



# Export Laboratory Programme

## Requirements for Laboratories and Persons Conducting the Testing of Live Animals and Germplasm for Export

1 May 2010

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## Table of Contents

<b>Part 1</b>	<b>Preliminary provisions .....</b>	<b>1.1</b>
<b>Part 2</b>	<b>Requirements for recognised laboratories conducting export testing .....</b>	<b>2.1</b>
<b>Part 3</b>	<b>Requirements for recognised persons .....</b>	<b>3.1</b>
<b>Part 4</b>	<b>Appendix I: Application and Declaration forms.....</b>	<b>4.1</b>
	<b>Appendix II: ELP Test List (List 1).....</b>	<b>4.1</b>
<b>Part 5</b>	<b>Documents incorporated .....</b>	<b>5.1</b>

## **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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### *Important Disclaimer*

*While every effort has been taken to ensure that the guidance material in this document is accurate and complete, Ministry of Agriculture and Forestry (including its employees and agents) does not accept liability or responsibility to any person for any loss caused by reliance on this material.*

## Status of this Issue

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: 0800 008 333  
Fax: + 64 4 894 0733

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

Microsoft Word versions of the Appendix forms are available separately for use on this website address also.

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

## Amendment Record

Amendment No.	Date
1. Amendment Record table has been amended by removing the “Initials” column.	
2. Some editorial changes have been made eg changing the term ‘audit’ to ‘assessment’, when referring to the accreditation body procedures.	
3. Figure 1 has been amended with editorial changes.	
4. Figure 2 has been amended with editorial changes.	
5. Clause 2.8.1 has been amended with the edition of a guidance text box that defines temporary closure.	
6. Table 2.1 has been amended to include any subcontracting of tests.	
7. Application Form 1 (6) has been amended to include the spreadsheet ELP Test List (List 1) Test Management Table including details of any subcontracted testing, and editorial changes made.	
8. Application Form 1 (7) has been amended by removing the words “or evidence of progress of quality system towards accreditation”	

## Part 1 Preliminary provisions

### 1.1 Application

- 1.1.1 The Animal Products Act 1999 (hereafter referred to as the Act) Part 8 provides for the recognition of agencies and persons responsible for providing verification or other specialised functions. Functions and activities for which an agency/person may be recognised include the testing, sampling and chemical or biological or other analysis of animal material or products.
- 1.1.2 The Animal Products (Export requirements for Live Animals and Germplasm) Notice 2008 (section 2.1.19) requires that all laboratory testing specified in the export requirements must be carried out by a laboratory approved by MAFBNZ for requisite export testing. Laboratories carrying out testing within New Zealand will be recognised under the Act, as per section 1.1.1. Where a particular test is unable to be carried out in New Zealand, for example testing of *Babesia* spp, MAFBNZ may approve an overseas laboratory to carry out that test where MAFBNZ IDC has approved the test and the overseas laboratory operates under a system of approval deemed by MAFBNZ to be equivalent to recognition of laboratories under the Act and Regulations or Notices or Specifications or Directions issued under the Act.
- 1.1.3 The Export Laboratory Programme (ELP) consolidates the legislative requirements of the Act and Regulations, Notices and Specifications and Directions issued under the Act as they relate to laboratories undertaking testing of live animals and germplasm for export.
- 1.1.4 The ELP applies to export laboratory testing in respect of live animals and germplasm (other than live animals and germplasm certified as food) for the purposes of obtaining official assurance for export and to:
- laboratories who are applying for recognition, or which have been recognised, to conduct such testing; and
  - persons who are applying for recognition, or have been recognised, to perform specialist functions in relation to such testing.
- 1.1.5 The ELP applies to export tests that are conducted in a laboratory on animal samples.
- 1.1.6 The ELP applies where export requirements specify tests (and usually the negative result from those tests) to be carried out on samples from live animals or donors of germplasm, or the germplasm itself, or the group of origin.

Examples of export testing requirements where this programme does apply are:

“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 semen was tested for.....”

“The day-old-chicks originate from parent flock(s) that have tested negative for .....

- 1.1.7 The ELP does not apply to export testing in the following situations:
- a. where the testing is carried out on the animal itself

Intradermal TB testing (i.e. the caudal fold test) and intradermal Johne's disease testing (i.e. with avian tuberculin) are examples where testing is carried out on the animal.

- b. surveillance testing that is conducted on populations to determine the disease status of those populations.

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

## 1.2 International obligations

- 1.2.1 MAF is the competent authority and is responsible for setting the requirements for export of live animals and germplasm and managing adherence to them. This function is administered by MAFBNZ acting under delegated authority.

- 1.2.2 MAFBNZ is responsible for all international communications on New Zealand's animal health status.

- 1.2.3 The World Organisation for Animal Health (OIE) is designated by the World Trade Organisation as the international animal health standard-setting organisation. The OIE produces a number of documents, including:

- a. the current OIE *Code*  
The *Terrestrial Animal Health Code*, which can be found on the OIE website:  
[http://www.oie.int/eng/normes/mcode/A\\_summry.htm](http://www.oie.int/eng/normes/mcode/A_summry.htm)

The *Aquatic Animal Health Code* which can be found on the OIE website:  
[http://www.oie.int/eng/normes/fcode/A\\_summry.htm](http://www.oie.int/eng/normes/fcode/A_summry.htm)

- b. the current OIE *Manual*  
The OIE *Manual of Diagnostic Tests and Vaccines for Terrestrial Animals* for diseases listed in the *Code*. This can be found on the OIE website:  
[http://www.oie.int/eng/normes/mmanual/a\\_summry.htm](http://www.oie.int/eng/normes/mmanual/a_summry.htm)

The OIE *Manual of Diagnostic Tests for Aquatic Animals* which can be found on the OIE website: [http://www.oie.int/eng/normes/fmanual/A\\_summry.htm](http://www.oie.int/eng/normes/fmanual/A_summry.htm)

## 1.3 Introduction

- 1.3.1 MAFBNZ policy and the Act aim to facilitate the entry of animal material and products into overseas markets by providing the controls and mechanisms needed to give and safeguard official assurances for entry into those markets. Most importing countries require official assurances for live animals and germplasm to provide confidence that their import requirements have been met. These assurances are provided on behalf of MAFBNZ by NZFSA.

- 1.3.2 The claims made on official assurances must be substantiated in order to maintain the integrity of New Zealand as a trading partner and MAFBNZ's reputation as a

competent authority. This is achieved through systems allowing information relating to the assurances to be independently verified.

