given clearance.
b) [*INEPROIC.ALL*, clause 6.7] Products composed only of human tissue from any country may be given clearance.
c) [*INEPROIC.ALL*, part of clause 6.9] Heparin and heparanoid from any country may be given clearance provided the product is commercially packaged.
d) [*INEPROIC.ALL*, clause 6.15] The following surgical implants may be given clearance:

i) Lonescu Shirley low profile cardiac valve prostheses manufactured by American Edwards Labs, Santa Ana, California, United States of America
ii) Mitroflow TM pericardial heart valves manufactured by MNZ Ltd, Richmond, BC, Canada
iii) Unilab Surgibone manufactured by Unilab Inc, Hillside, New Jersey, United States of America
iv) SJM Epic cardiac valve prostheses manufactured by St. Jude Medical Inc, United States of America
v) Pericardial Tissue Bioprosthetic Devices (of bovine and porcine origin) of USA or Australian origin only, manufactured by Edwards Lifesciences AG, Switzerland
vi) CYPHER Sirolimus-eluting stent from Australia supplied by Johnson and Johnson Medical
vii) Mastergraft Matrix, manufactured by Integra Lifesciences Corporation (ILC), Plainsboro, New Jersey

(3) Clause 6.7 of *INEPROIC.ALL* has been included in the revised biological products IHS under the section of Part 1 relating to eligibility. Biological products derived from humans are not subject to the IHS and are eligible for biosecurity clearance.

(4) Clause 6.15 of *INEPROIC.ALL* has been included and extended in the revised biological products IHS under the section under Part 2 relating to biological products for human use.

5.3 Tested, filtered and irradiated foetal bovine serum, calf serum and bovine serum from Australia

(1) All of the *Import Health Standard for Tested, Filtered and Irradiated Foetal Bovine Serum, Calf Serum and Bovine Serum from Australia, BOVFBSIC.AUS* has been incorporated into the revised biological products IHS.

(2) The importation requirements under *BOVFBSIC.AUS* state:

a) Product must be imported pre-packaged ready for use by the end-user and sealed so that contamination cannot occur during transit.
b) The veterinary certificate completed by the exporting country's Competent Authority must be in English.
c) The product must be subjected to:

i) filtration to 0.22 micron or less and irradiation with a single or multiple irradiation dose totalling 5 mrad (50 kgray); or
ii) triple 0.1 micron membrane filtration; and
iii) irradiation with a single or multiple irradiation dose totalling 2.5 mrad (25 kgray); and
iv) testing to confirm absence of disease of mycoplasma, bovine virus diarrhoea, infectious bovine rhinotracheitis, bluetongue and parainfluenza-3 using the methods described in the relevant Australian standard or, in its absence, described by relevant OIE guidelines.

5.3.1 Recommendation

(1) Amended to include New Zealand-origin serum that is further processed in Australia. Otherwise, no change to requirements of the *Import Health Standard for Tested, Filtered and Irradiated Foetal Bovine Serum, Calf Serum and Bovine Serum from Australia, BOVFBSIC.AUS*.

5.4 Foetal bovine serum, calf serum and bovine serum for further processing from Australia

(1) The majority of the *Import Health Standard for Foetal Bovine Serum, Calf Serum and Bovine Serum for Further Processing from Australia, BOVSFPIC.AUS* has been incorporated into the revised biological products IHS. The exceptions are the transitional facility clauses which are deemed to be a requirement of the transitional facility standard and are not importation requirements.

(2) The importation requirements under *BOVSFPIC.AUS* state:

a) Product must be imported pre-packaged ready for use by the end-user and sealed so that contamination cannot occur during transit.
b) An import permit is required.
c) The veterinary certificate completed by the exporting country's Competent Authority and the accompanying certified manufacturer's declaration must be in English.
d) Prior to the product leaving the exporting country, the product must be:

i) Manufactured using processes which comply with an industry accepted code of good manufacturing practice and using a quality system equivalent to the current version of ISO 9001 that records details of:

1) the product description;
2) the origin and nature of each batch of product;
3) the manufacturing process;
4) the quality control testing carried out; and
5) packaging and consignment details.

ii) derived from cattle born and reared in Australia and/or New Zealand (in the case of foetal bovine serum, the serum must be obtained from blood collected from foetuses whose dams were born and raised in Australia and/or New Zealand); and

1) sourced from abattoirs and derived from animals which passed ante-mortem and post-mortem inspection and were processed in premises under the supervision of the controlling authority and in accordance with the regulations of Australia or New Zealand; or
2) sourced from donor herds and derived from herds that were under veterinary supervision and the animals were clinically free from infectious or contagious diseases.

e) The product must be directed to an appropriately approved transitional facility and subjected to testing, treatments or procedures required by the Director Animal Health and Welfare, including

i) filtration to 0.22 micron or less; and
ii) irradiation with a single or multiple irradiation dose totalling 5 mrad (50 kgray).

f) Once the testing, treatments or procedures have been completed in the transitional facility, the product may be given biosecurity clearance.

