



# Export Laboratory Programme

Requirements for export of live animals and  
germplasm

# Prelims

Amendment 0

February 2009

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## **Explanatory Note**

Text contained within a border, other than tables, is non-mandatory and provided for guidance only. For example:

This text is for guidance and is not mandatory.

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## **Status of this Issue**

This issue cancels and replaces Version xx.

This programme is co-ordinated by:

The Animal Imports and Exports Group

Border Standards Directorate

MAF Biosecurity New Zealand

PO Box 2526

Wellington 6140

New Zealand

Phone: + 64 4 894 0513

Fax: + 64 4 894 0731

A copy of this document can be found at: <http://www.biosecurity.govt.nz>

If you have any queries, please contact: [animalexports@maf.govt.nz](mailto:animalexports@maf.govt.nz)

**Amendment Record**

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# 1 Preliminary Provisions

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## 1.1 Introduction

The Export Laboratory Programme describes the standards that need to be followed by a laboratory that is conducting tests that support official assurances for the export of live animals and germplasm (not being certified as food).

## 1.2 Purpose

The Export Laboratory Programme consolidates legislative specifications issued under the Animal Products Act 1999 (APA) for recognising laboratories and testing of live animals and donors of germplasm (not being certified as food).

The MAF Biosecurity New Zealand (MAFBNZ) Official Assurances Programme: Requirements for Export of Live Animals and Germplasm requires that

*“All laboratory testing specified in the export requirements must be carried out by a laboratory approved by MAFBNZ for requisite export testing.”*

Any laboratory conducting testing that supports the issuing of official assurances (e.g. in most cases official assurances will be in the form of export certificates) must comply with the Export Laboratory Programme. By doing so, laboratories are considered by MAFBNZ to be ‘approved’.

The Export Laboratory Programme describes the procedures to become a recognised laboratory and the other standards that need to be met.

## 1.3 Application

The Export Laboratory Programme applies to export tests that are conducted on animal tissue (e.g. serum, swabs) in a laboratory. This programme does not apply to export testing that occurs on the animal itself (compared with tissue taken from an animal and tested in a laboratory).

Intradermal TB (e.g. comparative cervical testing) and Johnes testing are examples where testing occurs on the animal itself.
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This programme does not apply to surveillance testing that is conducted on populations to determine disease status of those populations.

Surveillance testing are statements on export certificates such as “New Zealand is free from...” and “The flock of origin/semen collection centre has remained free of...”

The programme does apply where export requirements specify tests to be carried out on live animals, donors of germplasm, or the group of origin (e.g. parent flocks of origin).

Examples (i.e. not an all inclusive list) of export testing requirements where this programme does apply:

- “The donor animals were subjected to tests for the following diseases/disease organisms, with negative results in each case”
- “The animal for export was subjected to the following tests with a negative result in each case”
- “The day old chicks originate from parent flock(s) that have tested negative for”

#### **1.4 Interpretation**

**The Act, or APA** means the Animal Products Act 1999 unless otherwise stated

**Animal** means any member of the animal kingdom, including:

- any mammal, bird (including hatching eggs), finfish, shellfish, reptile, amphibian, insect, or invertebrate
- any other creature or entity that is declared by the Minister by notice in the Gazette to be an animal for the purposes of this Act

but does not include a human being.

**ANZSDP** is Australia and New Zealand Standard Diagnostic Procedures.

**Competence** is the demonstrated ability to apply knowledge and skills.

**Competent authority** means the Veterinary Authority or other Governmental Authority of a country having the responsibility and competence for ensuring or supervising the implementation of animal health and welfare measures, international veterinary certification and other standards and guidelines.

**Conflict of interest** is where the duties or responsibilities of a person required by this Export Laboratory Programme or under the Act could be improperly affected by some other interest or duty the person may have.

**Director-General** generally applies to the Director-General of NZFSA and for the purposes of this document includes his/her authorised delegates namely, the Director-General of MAF, Deputy Director-General of MAFBNZ, the Director Border Standards of MAFBNZ, Group Manager Animal Imports and Exports MAFBNZ, Team Manager Animal Exports MAFBNZ or other MAF employees with delegated authority to exercise appropriate powers under the Animal Products Act.

**Eligibility document** is a copy of an export certificate template with relevant sections completed, which is issued by a recognised person to an authorised person and which confirms information supporting the eligibility for export of any live animal (and germplasm where a germplasm declaration is not used) that requires an official assurance.