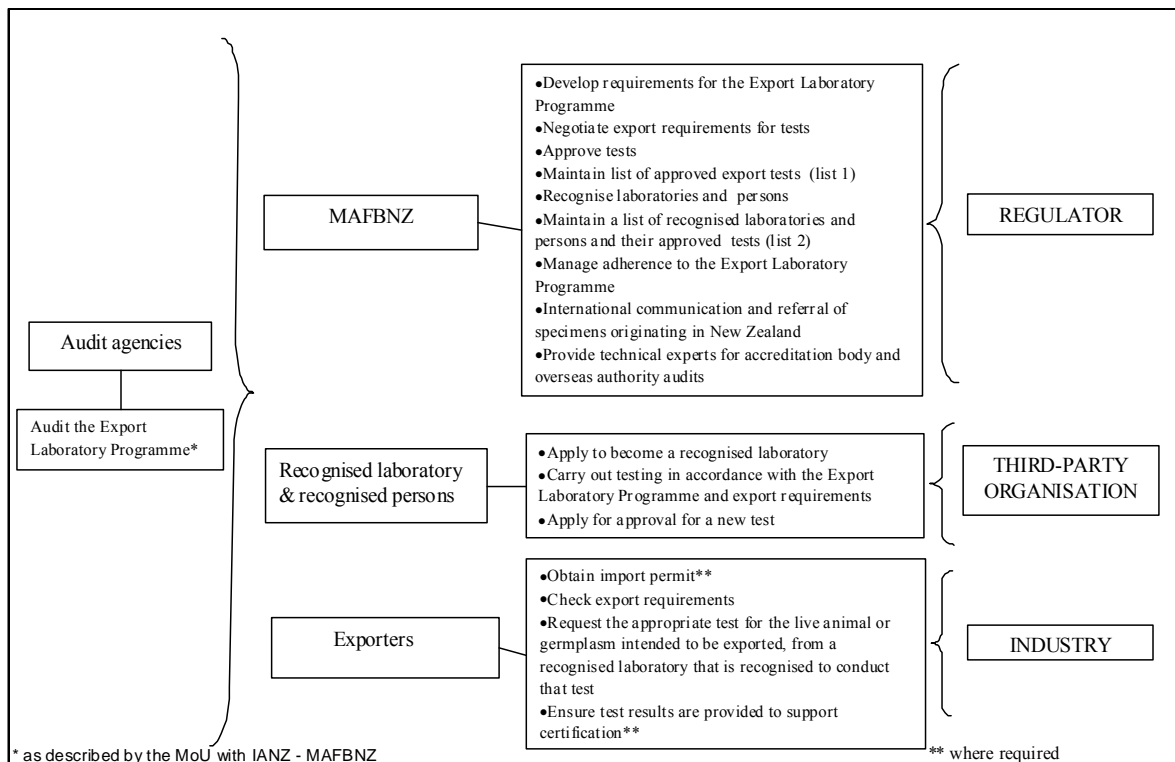
- 1.3.3 The Market Access and Official Assurance Principles<sup>1</sup> are particularly relevant to providing a robust, trusted and consistent system for official assurances of exports of live animals and animal germplasm. Five of the principles are of particular relevance.  
**Principle 3** – Only Government can provide the official assurances underpinning market access, and these will be supported by adequate systems and processes  
**Principle 6** – Export certification will be supported by adequate levels of verification and security  
**Principle 7** – Government certification systems will be aligned and integrated across Government agencies as appropriate and applied equitably across export sectors  
**Principle 8** – Third parties will be used at the verification step in the provision of official assurances wherever possible and their roles will be clearly defined  
**Principle 9** – Third party verifiers must meet internationally recognised standards that cover competencies, conflict of interest and quality systems. Government will define appropriate secondary / supplementary criteria to the international standards.
- 1.3.4 The Official Assurance Programme (OAP) for live animals and germplasm consolidates specifications, export requirements and directions that apply to official assurances issued under Part 5 of the Act. These assurances relate to export requirements specific to an identified overseas market(s) as related to the export of live animals and germplasm.
- 1.3.5 The requirements of this ELP allow laboratories to have different procedures for meeting the requirements, where practicable.
- 1.3.6 Any person involved in the export process must be aware of section 127(1) of the Act, which states:  
*“A person commits an offence who, with intent to deceive and for the purpose of obtaining any material benefit or avoiding any material detriment,—*  
(a) *Makes any false or misleading statement or any material omission in any communication, application, record, or return for the purpose of this Act, or destroys, cancels, conceals, alters, obliterates, or fails to provide any document, record, return, or information required to be kept or communicated under this Act; or*  
(b) *Falsifies, removes, misuses, alters, misapplies, misrepresents, or fails to apply any brand or material or product description or other form of identification of animal material or animal product required or authorised to be used under this Act; or*  
(c) *Falsifies, removes, misuses, alters, misapplies, misrepresents, or fails to apply any identification, differentiation, or security system or device specified or approved or required under section 158; or*

<sup>1</sup> Statement of Policy: Market Access and Official Assurances Principles (As signed off as the Pan-MAF Certification Principles by the SPS Forum, August 2006 )  
<http://www.nzfsa.govt.nz/animalproducts/publications/policystatements/exports/index.htm>

- (d) *Misrepresents, substitutes in whole or in part, adulterates, or otherwise tampers with animal material or animal product to which this Act applies so that it no longer matches or complies with its identification, description, certificate, label, or official assurance; or*
- (e) *Falsifies, alters, or misapplies any certificate or declaration or other statutory form attached or relating to any animal material or animal product that is required or authorised to be used under this Act, or any official assurance, or tampers with any animal material or animal product that is subject to such a certificate, declaration, form, or assurance; or*
- (f) *Falsifies, removes, suppresses, or tampers with any samples, test procedures, test results, or evidence taken or seized by an animal product officer, official assessor, or other recognised ... or authorised person or body in the exercise of their functions or powers under this Act; or*
- (g) *Falsifies, removes, suppresses, or tampers with any samples, test procedures, or test results taken by or for an operator of a registered risk management programme for the purposes of that programme or this Act, or by or for a person subject to the requirements of a regulated control scheme for the purposes of that scheme or this Act; or*
- (h) *Aids, abets, incites, counsels, procures, or conspires with any other person to commit an offence under this section."*

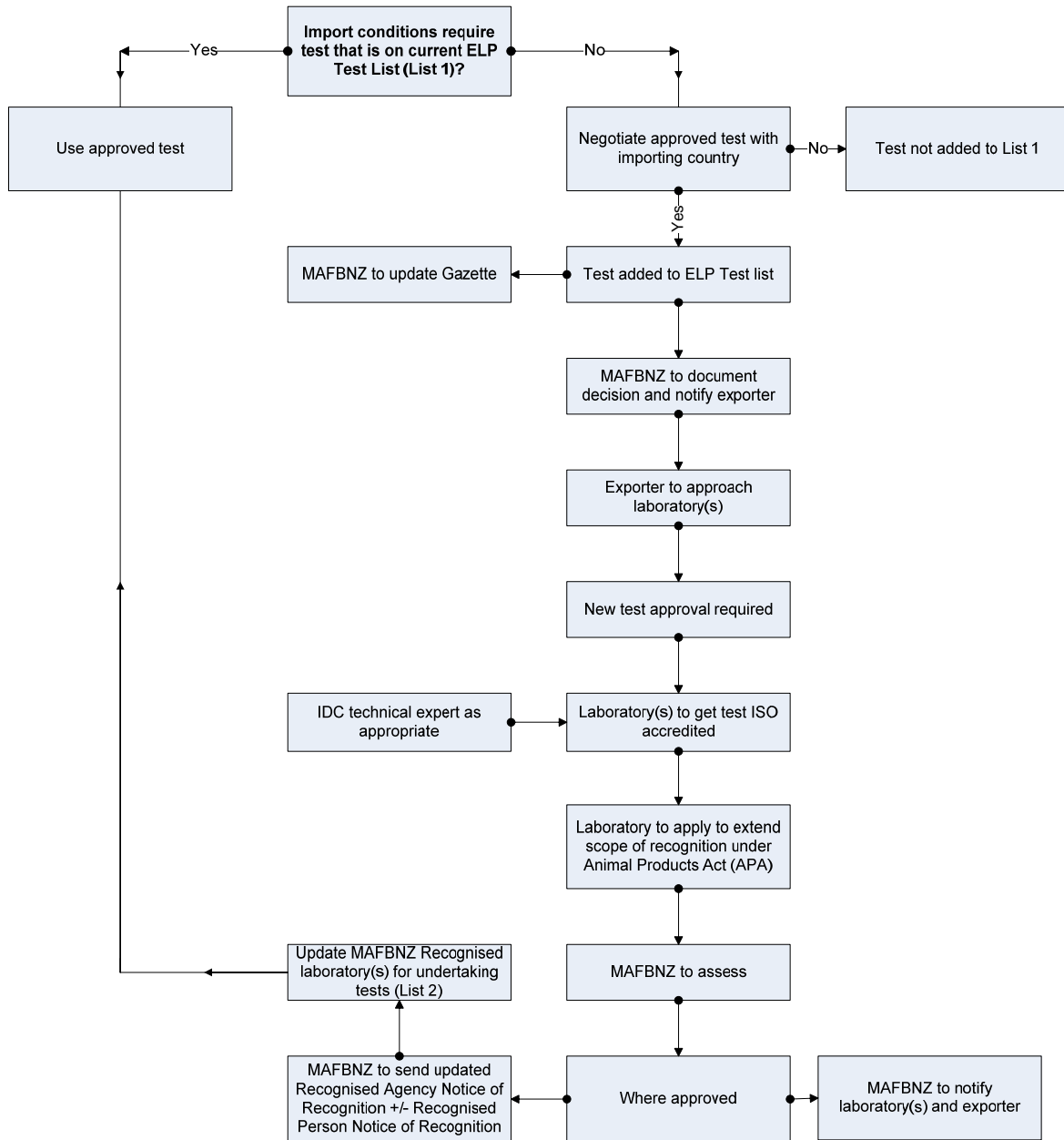
1.3.7 The roles and responsibilities of various groups of people involved in the ELP are shown in Figure 1 below.