5.4.1 Recommendation

(1) Amended to include New Zealand-origin serum. Otherwise, no change to importation requirements of the *Import Health Standard for Foetal Bovine Serum, Calf Serum and Bovine Serum for Further Processing from Australia, BOVSFPIC.AUS*.

6 Other biological products not covered by IRA 2005

6.1 Agricultural Compounds and Veterinary Medicines

(1) Agricultural compounds are defined in the Agricultural Compounds and Veterinary Medicines (ACVM) Act 1997 and are used in plant or animal management. They include veterinary medicines, agricultural chemicals, oral nutritional compounds, fertilisers, and vertebrate toxic agents.

(2) Agricultural compounds which contain imported ingredients of biological origin must undergo a biosecurity assessment as part of the ACVM registration or approval process, unless the imported biological ingredients in the product are listed in the Negligible Risk Ingredient Schedule included in the *Biosecurity Approval of Imported Agricultural Compounds and Veterinary Medicines – ACVM Guidance* document. This assessment is now linked with the ACVM applications. For veterinary medicine (excluding specified serological products and agricultural compounds intended for potency testing in animals) and vertebrate toxic agent categories of agricultural compounds, the assessment will be managed by the Animal Imports Team. The agricultural chemical category will be assessed by the Plant Product Imports Team.

(3) The risk assessment will use all existing MPI risk analyses, or may include assessment by the MPI Risk Analysis Team.

(4) Products that do not require ACVM registration (that is, are exempt from registration under the ACVM Act), and contain imported ingredients of biological origin, must meet an existing IHS or be accompanied by an import permit.

6.1.1 Recommendation

(1) Agricultural compounds (as defined in the ACVM Act) that contain imported ingredients of biological origin, and excluding specified serological products and agricultural compounds intended for potency testing in animals, and excluding those that are listed in the Negligible Risk Ingredient Schedule included in the *Biosecurity Approval of Imported Agricultural Compounds and Veterinary Medicines – ACVM Guidance* document, that are ACVM Act registered or approved will be subject to an MPI biosecurity risk assessment. If the biosecurity risk assessment concludes the risk is effectively managed, the product may be imported from any country.

(2) Specified ACVM products (such as plasma for transfusion) that have testing requirements for each consignment may be imported from any country when the import permit requirements are met. This may include provision of a veterinary certificate.

(3) Agricultural compounds exempt from ACVM Act registration which contain imported ingredients of biological origin, excluding those that are listed in the Negligible Risk Ingredient Schedule included in the *Biosecurity Approval of Imported Agricultural Compounds and Veterinary Medicines – ACVM Guidance* document, may be imported from any country as long as they meet an existing IHS or are accompanied by an import permit.

(4) Biological ingredients imported as raw materials for formulation into agricultural compounds in New Zealand, excluding those that are listed in the Negligible Risk Ingredient Schedule included in the *Biosecurity Approval of Imported Agricultural Compounds and Veterinary Medicines – ACVM Guidance* document, will be subject to an MPI risk assessment to determine if they are eligible to be imported. If the biosecurity risk assessment concludes the risk is effectively managed, the product may be imported from any country when accompanied by an import permit.

6.2 Glyoxal as an alternative tissue fixative

(1) Advice received from the MPI Animal and Aquatic Biosecurity Science & Risk Assessment Team in May 2018 discusses the use of glyoxal as an alternative tissue fixative.

(2) Glyoxal has rapid tissue penetration and should be a safe alternative to use as a tissue fixative, especially in 2mm or less thin sections of tissue. Although not effective in inactivating prions, it was surmised the likelihood of animal exposure to fixed thin sections of tissue or microscope slides is negligible.

6.2.1 Recommendation

(1) Specimens of animal tissue no more than 2mm thick fixed in glyoxal may be imported from any country.

6.3 Commodities eligible for clearance under another IHS

(1) Biological products, including samples, which are eligible for clearance under another IHS must be cleared under that IHS.

(2) Biological products, including samples, which do not comply with the clearance requirements of another IHS may be imported from any country on an import permit if the import permit requires the product to be held and/or used in an appropriately approved transitional facility (as listed on the import permit).

(3) Biological products that have an unknown health status, or are known to contain 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 the transitional facility has been approved for that type of product.

(4) If the intention is to carry out microorganism enrichment, isolation and / or culture on the products, including samples, they must be imported under the import health standard that relates to microorganisms.