**Export requirements** are the requirements, issued under section 60 of the Act, specific to an identified overseas market(s) as related to the export of live animals and germplasm.

**Exporter** is a person or entity that is registered for the purpose of exporting animal material and animal products under the Act, unless exempt from registration.

**Germplasm** means semen, embryos, and ova.

**IANZ** is International Accreditation New Zealand.

**ILPT** means inter-laboratory proficiency testing.

**ISO 17025** is ISO/IEC 17025 – General Requirements for the Competence of Testing and Calibration Laboratories.

**MAFBNZ** is Ministry of Agriculture and Forestry Biosecurity New Zealand. This is the department of the New Zealand Ministry of Agriculture and Forestry that fulfils the role of New Zealand's competent authority for export of live animals and germplasm

**MAFBNZ conflict of interest policy** is the "Policy for managing conflicts of interest when providing official assurances for export of live animals and germplasm"

**MAFBNZ IDC** is MAF Biosecurity New Zealand Investigation & Diagnostic Centre.

**MAFBNZ website** is <http://www.biosecurity.govt.nz>

**Official assurance** is a general statement to a foreign government, or an agent of a foreign government, attesting that certain conditions apply with respect to live animals or germplasm for export. This includes, but is not limited to, statements regarding New Zealand's animal

health status, the residency, isolation, health, testing, treatment and inspection status, and transportation of the commodity to be exported.

**OIE** is the World Organisation for Animal Health (the name Office International des Epizooties was abolished in 2003; the acronym has been maintained).

**Overseas market access requirements (OMAR)** means an export requirement specific to an identified overseas market or markets.

**Supporting documentation** is a document, provided by a person other than a recognised person, providing information to support the eligibility for export of any live animal or germplasm that requires an official assurance. A laboratory test report is considered to be supporting documentation for an official assurance when the testing described forms a component of the overseas market access requirements.

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## 2 How to get recognised

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### 2.1 What Laboratories need to have to become recognised

#### 2.1.1 New Zealand residency

A recognised laboratory must be a New Zealand resident according to the Income Tax Act 2007.

The meaning of New Zealand resident is defined in sections YD 1 and YD 2 of the Income Tax Act 2007. The Income Tax Act 2007 is available from [www.legislation.govt.nz](http://www.legislation.govt.nz).

There may be circumstances where a business defined as a resident under the Income Tax Act 2007 includes the recognised laboratory and other functions under the Animal Products Act 1999. For example a business could have:

- a recognised laboratory and be a recognised agency
- a recognised laboratory and be an exporter
- a recognised laboratory and also be a facility that provides donors for exported germplasm.

In these circumstances the MAFBNZ Conflict of Interest procedures must be used. These procedures are available from [www.biosecurity.govt.nz](http://www.biosecurity.govt.nz).

#### 2.1.2 International Accreditation New Zealand accreditation

A recognised laboratory must be IANZ accredited to ISO 17025 for the export tests the laboratory is intending to conduct.

#### 2.1.3 Environment, accommodation and equipment

The equipment, accommodation and working environment of the recognised laboratory must meet the standards in ISO 17025 and comply with the procedures for a Physical Containment Level 2 facility specified in the current Australian/New Zealand Standard;

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*Safety in laboratories: Part 3: Microbiological aspects and containment facilities: AS/NZS 2243.3.*

#### **2.1.4** Technical Manager

- a. A recognised laboratory must appoint a Technical Manager.

More than one Technical Manager may be appointed by a recognised laboratory, but each must be assessed individually and one must be identified as the primary contact for MAFBNZ Exports Group.

- b. At the time of application the laboratory must nominate a suitably skilled Technical Manager to MAFBNZ for assessment.
- c. The Technical Manager must have the relevant qualifications, training and experience for the position and must have been accepted as a Key Technical Person by IANZ.

Adequate training in particular tests could include participation in testing live animal and/or donor submissions and participation in an appropriate proficiency testing programme. The Technical Manager does not necessarily need to be competent to perform the test if they have a high level of scientific competency for the test and can provide evidence to confirm that (e.g. they have a comprehensive knowledge of the science of the test, an ability to identify and resolve problems and an understanding of environmental and producer conditions, seasonality and other factors which aid in the interpretation of the result).

- d. Where further evidence of suitability is required prior to accepting the nomination, MAFBNZ may require the nominee to perform acceptably in a panel of representative tests and submission of a report interpreting the results. The panel of representative tests will be designed and assessed by MAFBNZ IDC.