Figure 1



1.3.8 The process for approval of tests is shown below in Figure 2.

Figure 2



List 1 = ELP Test List  
 List 2 = Recognised Laboratory List  
 IT IS ANTICIPATED THAT TESTS COULD TAKE 3-12 MONTHS TO BE APPROVED AND LISTED

## 1.4 Definitions

1.4.1 Any term or expression that is defined in the Animal Products Act 1999, Animal Products (Ancillary and Transitional Provisions) Act 1999, or regulations made under those Acts and used but not defined in this ELP, has the same meaning as in those Acts or regulations.

In this ELP, unless the context otherwise requires, the following definitions, abbreviations and interpretations are used:

<b>the Act, or APA</b>	the Animal Products Act 1999
<b>Animal Imports and Exports Group</b>	the section within MAFBNZ responsible for the development, negotiation and setting of, and adherence to export requirements for live animals and germplasm
<b>antibody/antigen detection systems</b>	systems that detect the reaction of antigens with antibodies for the detection of either antibodies or proteins that act as antigens. The target of such systems may be antibodies in serum formed in response to exposure to micro-organisms, or may be the antigens themselves. Examples of tests using these systems are enzyme-linked immunosorbent assay (ELISA), complement fixation (CF) test, agar-gel immuno diffusion test (AGID), Western Blot technique, microscopic agglutination test (MAT), antigen/antibody-based lateral flow devices (LFD)
<b>ANZSDP</b>	the current edition of the Australia and New Zealand Standard Diagnostic Procedures
<b>closed out</b>	the corrective action for a non-compliance(s) identified in an audit or assessment has been verified as successfully completed
<b>competent authority</b>	the veterinary authority or other governmental authority of a member 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
<b>competence</b>	in relation to a recognised person, means a demonstrated ability to apply that person's knowledge and skills
<b>conflict of interest</b>	where the duties or responsibilities of a person required by this notice or the Act could be improperly affected by some other interest or duty the person may have
<b>controlled copy</b>	the correct and latest revision level of a document, which is retrieved and replaced when a change is made
<b>Director-General</b>	this term 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, Exports Manager MAFBNZ or other MAF employees with delegated authority to exercise appropriate powers under the Animal Products Act
<b>entity</b>	an organisation or person that is legally able to enter into a contract and possesses a separate existence for tax purposes.

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	An example of an entity would be a company, corporation, partnership, or trust.
<b>ELP</b>	Export laboratory programme
<b>export requirements</b>	any requirements issued under section 60 of the Act, specific to an identified overseas market(s) and related to the export of live animals and germplasm
<b>exporter</b>	a person or entity that is registered for the purpose of exporting animal products under the Act, unless exempt from registration
<b>export test</b>	a laboratory test on samples from live animals or germplasm, that is required by specifications made, or export requirements issued, under the Act, to be conducted by a recognised laboratory in order for an export consignment of live animals or germplasm to be eligible for an official assurance under the Act
<b>germplasm</b>	semen, embryos, and ova of animals
<b>ILPT</b>	means inter-laboratory proficiency testing
<b>ISO 17025</b>	AS/NZS ISO/IEC 17025 – General Requirements for the Competence of Testing and Calibration Laboratories
<b>MAF</b>	Ministry of Agriculture and Forestry
<b>MAFBNZ</b>	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
<b>MAFBNZ conflict of interest policy</b>	“Policy for managing conflicts of interest when providing official assurances for export of live animals and germplasm”
<b>MAFBNZ IDC</b>	MAF Biosecurity New Zealand Investigation and Diagnostic Centre
<b>MAFBNZ website</b>	<a href="http://www.biosecurity.govt.nz/">http://www.biosecurity.govt.nz/</a>
<b>molecular biology diagnostic systems</b>	systems that target DNA, RNA or non-antigenic proteins. Examples of tests using these systems are: DNA and RNA amplification assays, nucleic acid and peptide arrays, nucleic acid and protein sequencing
<b>non-compliance</b>	these are rated as follows: <ol style="list-style-type: none"><li>critical non-compliance</li><li>major non-compliance</li><li>minor non-compliance.</li></ol> <p>A critical non-compliance compromises the integrity of export certification.</p> <p>Examples include but are not limited to:</p> <ul style="list-style-type: none"><li>negligence</li></ul>

- non-disclosure of unfavourable test or examination results
- substitution of animals or samples
- failure to keep essential records
- false certification and/or altered signature
- failure to declare a conflict of interest
- failure to rectify any major non-compliance(s) within the agreed timeframe.

A major non-compliance is one that demonstrates a major failure in the operation of a documented procedure or a deficiency in veterinary science application. It may be a specific non-compliance or a system with multiple non-compliances having a cumulative effect. Major non-compliances may be created by escalation of outstanding issues from previous audits or assessments.

A major non-compliance may compromise the integrity of the official assurance.

Examples include but are not limited to:

- unsatisfactory submission of samples for testing
- major omission or inaccuracy in record-keeping.

A minor non-compliance is one that does not represent a major failure of an operation or system but that does require correction

**official assurance**

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 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. For the purposes of this ELP, once an export certificate template is completed, it becomes an official assurance. Only authorised persons may issue an official assurance.

**OIE**

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

**OIE Code**

the current edition of the Terrestrial Animal Health Code, which can be found on the OIE website:  
[http://www.oie.int/eng/normes/mcode/A\\_summry.htm](http://www.oie.int/eng/normes/mcode/A_summry.htm)  
the current edition of the Aquatic Animal Health Code, which can be found on the OIE website:  
[http://www.oie.int/eng/normes/en\\_amanual.htm](http://www.oie.int/eng/normes/en_amanual.htm)

**OIE Manual**

the current edition of the OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, which can be found on the OIE website:  
[http://www.oie.int/eng/normes/mmanual/a\\_summry.htm](http://www.oie.int/eng/normes/mmanual/a_summry.htm)

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	<p>the current edition of the Aquatic Animal Health Code, which can be found on the OIE website: <a href="http://www.oie.int/eng/normes/en_amanual.htm">http://www.oie.int/eng/normes/en_amanual.htm</a></p>
<b>pathology diagnostic systems</b>	<p>systems that rely on either gross pathology or histopathology for the detection of lesions and diagnosis of disease. Examples of tests using these systems are histopathology, post-mortem examination</p>
<b>propagation-based assays</b>	<p>diagnostic systems that use the biological propagation of the organism as the primary diagnostic method for confirming presence or absence. Examples of tests using these systems are virus isolation, bacterial culture, <i>in-vivo</i> inoculation, fungal culture</p>
<b>recognised laboratory</b>	<p>in relation to any function or activity set out in this ELP means a laboratory recognised as an agency under section 103 of the Act for the purpose of performing specified tests and/or activities required for export certification of animals and germplasm to which this ELP applies</p>
<b>recognised person</b>	<p>in relation to any function or activity set out in this ELP means a person recognised under section 103 of the Act for the purpose of performing specified functions and/or activities relating to testing for export of live animals and germplasm to which this ELP applies</p>
<b>relevant function</b>	<p>a function or functions for which a laboratory or person is recognised by the Director-General under Part 8 of the Act; being functions relating to laboratory testing in respect of live animals and germplasm (other than live animals and germplasm certified as food) for the purposes of official assurance</p>
<b>SCAHLs</b>	<p>the Sub-Committee on Animal Health Laboratory Standards, representing the activities of the veterinary laboratory network of Australia and New Zealand and being a sub-committee of the Animal Health Committee, reporting to the Primary Industries Standing Committee</p>
<b>signatory function</b>	<p>one or more of the following specialist laboratory functions that a person may be recognised to perform for the purposes of this ELP:</p> <ul style="list-style-type: none"><li>• assessing that the quality control(s) of an export test conducted by a recognised laboratory is or are acceptable</li><li>• interpreting the results of an export test</li><li>• providing the signatory for the test report.</li></ul>
<b>technical manager</b>	<p>a person with overall responsibility for the technical activities of the recognised laboratory and who acts as the recognised laboratory's point of contact with the organisation for the time being responsible for the management of official assurances relating to live animals and germplasm</p>