Refer to section 3.3.1 for functions/activities a Technical Manager must conduct.

#### **2.1.5** Test accreditation

- a. The recognised laboratory must have tests accredited by IANZ for those tests to be included in the scope of recognition.
- b. The scope of tests for which the Laboratory is recognised will be listed against the laboratory's name on the web-based 'Recognised Laboratories and Tests' list.

## **2.2 How Laboratories apply to become recognised**

To become recognised, the laboratory must apply to MAFBNZ on the application form in Appendix I. Where required, evidence will need to be provided with the application (e.g. IANZ accreditation of the laboratory and the tests, evidence to support the nomination of the Technical Manager), and the required fee must be paid.

## **2.3 Amending the scope of the recognition**

A recognised laboratory that decides to alter the scope of tests it is recognised to conduct must:

- a. Ensure that the new test is accredited by IANZ; and
- b. Apply for an amendment to the scope of recognition using the application form in Appendix I.

This includes if a test is to be deleted from the recognised laboratory's scope of tests.

## **2.4 How Recognised Laboratories maintain recognition**

### **2.4.1 Maintaining IANZ accreditation**

To maintain recognition the recognised laboratory must:

- a. Be fully assessed by IANZ in accordance with the accreditation body's standards and procedures from the date of application of recognition to confirm the requirements of ISO 17025 and any additional requirements specified by MAFBNZ. This may include requiring a MAFBNZ technical person to be a part of the audit team or present as an observer;
- b. Be subject to annual surveillance assessments in the years between technical (routine) assessments to confirm continued compliance with the above; and
- c. Forward a copy of the assessment report from IANZ to MAFBNZ.

### **2.4.2 Accreditation assessment requirements**

- a. The recognised laboratory must ensure that:
  - The IANZ assessment team is able to review the findings of the on-site assessment with the recognised laboratory; and

- References to all non-compliances are noted in terms of the specific requirements applicable, including the requirements of the Animal Products (Recognised Laboratories and Recognised Signatories) Notice 200x and the Animal Products (Testing Specification) Notice 200x; and
  - The results of the IANZ assessments are understood; and
  - All required actions are identified, and the time frame for these agreed.
- b. The recognised laboratory must also ensure that:
- All necessary corrective action requests are actioned within the agreed time frame on the non-conformances identified in the IANZ assessment report; and
  - IANZ is provided with any documentation to substantiate the actions referred to above.

#### **2.4.3** Annual renewal for recognition

Recognition must be renewed on an annual basis before the anniversary of recognition. The application form in Appendix I must be used and fees paid. At annual renewal, the recognised laboratory must provide management and technical reports stipulated in section 2.4.4.

#### **2.4.4** Annual reporting

- a. Annual reporting to MAFBNZ (Animal Export Adviser) is required at the renewal of recognition. The reporting will consist of management and technical reports and will be used for the purpose of ensuring the laboratory remains fit to be recognised for the tests that it conducts.
- b. The recognised laboratory must provide the following information for management reports
- Update on laboratory management structure and changes to duties of senior staff;
  - Significant changes to accommodation and equipment;
  - A list of senior technical personnel with verifiable and relevant qualifications;
  - An update on the quality manual;
  - The results of any inter-laboratory quality assurance testing undertaken; and

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- Evidence that the laboratory has maintained accreditation to ISO 17025.
- c. The recognised laboratory must provide the following summarised information for export testing of live animals and germplasm technical reports:
- Species and the product that is exported (live animal or germplasm of the donor tested);
  - Tests performed; and
  - The results of those tests (number suspicious, number positive, number negative and total number tested).

Also report summary information where tests have equivocal results due to unclear cut-offs for positives and negatives.

#### **2.4.5** Requirements for Recognised Laboratories to disclose certain information

The recognised laboratory must:

- a. Authorise IANZ to report to MAFBNZ Animal Exports Group on any critical non compliance found that relate to the MAFBNZ Export Laboratory Programme, and when requested by MAFBNZ in writing, to make available a copy of any accreditation or other type of report; and
- b. Authorise the supplier of any designated inter-laboratory proficiency testing programme that is required as a condition of a test listed in the 'Export Tests, Methods and Conditions' list to report to MAFBNZ Animal Exports Group on any critical non compliance found, and when requested by MAFBNZ in writing, to make available a copy of any performance report; and
- c. Notify MAFBNZ Animal Exports Group of any change in circumstances relating to its conduct, or its ability to conduct export tests, including:
  - Any matter that may indicate a critical non-compliance with the requirements of the Animal Products (Testing Specifications) Notice 200x, or requirements set out in the conditions of recognition;
  - Any changes within the laboratory that have the potential to adversely affect test results,
  - Any pressure from a client or any other person to alter test results, or to re-test, without good reason;

An example of a 'good reason' is if the client has identified an error and the recognised laboratory has agreed it is an error.