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**visualisation diagnostic systems** that rely on the morphological identification of the pathogen/agent using visual inspection, often through microscopy. Examples of tests using these systems are the use of blood smears for *Babesia* spp., faecal egg counts, parasite identification

- 1.4.2 **Interpretation of export requirements**  
See the OAP for the interpretation of terms occurring in some export certificate templates.

## 1.5 **Complaints and appeals procedure**

Where any exporter believes that information, clarification, or sanction is demonstrably unfair, inaccurate, or impinges on the exporter's ability to conduct operations, they may follow the complaints and appeals procedure as can be found on the MAFBNZ website:  
<http://www.biosecurity.govt.nz/>.

## Part 2 Requirements for recognised laboratories conducting export testing

This Part sets out the requirements for a laboratory conducting tests and activities which support the issuance of official assurances for the export of live animals and germplasm. Recognised laboratories are recognised under section 100 of the Act. Registered exporters wishing to export live animals or germplasm should request the appropriate test(s) from a laboratory recognised to conduct that test(s).

### 2.1 Requirements for recognised laboratories conducting export testing functions

- 2.1.1 A recognised laboratory performing export testing functions to which this notice applies must:
- a. at the time of performing any such functions, be accredited to ISO 17025 to the scope of the export tests the laboratory is intending to conduct, if required by the Director-General

The situations whereby an exemption may be granted are provided for in sections 2.2.3 and 2.20.1.

- b. demonstrate to the Director-General a successful assessment, as conducted by the accreditation body, for its compliance with this ELP (see section 2.18.1). A copy of the assessment report from the accreditation body must be forwarded to the Director-General
- c. demonstrate to the Director-General completion by the recognised laboratory of an annual internal audit of their systems
- d. make payment of any fees and charges required under the Act
- e. appoint a technical manager who will have overall responsibility for:
  - i. technical operations of the laboratory including systems for calibration of equipment and checking of test results
  - ii. the competency of technical personnel conducting the testing
  - iii. the provision of the resources needed to ensure the required quality of the laboratory operations
  - iv. annual internal audits being carried out
  - v. being the contact point between the recognised laboratory and the organisation for the time being responsible for the management of official assurances relating to animals and germplasm.

A recognised laboratory may appoint more than one technical manager, but one must be identified as the primary contact for MAFBNZ. The technical manager may also be a recognised person.

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

2.1.2 The recognised laboratory, as referred to in clause 2.1.1, must meet all other technical requirements as prescribed by the Director-General under the Act for the tests and functions for which the laboratory is seeking recognition.

## **2.2 Application to become a recognised laboratory and provision of a controlled copy of systems and processes**

2.2.1 Any person or agency wishing to become a recognised laboratory must apply to the Animal Imports and Exports Group using Form 1 in Appendix I, and pay any fees and charges required under the Act.

Fees and charges are set by regulation and are subject to change. This information is available on the MAFBNZ website: [www.biosecurity.govt.nz](http://www.biosecurity.govt.nz).

2.2.2 A recognised laboratory must apply to an accreditation body authorised to accredit to AS/NZS ISO/IEC 17025, who will assess the laboratory's application and its procedures for compliance to AS/NZS ISO/IEC 17025, the Act or Regulations or Notices or Specifications or Directions made under the Act, and this ELP.

2.2.3 MAFBNZ may give approval to the laboratory to undertake testing according to the requirements of the 'ELP Test List' (list 1) under conditions specified by MAFBNZ.

Section 2.19 contains the requirements for the 'ELP Test List' list.

2.2.4 A controlled copy of the recognised laboratory's systems and procedures must be provided to the Director-General as soon as practicable after recognition.

Costs associated with assessments are the responsibility of the recognised laboratory. MAFBNZ costs will be charged to the laboratory in accordance with charges current at the time of assessment. The fees and direct charges are set by regulation and are subject to change. Following the decision to grant recognition, the Director-General will supply a notice of recognition specifying the functions that the applicant may undertake and any other conditions as specified in section 103 and section 105 of the Act.

## **2.3 Amendments to functions of the recognised laboratory**

2.3.1 A recognised laboratory that decides to vary the range of tests and functions for which it is recognised, must apply to the Director-General for a variation to its conditions of recognition using Form 1 in Appendix I.

Amendments include the situation where a test is removed from the recognised laboratory's scope of tests.

- 2.3.2 In approving a variation to the functions of the laboratory, the Director-General may require that any new test must be accredited by the chosen accreditation body.

## **2.4 Refusal to grant recognition**

- 2.4.1 If the Director-General proposes to refuse to grant recognition of a laboratory, the laboratory must be notified 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 where a decision has been made by a person acting under the delegated authority of the Director-General of NZFSA. These processes are detailed in section 162 of the Act.

## **2.5 Retention of status of a recognised laboratory**

- 2.5.1 A recognised laboratory retains recognition on the basis of:
- a. maintaining accreditation to AS/NZS ISO/IEC 17025. The recognised laboratory must:
    - i. be fully assessed by an accreditation body in accordance with the accreditation body's standards and procedures from the date of recognition to confirm the requirements of ISO 17025 to the scope of the requirements specified by MAFBNZ

This may include requiring a MAFBNZ technical person to be a part of the assessment team or present as an observer.

- ii. be subject to annual surveillance assessments in intervening years to confirm continued compliance with the above
    - iii. forward a copy of the assessment report from the accreditation body to MAFBNZ.
  - b. submission of the completed Form 1 in Appendix I to the Imports and Exports Group
  - c. a successful assessment, as determined by the accreditation body, to be carried out at least once a year. A copy of the assessment report from the accreditation body must be forwarded to MAFBNZ
  - d. completion by the recognised laboratory of an annual internal audit of their systems
  - e. full payment of any fees and charges required under the Act.

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

- 2.6.1 The Director-General may at any time, by notice in writing, propose to withdraw the recognition of a laboratory if satisfied that the laboratory:
- a. is no longer fit and proper to undertake the tests and functions for which recognition was granted
  - b. has failed to comply with any term or condition of the recognition or has failed to meet any performance criteria specified by the Director-General by notice under section 167 of the Act
  - c. has contravened or failed to comply with any requirement of the Act.

- 2.6.2 MAFBNZ must give the laboratory reasonable opportunity to be heard prior to withdrawal of the recognition status. Review rights may be exercised in accordance with section 162 where the decision is made by a person acting under the delegated authority of the Director-General.

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

- 2.6.3 The recognised laboratory must acknowledge receipt from MAFBNZ of the withdrawal of their recognition and must not perform any further tests/methods and functions as a recognised laboratory.
- 2.6.4 As soon as is practicable following the withdrawal of recognition, the recognised laboratory must take all reasonable steps to formally notify this to all organisations and persons to which it was providing services immediately prior to the withdrawal of recognition.
- 2.6.5 If recognition is withdrawn, the laboratory must return the notice of recognition to the Animal Imports and Exports Group within 20 working days of the effective date of the withdrawal of recognition.