- Any significant change in the circumstances of the laboratory including changes in:
    - legal, commercial or organisational status;
    - organisation or management structure, including any changes involving the directorship, day-to-day manager and other key managerial staff;
  - Any significant changes to policies or procedures;
  - Any alterations to premises;
  - Changes to personnel, equipment, facilities, working environment or other resources that have the potential to have an adverse effect on test results;
  - Any other matters that may affect the capability of the laboratory to meet the requirements set out in the Animal Products (Testing Specifications) Notice 200x, or requirements set out in the conditions of recognition.
- d. Submit to MAFBNZ Animal Exports Group any reports on such matter as MAFBNZ may request (for example, refer to section 2.4.4).

## 3 Standards for Recognised Laboratories

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### 3.1 Conditions of recognition

The recognised laboratory must:

- a. Adhere to the duties of recognised agencies as required by APA section 106;
- b. Comply with the requirements of the Animal Products (Recognised Laboratories and Recognised Signatories) Notice 200x and the Animal Products (Testing Specifications) Notice 200x;
- c. Ensure that it meets the requirements of ISO 17025 and that at the time of conducting any test, it holds current accreditation from IANZ for that test; and
- d. Comply with the conditions of recognition issued to the recognised laboratory with the Notice of Recognition.

### 3.2 Quality Systems

#### 3.2.1 Quality Manual

The recognised laboratory must incorporate requirements from the Export Laboratory Programme and requirements from associated Animal Product notices into the laboratory's quality manual. Internal audits must also cover these aspects of the quality manual.

#### 3.2.2 Record keeping

The recognised laboratory must:

- a. Retain technical records (e.g. maintaining original test observations, copy of report issued and other information necessary to maintain an audit trail) for 7 years;
- b. Record proficiency and performance of staff undertaking export tests;
- c. Record circumstances and corrective actions following advice from the supplier of the proficiency testing programme; and

ILPT providers may advise laboratories to retest or review quality controls when proficiency test results are outside normal parameters.

- d. Record the circumstances and corrective actions arising from a non-compliance with the notices or conditions of recognition that is likely to directly affect the technical integrity of the recognised laboratory's output.

### **3.3 Personnel**

#### **3.3.1 Technical Manager**

- a. The Technical Manager must be responsible for supervising the export testing for the disciplines for which the laboratory's recognition is given (e.g. serology or bacteriology). This means that they:
  - are based at the premises where the laboratory is situated
  - are available to the laboratory during the testing

This is to ensure discussions of testing can occur. MAFBNZ expects that if away, the Technical Manager can be present in the laboratory within 24 hours.

- assess that the quality controls of the test are acceptable
  - are able to interpret the results of the test
  - provide the signatory for the test report, and
  - are a contact point between the recognised laboratory and MAFBNZ Animal Exports Group
- b. The recognised laboratory must notify MAFBNZ Animal Exports Group when a Technical Manager is not available to that laboratory either temporarily or permanently.

An example of temporary unavailability would be where a laboratory only has one Technical Manager and that person is on leave out of the country. The recognised laboratory would not be able to meet the obligations under the Export Laboratory Programme and must not conduct export tests during that time.

#### **3.3.2 Staff**

- a. The recognised laboratory must be adequately staffed to carry out the tests for which it is recognised.

- b. The recognised laboratory must have disciplinary procedures in place to deal with staff misconduct. These must be used in situations where staff have affected the laboratory's ability to meet the requirements set out in the Animal Products (Testing Specifications) Notice 200x, or requirements set out in the conditions of recognition.
- c. All staff must:
- Have an understanding of the Export Laboratory Programme and associated legal notices;
  - Be competent to undertake the testing they are assigned;
  - Have their competency assessed every 12 months; and

Competency assessment should be a formal planned process. Staff that are new to a test should be assessed more frequently than 12 months.

Competency could be assessed using results from inter-laboratory proficiency testing conducted by staff, IANZ assessments of Key Technical Persons, by reviewing that the test is conducted according to laboratory procedures, or other similar mechanisms.