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

A recognised laboratory may surrender its status as a recognised laboratory 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.

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

## **2.8 Temporary closure of a recognised laboratory**

- 2.8.1 A recognised laboratory must advise the Director-General in writing of any intended temporary closure of the laboratory, or any of its facilities which are required for export testing, such notice to be given no later than 20 working days prior to the closure.

A recognised laboratory will set their hours of business for export lab testing as part of their commercial operation. Temporary closure is defined as when the testing services of the laboratory are not able to be delivered within the stated operating hours of the laboratory.

- 2.8.2 Where a closure is unplanned, the recognised laboratory must notify the Director-General in writing (including reasons) within 48 hours of the closure taking place.

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

- 2.8.3 No test report issued by a recognised laboratory during a period that all or part of the laboratory, or any facilities used by the laboratory for official export testing, is or are closed, may be used for the purpose of supporting an official assurance for the export of animals or germplasm, unless the test was completed prior to closure.

## **2.9 System and facility requirements for recognised laboratories**

- 2.9.1 A recognised laboratory must establish, document and maintain systems and procedures that comply with the Act, associated Regulations, Notices, Specifications and Directions and its conditions of recognition (if any).
- 2.9.2 Any facilities and equipment of the recognised laboratory used to perform export testing must, at a minimum, comply with the procedures for a Physical Containment Level 2 facility specified in the current Australian/New Zealand Standard; Safety in laboratories: Part 3: Microbiological aspects and containment facilities: AS/NZS 2243.3.
- 2.9.3 Recognised laboratories must ensure that:
- a. at the time any particular export testing is being conducted, they are recognised for the export test being carried out
  - b. functions for which the laboratory is recognised are carried out only by persons who are themselves recognised for those functions

Administrative activities and related support matters may be carried out by non-recognised persons.

- c. the competency of any recognised persons performing specialist functions in relation to export testing is assessed and maintained.
  - d. recognised persons are not placed in situations that compromise their impartiality and independence in the performance of their functions as recognised persons
  - e. the laboratory is adequately resourced to carry out its tests and functions.
- 2.9.4 In order for recognised persons to maintain impartiality and independence in conducting the functions for which they are recognised, the recognised laboratory must assist in the resolution of any situation that compromises the recognised persons' impartiality and independence.
- 2.9.5 A recognised laboratory must ensure that directions given by the Director-General to the laboratory under section 81 of the Act, and relating to the functions for which the laboratory is recognised, are implemented by the laboratory and communicated to the appropriate recognised persons within the laboratory.
- 2.9.6 A recognised laboratory must ensure that its recognised persons, who are performing relevant functions, have access to:
- a. an up-to-date version of the Act, this ELP, ISO 17025, and where appropriate, the current OIE *Code* and/or OIE *Manual*
  - b. the laboratory's own systems and procedures
  - c. communication systems of telephone, fax, email and courier services
  - d. all policies and procedures issued by the Director-General, that are relevant to the performance of the functions of that laboratory including (without

limitation) policies on conflict of interest, and access to relevant departmental websites.

## **2.10 Requirements for a laboratory where a person applies for recognition**

2.10.1 Where a person applying for recognition is employed or contracted by a recognised laboratory, that laboratory must:

- a. assess the person against the criteria relevant to the proposed functions under Part 3 of this ELP, and the criteria specified in section 101(2) of the Act
- b. forward the application for recognition to the Director-General on the applicant's behalf when satisfied that the person meets the criteria
- c. provide documentation to the Director-General which attests that the person meets the criteria.

2.10.2 Where a person applying for recognition is employed or contracted by more than one laboratory, each laboratory must assess the applicant's competence to perform the functions for which recognition is sought.

## **2.11 Movement of recognised persons and functions between recognised laboratories**

2.11.1 Where a recognised person is conducting ongoing recognised laboratory export tests and functions and informs the recognised laboratory that he/she intends to leave and as a consequence the recognised laboratory will no longer be able to provide those export tests and functions after the recognised person has moved, the recognised laboratory must notify the Director-General within 24 hours of being so informed and use its best endeavours to ensure that any export testing and functions already in progress, are completed.

2.11.2 Where a recognised person elects to be contracted or employed by another recognised laboratory, the new laboratory must ensure that any outstanding non-compliances of the recognised person are closed out before he/she commences export testing for the new laboratory.

## **2.12 Communication of status as a recognised laboratory**

2.12.1 The recognised laboratory, in making reference to its recognised status, must use only the following phrase or an equivalent phrase approved by the Director-General:

“Approved by the Director-General [of either NZFSA or MAF, whichever currently holds primary or delegated powers to recognise laboratories] to provide [*state the functions for which the laboratory is recognised* ]”.

2.12.2 A recognised laboratory must not, except as provided in clause 2.12.1, make reference to, or use a logo associated with NZFSA, MAF, or any other department of state.

## **2.13 Information**

- 2.13.1 For the purpose of determining the recognised laboratory’s compliance with this ELP, all information obtained by a recognised laboratory whilst conducting its functions and activities relating to export testing must:
- a. where it is “personal information” be managed in accordance with the Privacy Act 1993
  - b. except where non-disclosure is permitted by law, be made available to the Director-General if requested by the Director-General
  - c. not be released to a third party without prior approval from the Director-General.

## 2.14 Management of consignments for export

- 2.14.1 Where two or more recognised persons share testing functions/activities for the same export consignment of animals or germplasm, one recognised person must be appointed to have overall signatory accountability for that consignment.

## 2.15 Reporting

- 2.15.1 The recognised laboratory must provide to the Director-General the following reports at specific frequencies, as shown in Table 2.1

**Table 2.1: Reporting requirements**

Reports	Event	Annual
Management information of: <ol style="list-style-type: none"> <li>a. significant changes to personnel, facilities and equipment</li> <li>b. results of internal audits</li> <li>c. results of any inter-laboratory quality assurance testing undertaken.</li> </ol>		X summary
Significant updates to the controlled copy of the recognised laboratory’s systems and procedures, including any subcontracting of tests.  The Director-General may audit such significant changes.	X <sup>3</sup>	
Any change in circumstances relating to the recognised laboratory’s conduct, or its ability to conduct export tests itself, or that might adversely affect test results or other matters which may affect the capability of the laboratory to meet the requirements set out in the Act, associated Regulations, Notices, Specifications and Directions.	X <sup>1</sup>	
Major and critical non-compliance findings identified within the recognised laboratory’s own system identified during internal audits or via other sources, and corrective actions undertaken.	X <sup>3</sup>  X <sup>1</sup> where critical	

Reports	Event	Annual
Technical information of: <ol style="list-style-type: none"> <li>name of species and the commodity (live animals or donors of germplasm, or the germplasm itself, or the group of origin) that is tested</li> <li>number and type of tests performed</li> <li>the results of those tests (number suspicious, number positive, number negative, equivocal results due to unclear cut offs for positives and negatives).</li> </ol>		X summary
Disputes and appeals, identifying: <ol style="list-style-type: none"> <li>background to the issue</li> <li>outcome</li> <li>legal action and settlements where applicable.</li> </ol>		X summary
Potential issues likely to compromise the integrity of export certification.	X <sup>1</sup>	
Pressure from a submitter or any other person to alter test results, or to re-test, without good reason.	X <sup>1</sup>	
Changes to the recognised laboratory's ownership, directorship, management or recognised persons.	X <sup>2</sup>	

<sup>1</sup> Written notification to the Director-General must be within 48 hours of this event.

<sup>2</sup> Written notification to the Director-General must be within five working days of this event.

<sup>3</sup> Written notification to the Director-General must be within ten working days of this event.

2.15.2 Any event report must contain the following information:

- name of organisation
- description of the event and implications
- action(s) taken
- recognised laboratory's recommendation to the Director-General.

2.15.3 Annual reports for the previous calendar year must be submitted to the Director-General by 31 January.

2.15.4 A recognised laboratory must submit to the Director-General any report on any such matter as the Director-General may request.

## 2.16 Requirements for disclosure of information

2.16.1 A recognised laboratory must authorise its accreditation body to promptly report to the Director-General on any critical non-compliance of the laboratory found by that body that relates to export testing and, when requested by the Director-General in writing, to make available a copy of any assessment report.

- 2.16.2 A recognised laboratory must authorise the supplier of any designated inter-laboratory proficiency testing programme, which is required as a condition of a test listed in the 'ELP Test List', to report to the Director-General on any critical non-compliance found and, when requested MAFBNZ in writing, to make available a copy of any assessment report.

## **2.17 Records**

- 2.17.1 A recognised laboratory must keep a record of all documentation for testing functions/activities for the export of live animals and germplasm in order to maintain an audit trail. In addition, the following records must be kept:
- a. reports issued of export tests
  - b. species and the commodity (live animals or donors of germplasm, or the germplasm itself, or the group of origin) that are tested
  - c. type of tests performed
  - d. the results of those tests including number suspicious, number positive, number negative and total number tested
  - e. equivocal results due to unclear cut offs for positives and negatives
  - f. original test results and/or observations
  - g. competency/skills assessments of its recognised persons
  - h. proficiency and performance of staff undertaking export tests
  - i. internal and external audit/assessment reports
  - j. non-compliances found during internal/external audits/assessments of the recognised laboratory and the associated corrective actions
  - k. circumstances and corrective actions following advice from the supplier of the inter-laboratory proficiency testing programme
  - l. disputes and appeals
  - m. service contracts.
- 2.17.2 The records referred to in clause 2.17.1 must be:
- a. retrievable as hard or electronic copies for a period of seven years
  - b. uniquely identified, dated and traceable to the recognised person undertaking the signatory activity.
- 2.17.3 Copies of all records referred to in clause 2.17.1 must be provided to the Director-General upon request by the Director-General.

## **2.18 Audit and assessment requirements**

- 2.18.1 A recognised laboratory must be assessed by its chosen accreditation body and covering at least the following areas:
- a. assessment of the technical manager for compliance with requirements, at least once every 12 months
  - b. assessment of the laboratory processes for determining competency of each recognised person, employed or otherwise used by the laboratory for export testing at least once during a three-year accreditation period
  - c. assessment of the laboratory processes for each signatory function at least once during a three-year accreditation period

- d. assessment of a sample of accredited tests within each signatory function specified in the scope of recognition for the laboratory.

The sample size is to be determined based on the professional judgement of the accreditation body, in conjunction with any requisite technical expert.

- 2.18.2 The Director-General may carry out audits or investigations independently from the assessments by the chosen accreditation body, for the purposes of determining the recognised laboratory's compliance with this ELP.
- 2.18.3 The recognised laboratory must make its facilities, staff involved in export testing, and records relating to export testing, reasonably available for the purposes of an inspection or audit:
- by any agency or person appointed for that purpose by the Director-General
  - by the representatives of any other country, where notified by the Director-General, as part of an assessment of compliance of the export testing system assurance programme with that country's import requirements.

## 2.19 ELP Test List (list 1)

Where an importing country requires a test that is not currently approved, MAFBNZ will firstly negotiate an equivalent and currently approved test. In the event that the importing country does not accept the alternative test, the new test will be approved by MAFBNZ prior to being listed on the web-based 'ELP Test List' on the MAFBNZ website: [www.biosecurity.govt.nz](http://www.biosecurity.govt.nz). After tests have been listed, a recognised laboratory may apply to the accreditation body to be accredited for that test and their scope of recognition extended by MAFBNZ as per section 2.20 below.

- 2.19.1 Only tests that are listed in the 'ELP Test List' (list 1), as set out in Appendix II, may be carried out in accordance with the methodology described in one of the following:
- the current OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals
  - the current Australia and New Zealand Standard Diagnostic Procedures (ANZSDP), or any procedure that replaces these, developed by the Subcommittee on Animal Health Laboratory Standards (SCAHLs), or any body that replaces this sub committee
  - export requirements for an importing country where an agreement has been reached between MAFBNZ and that country's competent authority
  - a recognised laboratory's standard operating procedure for the approved test where the methodology is proven to be at least equivalent to the OIE prescribed test, using the OIE principles for test validation
  - the recognised laboratory's own standard operating procedure.

Approval for an alternative test will be based on:

- a description of the method in a standard operating procedure
- appropriate test validation records, references and/or other appropriate evidence.

- 2.19.2 Where commercial serological kits are used the following criteria apply:
- the current OIE Manual and ANZSDP acknowledge that commercial kits are available
  - the commercial kits have been validated using the principles for test validation in the OIE Manual and/or ANZSDP
  - the diagnostic specificity and sensitivity are the same for the kits as for tests prescribed by the OIE Manual and/or ANZSDP.

## 2.20 Recognised laboratory(s) for undertaking tests (List 2)

A list (List 2), which contains the recognised laboratory, and that laboratory's approved tests, its recognised persons and their signatory functions, is available on the MAFBNZ website:

[www.biosecurity.govt.nz](http://www.biosecurity.govt.nz).

Note that MAFBNZ may restrict approval for testing in situations where positive controls are required, e.g. testing of an exotic disease.

- 2.20.1 A recognised laboratory that wants to undertake a new test must, where required by the Director-General:
- obtain accreditation for that test from the accreditation body
  - apply to the Director-General for approval to extend the scope of recognition using Form 1 in Appendix 1.

MAFBNZ will assess the application, and notify the recognised laboratory if the scope of recognition has been extended to cover the test. The test can then be conducted.

- 2.20.2 The recognised laboratory must conduct tests according to the requirements of sections 2.19.1 and 2.19.2.
- 2.20.3 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. Such positive control material must be traceable to:
- a confirmed positive case, or
  - a reference standard with appropriate traceability purchased for the purpose, or
  - a national standard held and provided under agreement by MAFBNZ and that is traceable to an international standard recognised as such by the OIE, or
  - an international standard from an international OIE reference laboratory.
- 2.20.4 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.
- 2.20.5 The recognised laboratory must take part in an inter-laboratory proficiency testing (ILPT) programme, where one is available, for tests the laboratory is recognised to conduct, provided that the ILPT provider is:
- accredited for proficiency testing by an international accreditation body; or
  - 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).

- 
- 2.20.6 Every recognised laboratory must ensure that all reports for tests conducted under this ELP:
- a. conform to good laboratory practice and the requirements of this ELP
  - b. are not used in a misleading manner
  - c. relate only to tests where the requirements of this ELP have been met
  - d. do not make any misleading statement in relation to its recognition
  - e. do not make any statement either directly or by implication that the laboratory's recognition is in itself an approval or assurance in relation to any animal product.
- 2.20.7 The recognised laboratory may subcontract any test for which it is recognised, provided that the subcontracted laboratory is itself recognised to conduct that test.
- 2.20.8 The recognised laboratory must obtain the written permission of the Director-General, prior to sending any animal tissues, body fluids or cultures of animal pathogens offshore.

Approval for particular categories of samples to be sent offshore may be subject to conditions, whose purpose is the protection of New Zealand's animal health status.

## Part 3 Requirements for recognised persons

This document sets out the requirements for persons recognised to perform functions associated with laboratory testing for the export of live animals and germplasm. Recognised persons are recognised under section 101 of the Act. The requirements for recognised persons are established and administered by MAFBNZ.

### 3.1 Requirements to be a recognised person

3.1.1 Persons who carry out functions at or for a recognised laboratory in relation to laboratory testing of live animals and germplasm in order to facilitate entry of those animals and germplasm into export markets, must be recognised under the Act.

See section 3.9 for the functions for which a person may be recognised.