- Be aware of the MAFBNZ conflict of interest policy “Policy for managing conflicts of interest when providing official assurances for export of live animals and germplasm” which can be found on the MAFBNZ website [www.biosecurity.govt.nz](http://www.biosecurity.govt.nz).

### **3.4 Testing requirements**

#### **3.4.1 Test accreditation**

- a. All tests a recognised laboratory wishes to undertake must be included within the scope of the recognised laboratory's accreditation to ISO 17025.
- b. Where a new test is added to the suite of tests the recognised laboratory is conducting, the test must be accredited by IANZ. The recognised laboratory must then apply to MAFBNZ using the application form in Appendix I to extend the scope of the recognition.

#### **3.4.2 Test conditions**

The recognised laboratory must conduct tests according to any stipulated conditions and test methods which will be published on the web-based 'Export Tests, Methods and Conditions' list.

### 3.4.3 Test method approval

- a. Tests must be conducted according to the test method described in:
- The current OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals or the current OIE Manual of Diagnostic Tests and Vaccines for Aquatic Animals; or
  - The Australia and New Zealand Standard Diagnostic Procedures (ANZSDP) developed by the Subcommittee on Animal Health Laboratory Standards; or
  - Overseas market access requirements (OMARs) of an importing country where an agreement has been reached between MAFBNZ and that country's competent authority; or
  - The recognised laboratory's standard operating procedure (SOP) for the approved test method where the method is proven to be at least equivalent to the OIE prescribed method using the OIE principles for test validation (refer to 3.4.3 c); or
  - The recognised laboratory's SOP for the approved test method where it has otherwise been approved by MAFBNZ (refer to 3.4.3 c).

Commercial serological kits can be checked against the OIE and ANZSDP methods by ensuring:

- the standards acknowledge that commercial kits are available
- the dilution cut-offs are the same for the kits and for the standards
- the diagnostic specificity and sensitivity are the same for the kits and for the standards

Current OIE Manuals for terrestrial and aquatic animals can be found under Health Standards on: [http://www.oie.int/eng/en\\_index.htm](http://www.oie.int/eng/en_index.htm).

Current ANZSDP is found on: <http://www.scahls.org.au/standardprocedures/standards.htm>.

- b. Where the test method is not the current OIE Manual method or an ANZSDP method, the method will be stipulated in the 'Export Tests, Methods and Conditions' list. This will either be the OMAR of the country the product is exported to or the name of the recognised laboratory and the dated SOP identifier that has been approved.
- c. To have alternative test methods approved, the recognised laboratory must apply to MAFBNZ, supplying a description of the method in an SOP and appropriate validation records (and/or other appropriate evidence, e.g. references). MAFBNZ will utilise the services of technical experts (such as those at MAFBNZ IDC) to approve test methods.

MAFBNZ will notify the recognised laboratory of the approval (or reasons for refusal to approve), and will update the 'Export Tests, Methods and Conditions' list with the method.

#### **3.4.4** Annual review of methods

The recognised laboratory must check the test method it uses against the standard the method is approved under (e.g. OIE, ANZSDP, country OMAR) on at least an annual basis.

#### **3.4.5** Confirming ongoing validity of test results

- a. The recognised laboratory must confirm the validity of test results on an ongoing basis using positive control material (sera and cultures) as an independent control.
- b. Positive control material (sera and cultures) must be traceable to either:
  - A confirmed positive case; or
  - A reference standard with appropriate traceability purchased for the purpose; or
  - A national standard serum held and provided under agreement by IDC that is traceable to an international standard recognised as such by the OIE; or
  - An international standard serum from an international OIE reference laboratory.
- c. The recognised laboratory must confirm the validity of test results using positive control material (sera and cultures) as an independent control when training staff new to the test method.

#### **3.4.6** Inter-laboratory Proficiency Testing to check ongoing test performance

The recognised laboratory must take part in inter-laboratory proficiency testing (ILPT) programme where one is available for tests the laboratory is recognised to conduct, provided that:

- a. The ILPT provider is accredited for proficiency testing for those tests by an international accreditation body; or
- b. The ILPT provider is reputable and working to the International Laboratory Accreditation Cooperation (ILAC) *Guidelines for the Requirements for the Competence of Providers of Proficiency Testing* (ILAC-G13: current version).