3.1.2 A recognised person may perform certain functions under the management of one or more recognised laboratories.

3.1.3 All information obtained by a recognised person conducting functions in relation to export testing of live animals and germplasm, which relates to the functions for which that person is recognised, shall:

- a. where it is personal information, be managed in accordance with the Privacy Act 1993
- b. except where non-disclosure is permitted by law, be made available to the Director-General when requested by the Director-General
- c. not be released to a third party without prior approval from the Director-General.

3.1.4 Recognition to carry out a function while contracted or employed by one recognised laboratory does not automatically allow the person to perform that same function while contracted or employed by another laboratory. Separate recognition must be sought for each recognised laboratory the person is contracted to or employed by.

3.1.5 Recognised persons must comply with the requirements of the Act, associated regulations, notices, and directions, and this ELP, relevant to their functions.

3.1.6 Recognised persons must maintain impartiality and independence in carrying out the functions for which they are recognised. Recognised persons must ensure that any conflicts of interest are identified, disclosed and managed to the satisfaction of MAFBNZ. The recognised laboratory and the technical manager of the recognised laboratory must assist in the resolution of any such conflict of interest.

3.1.7 For a person to be recognised, the Director-General must be satisfied that the person is suitable, and will consider the:

- a. relevant competencies and resources of the applicant to reliably meet and maintain the specified function(s)
- b. reputation of the applicant
- c. ability of the applicant to remain impartial when carrying out their function(s)
- d. requirements of any regulations or specifications made under the Act.

- 3.1.8 A recognised person must meet all other technical requirements as specified by the Director-General relating to the function(s) for which he or she is seeking recognition, including payment of any fees and charges required under the Act.

### **3.2 Application to become a recognised person**

- 3.2.1 A person applying to become recognised or a recognised person wishing to change his/her current recognition must apply (in accordance with section 102 of the Act) to the Director-General, using the Form 2 in Appendix I, and pay any fees and charges required under the Act.

The fees and charges are set by regulation and are subject to change. This information is available on the MAFBNZ website: [www.biosecurity.govt.nz](http://www.biosecurity.govt.nz).

### **3.3 Variations to the functions of a recognised person**

- 3.3.1 A recognised person may apply to the Director-General to vary the function(s) for which he or she is recognised under section 105(5) of the Act, using the application Form 2 in Appendix I.

### **3.4 Refusal to grant recognition as a recognised person**

- 3.4.1 Where the Director-General proposes to refuse to grant recognition, the applicant must be notified, through the relevant recognised laboratory, of that intention, together with reasons (see section 104 of the Act).

The Act makes provision for review processes and these are detailed in section 162 of the Act.

### **3.5 Retention of status of a recognised person**

- 3.5.1 The recognised person retains his/her recognition on the basis of:
- annual submission of the completed application Form 2 in Appendix I to the Director-General
  - full payment of any fees and charges as required by the Act.

### **3.6 Suspension of status as a recognised person**

- 3.6.1 Recognition of a person can be suspended by the Director-General, in full or part, for a specified period not exceeding three months, where she/he has reasonable grounds to believe that the performance of the person is unsatisfactory, having regard to the requirements of the position. Reasonable grounds would be established where, for example:
- an assessment by MAFBNZ or its representatives identifies significant non-compliance findings that confirm that the recognised person is either not in compliance with the Act or is not operating in accordance with approved procedures
  - agreed corrective actions for significant non-compliance findings have not been implemented by the recognised person within the agreed timeframes

- c. the recognised person fails to make full payment of any fees and charges as required under the Act to MAFBNZ, unless in dispute
- d. it is requested by the recognised person.

3.6.2 While suspended, the recognised person must not perform any functions for which they are suspended.

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

3.7.1 Following the surrender of status by the recognised person, he/she must return his/her notice of recognition to MAFBNZ (see section 110 of the Act) and must no longer perform any functions for which he/she is recognised.

A recognised person may surrender his/her status at any time by giving notice to MAFBNZ in writing. Such surrender will normally take effect three months from the receipt of notice by MAFBNZ.

### **3.8 Withdrawal of status as a recognised person**

3.8.1 Recognition of a recognised person may be withdrawn if the person no longer meets the requirements for recognition, has failed to comply with any term or condition of recognition, has contravened the Act failed to pay any fees and charges as required under the Act. Where MAFBNZ considers it appropriate to remove recognition, MAFBNZ must notify the recognised person in writing and give him/her a reasonable opportunity to be heard (see section 109 of the Act).

3.8.2 Where recognition is withdrawn, the recognised person must not perform any further functions as a recognised person and must return the notice of recognition to the Director-General within 20 working days of the date of withdrawal.

MAFBNZ maintains a list of all recognised persons and the functions for which they are recognised. The purposes of this list are:

- to enable members of the public to know where to locate a recognised person having the required functions
- to facilitate audit functions by MAFBNZ.

This list is available on the MAFBNZ website: [www.biosecurity.govt.nz](http://www.biosecurity.govt.nz).

### **3.9 Functions for which persons may be recognised**

3.9.1 For the purpose of providing laboratory testing for the export of live animals and germplasm, a person may be recognised to carry out the following functions, as appropriate:

- a. signatory for antibody/antigen detection systems, covering multiple agents
- b. signatory for molecular biology diagnostic systems, covering multiple agents
- c. signatory for propagation-based assays, covering multiple agents
- d. signatory for pathology diagnostic systems, covering multiple agents
- e. signatory for visualisation diagnostic systems, covering multiple agents

- f. such other testing functions and activities in relation to export requirements for live animals and germplasm, as may be prescribed by the Director-General under the Act.

3.9.2 A person recognised for a signatory function must carry out the following roles:

- a. assess that the quality control(s) of the test is acceptable
- b. interpret the results of the test
- c. provide the signatory for the test report.

3.9.3 A recognised person must ensure that he/she has adequate knowledge of what is happening at the laboratory on a day-to-day basis and is able to be present at reasonable notice when testing is occurring.

### **3.10 Competencies for recognised persons**

3.10.1 Any person applying to be recognised for any of the functions in 3.9.1 above must:

- a. demonstrate sound knowledge of:
  - i. the Act and any associated Regulations, Notices, and Directions, relevant to the person's function(s)
  - ii. the requirements of this ELP
  - iii. export requirements relating to the testing of live animals and germplasm
  - iv. the current OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals, as appropriate to the test being conducted
  - v. the current Australia and New Zealand Standard Diagnostic Procedures (ANZSDP), or any procedure that replaces these, developed by the Sub-Committee on Animal Health Laboratory Standards (SCAHLs), or any body that replaces this sub committee
  - vi. relevant departmental policies of departments with primary or delegated responsibility for export of live animals and germplasm, including the MAFBNZ Conflict of Interest Policy
  - vii. the recognised laboratory's own Standard Operating Procedures.
- b. provide evidence of the relevant competencies (see section 3.10.2).

3.10.2 In addition to meeting the requirements of clause 3.10.1, a recognised person providing a signatory function must:

- a. have relevant technical qualifications, training and experience
- b. be able to demonstrate sound knowledge of the operational norms of laboratory testing for the live animal and germplasm export industry
- c. have demonstrated that he/she is able to:
  - i. have an in-depth understanding of the science of the test
  - ii. assess that the quality controls of a test are acceptable
  - iii. interpret the results of the test in all relevant circumstances
  - iv. identify and resolve any problems.
- d. have been signatory for two or more test reports under the direct supervision of a recognised person. The supervising recognised person must be recognised for that function. This applies only to the initial recognition.

Adequate training in particular tests could include participation in testing and participation in an appropriate proficiency testing programme.

Competency could be assessed using results from inter-laboratory proficiency testing

The recognised person 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.

### **3.11 Reporting**

- 3.11.1 Where in the course of performing his/her function(s), a recognised person detects any non-compliance with any relevant requirement of the Act, this ELP, and/or export requirements relating to live animals and germplasm, which he/she considers will compromise the integrity of an official assurance for live animals or germplasm, he/she must report this in writing within 24 hours to the technical manager of the recognised laboratory.