### **3.4.7** Use of reports for tests conducted under this programme

Every recognised laboratory must:

- a. Ensure that all test reports conform to good laboratory practice and any applicable conditions required by the Animal Products (Testing Specifications) Notice 200x; and
- b. Ensure that test reports are not used in a misleading manner; and
- c. Issue test reports for only the tests for which the laboratory has been recognised to issue when the Export Laboratory Programme has been met; and
- d. Not make any statement that may be considered misleading, or unauthorised by the Director-General, in relation to the functions or competence of the laboratory in testing under this programme; and
- e. Ensure it does not make any statement directly or by implication that the laboratory's recognition is in itself an approval or assurance in relation to any animal material or product.

### **3.4.8** Subcontracting tests to other laboratories

- a. The laboratory may subcontract any test for which it is recognised, provided that the subcontracted laboratory is itself recognised to conduct that test under the Animal Products (Recognised Laboratory) Notice 200x.
- b. Should the laboratory find that there is no laboratory that meets the above requirement where it is prevented from conducting the test itself, it must advise MAFBNZ immediately.

## **3.5 Identifying the laboratory as recognised**

The recognised laboratory may identify itself as such only when a test it is recognised to conduct is specifically referenced. This identification can be made on test reports or any other document but only in the following manner:

- “MAFBNZ Recognised”
- “Recognised Under the Animal Products Act 1999”
- “Recognised Laboratory Under the Animal Products Act”
- Or any reasonable variation of the above.

For example, it would be acceptable for a recognised laboratory to state the following on a test report for tests they are recognised to conduct:

- Enzootic bovine leucosis ELISA; Result: xxx; MAFBNZ Recognised
- Infectious bovine rhinotracheitis ELISA; Result: xx; Recognised Under the Animal Products Act 1999

### **3.6 When the laboratory has a planned closure**

The recognised laboratory must:

- a. Promptly advise MAFBNZ if it ceases to operate as a laboratory;
- b. Promptly advise MAFBNZ of any temporary closure of the recognised laboratory, or any of its facilities that are required for official export testing, including:
  - Any short term closure (which is a closure for a duration of more than 24 hours (outside of the laboratory's normal working hours) and less than three months); and
  - Any long term closure (which is a closure of three months or more).

MAFBNZ Animal Exports Group requests that it is informed as far in advance as possible so proactive steps can be taken if deemed necessary.

- c. Ensure that no test report is issued during the period that the recognised laboratory is closed, unless the test has been completed prior to closure.

### **3.7 Surrender of status as a recognised laboratory**

A recognised laboratory may surrender its status as a recognised agency at any time by giving notice to MAFBNZ in writing (refer to section 110 of the Act).

Such surrender will normally take effect three months from the receipt of notice by MAFBNZ or on an earlier date as approved by MAFBNZ.

- a. Following the surrender of status as a recognised laboratory the laboratory must return its notice of recognition to MAFBNZ.
- b. A recognised laboratory must continue to provide all functions up until the agreed date of surrender unless doing so would violate the conditions of recognition.

### **3.8 International communications**

MAFBNZ is responsible for all international communications on the animal health status of New Zealand animals. The Director, IDC (or his/her delegate) must provide written permission for all laboratory specimens originating from New Zealand animals that are to be referred overseas.

### **3.9 Availability for MAFBNZ or overseas audit**

**3.9.1** MAFBNZ may elect to carry out audits independently from assessments carried out by IANZ.

**3.9.2** The recognised laboratory must make its facilities, staff and records available for the purposes of an inspection, assessment or audit:

- a. By any agency or person appointed for that purpose by MAFBNZ; or
- b. Where notified by MAFBNZ, by the representatives of any other country as part of an assessment of compliance of the export testing system assurance programme with that country's market access requirements.

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## 4 Exemptions from recognition

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### 4.1 Purpose of the exemption

This section describes exemptions from recognition that may be permitted under certain conditions. This flexibility is to allow for emergency or unusual circumstances without affecting the technical requirements or credibility of the Export Laboratory Programme.

### 4.2 Application

**4.2.1** A recognised laboratory may be exempt from the requirement to have a specific export test on its scope of recognised tests where that test is:

- a. To be performed by an overseas laboratory; or
- b. Not IANZ accredited because it is
  - In the process of being accredited
  - Unable to be accredited by IANZ
  - An emergency situation that requires the testing to be done urgently

**4.2.2** A laboratory may be exempt from recognition where testing needs to be conducted under an emergency situation.

### 4.3 How to apply for an exemption to a test or laboratory

A laboratory must apply to MAFBNZ on the application form in Appendix I. Evidence of equivalence to the Export Laboratory Programme must be provided with the application, and the required fee must be paid.

Exemptions for tests will usually be associated with IANZ accreditation. Equivalence for test accreditation could be where another very similar test method is IANZ accredited. Evidence of this equivalence will need to be presented on application.

#### **4.4 Listing on Schedule of the Testing Specification Notice**

**4.4.1** MAFBNZ must notify the applying laboratory where exemption is permitted.

**4.4.2** MAFBNZ must list the laboratory and the relevant tests on the Schedule attached to the Animal Products (Testing Specification) Notice 200x.

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## 5 What MAFBNZ will do

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### 5.1 Notification of recognition

MAFBNZ must provide a notice of recognition to the recognised laboratory where recognition is granted. Attached to this recognition will be the conditions of recognition. MAFBNZ may from time to time update the conditions of recognition.

### 5.2 Refusal to grant recognition

MAFBNZ can refuse to grant recognition, but must first notify the laboratory of that intention together with reasons. The laboratory will be given reasonable opportunity to make written or oral submissions prior to a final decision being made.

Section 104 of the Act specifies the details of a refusal. The Act makes provision for review processes which are detailed in section 162 of the Act. The laboratory has the right to request a review where recognition has been refused.

### 5.3 Approval of a Recognised Laboratory's Technical Manager

MAFBNZ must assess the Recognised Laboratory's nomination of a Technical Manager. Approval will be granted and notified in writing where the nomination meets the criteria required in section 2.1.4.

### 5.4 Approval of Test Methods

**5.4.1** MAFBNZ must assess alternative test methods according to the criteria in section 3.4.3 c. Approval will be granted and notified in writing where the criteria are met.

**5.4.2** MAFBNZ will update the 'Export Tests, Methods and Conditions' list with the method SOP identifier.

## **5.5 'Recognised Laboratory and Tests' List**

**5.5.1** MAFBNZ must list the recognised laboratory and the tests the laboratory is recognised to conduct in the 'Recognised Laboratory and Tests List'.

The 'Recognised Laboratory and Tests List' is a web-based list and is on the [www.biosecurity.govt.nz](http://www.biosecurity.govt.nz) website.

Section 112 of the Act requires MAFBNZ to keep and maintain a list of recognised laboratories and their functions/activities (i.e. tests they are recognised to conduct)

## **5.6 'Export Tests, Methods and Conditions' List**

**5.6.1** MAFBNZ must list the tests and, if necessary, the methods and conditions of those tests that are required by the MAFBNZ Official Assurance Programme and Overseas Market Access Requirements.

The 'Export Tests, Methods and Conditions' list is a web-based list and is on the [www.biosecurity.govt.nz](http://www.biosecurity.govt.nz) website.

The 'Export Tests, Methods and Conditions' list is incorporated by reference into the Animal Products (Testing Specification) Notice 200x.

## **5.7 List of laboratories and tests exempt from recognition**

**5.7.1** Where exemption from recognition has been permitted, MAFBNZ must list the laboratory and the relevant tests on the Schedule attached to the Animal Products (Testing Specification) Notice 200x.

It is intended that the Schedule will be duplicated on the same web-page as the 'Recognised Laboratory and Tests' list to ensure easy access to all information about laboratories and the tests they conduct.

## **5.8 Suspension of status as a recognised laboratory**

For details of this process refer to section 108A of the Act.

**5.8.1** MAFBNZ may suspend recognition for a maximum period of three months if MAFBNZ has reasonable grounds to believe that the performance of the laboratory is unsatisfactory. MAFBNZ must notify the laboratory in writing.

**5.8.2** MAFBNZ may impose conditions or requirements that must be satisfied if the suspension is to be lifted.

**5.8.3** If MAFBNZ considers that conditions or requirements have not been satisfied within the suspension period, MAFBNZ may extend the suspension for a further maximum period of three months. MAFBNZ will again notify the laboratory in writing.

**5.8.4** The notice of suspension or extension will specify:

- a. the reason for the suspension or extension;
- b. the period of the suspension or extension;
- c. the date and time the suspension or extension commences;
- d. the tests that the suspension or extension relates to; and
- e. any conditions or requirements to be met before or during the suspension.

**5.8.5** MAFBNZ may direct the suspended laboratory to take appropriate action to remedy the deficiency or failure that gave rise to the suspension.

The Act makes provision for review processes which are detailed in section 162 of the Act. The laboratory has the right to request a review where suspension of recognition has occurred.

## **5.9 Withdrawal of status as a recognised laboratory**

**5.9.1** MAFBNZ may withdraw the recognition of a laboratory if satisfied that the laboratory:

- a. is no longer fit and proper to undertake the testing for which recognition was granted; or
- b. has failed to comply with any term or condition of the recognition or has failed to comply with the requirements of the Animal Products (Recognised Laboratories and Recognised

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Signatories) Notice 200x and the Animal Products (Testing Specifications) Notice 200x;  
or

c. has contravened or failed to comply with any requirement of the Act.

**5.9.2** MAFBNZ must notify the laboratory in writing.

**5.9.3** MAFBNZ must give the laboratory reasonable opportunity to be heard prior to withdrawal of the recognition status.

For details of the withdrawal process refer to section 109 of the Act.

The Act makes provision for review processes which are detailed in section 162 of the Act. An Appeal Process is yet to be developed but for general principles refer to the Complaints and Appeals Process for Exporters found on the MAFBNZ website [www.biosecurity.govt.nz](http://www.biosecurity.govt.nz).

**5.9.4** The recognised laboratory must acknowledge receipt from MAFBNZ of the withdrawal of their recognition and must not perform any further functions as a recognised laboratory.

**5.9.5** The laboratory must formally notify the withdrawal of recognition to all organisations and persons who were utilising the laboratory's services. This must be done as soon as practicable.

**5.9.6** The laboratory must return the notice of recognition to the MAFBNZ Animal Exports Group within 20 working days of the effective date of the withdrawal of recognition.

## 6 Appendix I

Amendment Number

Amendment Date

### 6.1 Application Form

To be added at a later date.

The application form is likely to be used for:

- New applications and annual renewal of recognised laboratory
- Nomination of a Technical Manager
- Approval of alternative test methods (refer to section 3.4.3)
- Changes to scope of tests
- Applying for exemption from recognition for a test/laboratory

The application form is likely to contain (refer to OAP on MAFBNZ website for an example of an application form):

- A tick box determining a new application, amendment, or annual renewal
- The applicant's name (full legal name of applicant and organisation)
- Address (physical and postage) and contact details of applicant and recognised laboratory
- Names of directors of the applicant or those responsible for its management or control (listing all persons)
- A tick box for consent to being provided with electronic information
- Name of the nominated Technical Manager, qualifications, training, experience, accepted as a Key Technical Person
- Tests and methods to be included in scope of recognition (including alternative test methods)
- A tick box to confirm alternative test method information supplied
- A tick box to confirm evidence of accreditation to ISO 17025 supplied

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- A tick box to confirm individual consents for disclosure forms for all directors of the applicant. (Consent for Disclosure forms are for police checks)
  - A tick box to confirm evidence for exemption from recognition supplied
  - Applicant declaration
  - MAFBNZ fees for application and assessment
  - Information about the collection of personal information on individuals

## 7 Appendix II - Roles and Responsibilities

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### 7.1 Recognised Laboratories

- Apply to become a recognised laboratory
- Continue to meet the requirements to be a recognised laboratory including annual renewal of recognition and the reporting requirements associated with that
- Comply with the conditions of recognition
- Use only approved test methods or apply for approval for a test method

### 7.2 Exporters, Approved Semen Centres, Approved Embryo Centres, Approved Bee Teams and Approved Pre-export Isolation Facilities

- Request the appropriate test for the live animal or germplasm intended to be exported that is stipulated in the export requirements (overseas market access requirements or export certificates) from a recognised laboratory that is recognised to conduct that test.

### 7.3 Recognised Agencies and Recognised Persons

- Ensure that export requirements for tests have been met, including that the correct test has been conducted by a recognised laboratory that is recognised to conduct that test.

### 7.4 MAFBNZ

- Develop requirements for recognised laboratories
- Assess applications for recognition
- Provide technical experts to assess Technical Manager qualifications and new test methods
- Recognise laboratories, provide with a notice of recognition and conditions of that recognition
- Maintain records of laboratory recognition

- Maintain a register of recognised laboratories and tests on the 'Recognised Laboratory and Tests' list. Update when laboratories become recognised, surrender recognition or have recognition withdrawn or when new tests are added to or deleted from the recognition
- Maintain the 'Specified Tests' list with test, test methods and conditions when export requirements are promulgated or amended
- Notify recognised laboratories of MAFBNZ or overseas authority audits
- Provide technical experts for IANZ, MAFBNZ and overseas authority audits
- International communication and referral of specimens originating in New Zealand