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## Part 4      **Appendix I: Application and Declaration forms**

Application Form 1:	Recognised Laboratory (Conducting Testing of Live Animals and Germplasm for Export)
Application Form 2:	Recognised Person (Conducting Testing of Live Animals and Germplasm for Export)
	Consent to Disclosure of Information
	Comments of the New Zealand Police
Declaration Form 1	Conflict of Interest Declaration Form

Microsoft Word versions of the Appendix forms are available separately for use at:  
<http://www.biosecurity.govt.nz>

## **Appendix II: ELP Test List (List 1)**



MAF Biosecurity New Zealand  
 Animal Imports and Exports Group  
 PO Box 2526  
 Wellington 6140  
 Ph: 0800 008 333  
 Fax: (04) 894 0733

## Application Form 1: Recognised Laboratory (Conducting Testing of Live Animals and Germplasm for Export)

This application for initial and annual recognition as a laboratory is made under section 102 of the Animal Products Act 1999.

The form for consent for disclosure of information form by the NZ Police must be printed on letterhead paper of the recognised laboratory, be completed by the director(s)/those responsible for the management of the recognised laboratory and returned with the application form. The consent for disclosure of information form must be completed at each annual application for recognition.

Send the completed application and other appropriate documentation to MAFBNZ, attention: Group Manager, Animal Imports and Exports Group, at the above address.

An application fee and assessment fee may be charged each time any of the following is applied for:

- \*addition of a new function or a new test to the scope of recognition
- \*removal of a function or test from the scope of recognition

Where an applicant is refused recognition as a laboratory, these fees will not be refunded as the work they cover must still be undertaken regardless of the outcome.

If there are any changes to the contact details provided in this application subsequent to recognition, the recognised laboratory must inform the Group Manager Animal Imports and Exports in writing.

The MAFBNZ conflict of interest policy is available on the MAFBNZ website at <http://www.biosecurity.govt.nz>.

**1. Applicant name** (registered company name or partnership names (including the trading name) or sole trader name)

Full legal name of applicant: .....

Company - provide the name of the company as registered under the Companies Act 1993.

Partnership - provide the full legal names of all individuals or companies within the partnership and if applicable, the trading name used by the partnership. The use of initials for individuals is not permitted and the full legal name of all individuals or companies must be supplied. The name will appear on the Notice of Recognition in the format "<partner names>, a partnership trading as <trading name>", and as stated in the application form.

**2. Address and contact details of applicant**

Physical address (for service): .....

Postal address (for communication): .....

Phone No: .....

Mobile No: .....

Fax No: .....

Email: .....

**3. Names of directors of the applicant or those responsible for its management or control**

List all persons (full legal name): .....

Each person listed above must also complete and sign a separate Consent for Disclosure of Information form provided below.

**4. Name of technical manager:**

Full legal name: .....

**5. Functions management table:**

<b>List of functions</b>	
1. Signatory for antibody/antigen detection systems, covering multiple agents	
2. Signatory for molecular biology diagnostic systems, covering multiple agents	
3. Signatory for propagation-based assay, covering multiple agents	
4. Signatory for pathology diagnostic systems, covering multiple agents	
5. Signatory for visualisation diagnostic systems, covering multiple agents.	
<b>Names of persons to be recognised</b>	<b>Specified functions (list No's as above)</b>
e.g. Mary Smith	e.g. 1, 3, 5

**6. Test management table**

Please complete the ELP Test List (List 1) Test Management Table, providing details of any subcontracting of tests and the details of the subcontracting laboratory(s).

**7. Documentation required and to be attached:**

- The ISO 17025 accreditation report.
- Individual Consent for Disclosure forms for all those listed in section 3.
- A copy of the recognised laboratory's annual internal audit.

**Applicant declaration:**

I declare that:

- a. I am authorised to make this application on behalf of the applicant

- b. the information supplied in this application is accurate
- c. the directors of the applicant or those responsible for its management or control are of good character and reputation
- d. there is no other information that I am aware of that affects the ability of the applicant to maintain an appropriate degree of impartiality and independence in managing the function(s) and activities for which the applicant has applied to be recognised.

Name(s):

Date:

Designation(s):

Signature(s):

## ELP Test List (List 1) Test Management Table

Recognised Laboratories and Persons Specifications for Conducting Testing of Live Animals and Germplasm for Export

<input checked="" type="checkbox"/> test Lab seeks recognition for	<input checked="" type="checkbox"/> if subcontracted & complete table below	Organism / disease tested		Test method	Type of test method	Function for which person may be recognised
		Aerobic bacteria		Bacterial culture	Propagation	Propagation
		<i>Aeromonas salmonicida</i>		Bacterial culture	Propagation	Propagation
		Akabane virus		VNT	Antibody detection	Antibody/antigen detection
		Anaplasmosis	*	CFT	Antibody detection	Antibody/antigen detection
		Avian influenza virus		AGID test	Antibody detection	Antibody/antigen detection
		Avian influenza virus		ELISA-Ab	Antibody detection	Antibody/antigen detection
		Avian influenza virus		HI	Antibody detection	Antibody/antigen detection
		Avian influenza virus		VI	Propagation	Propagation
		Avian paramyxovirus serotype 1 (APMV-1) / NDV		PCR	Molecular biology	Molecular biology
		Avian paramyxovirus serotype 2 (APMV-2) Yucaipa		HI	Antibody detection	Antibody/antigen detection
		Avian paramyxovirus serotype 2 (APMV-2) Yucaipa		PCR	Molecular biology	Molecular biology
		Avian paramyxovirus serotype 3 (APMV-3)		HI	Antibody detection	Antibody/antigen detection
		Avian paramyxovirus serotype 3 (APMV-3)		PCR	Molecular biology	Molecular biology
		Avian pneumovirus (referred to as turkey rhinotracheitis in turkeys)		ELISA-Ab	Antibody detection	Antibody/antigen detection
		Avian virus		VI	Propagation	Propagation
		<i>Babesia</i>		Blood smear	Visualisation	Visualisation

Appendices

		<i>Babesia caballi</i>		ELISA-Ab	Antibody detection	Antibody/antigen detection
		<i>Babesia caballi</i>	*	IFAT	Antibody detection	Antibody/antigen detection
		<i>Babesia gibsoni</i>	*	IFAT	Antibody detection	Antibody/antigen detection
		<i>Babesia gibsoni</i>	*	PCR	Molecular biology	Molecular biology
		Blood parasites ( <i>Babesia spp.</i> )	*	Blood smear	Visualisation	Visualisation
		Bluetongue virus		AGIDT	Antibody detection	Antibody/antigen detection
		Bluetongue virus		ELISA-Ab	Antibody detection	Antibody/antigen detection
		Bovine herpesvirus 1		PCR	Molecular biology	Molecular biology
		Bovine viral diarrhoea virus (BVDV)		ELISA-Ab	Antibody detection	Antibody/antigen detection
		Bovine viral diarrhoea virus (BVDV)		ELISA-Ag	Antigen detection	Antibody/antigen detection
		Bovine viral diarrhoea virus (BVDV)		PCR	Molecular biology	Molecular biology
		Bovine viral diarrhoea virus (BVDV)		VI	Propagation	Propagation
		Bovine viral diarrhoea virus (BVDV)		VNT	Antibody detection	Antibody/antigen detection
		Bovine viral diarrhoea virus (BVDV)		2 passages	Propagation	Propagation
		<i>Brucella abortus</i>		SAT AM	Antibody detection	Antibody/antigen detection
		<i>Brucella abortus</i>		SAT EU	Antibody detection	Antibody/antigen detection
		<i>Brucella spp. (B. melitensis; B. suis)</i>		ELISA-Ab	Antibody detection	Antibody/antigen detection
		<i>Brucella spp. (B. melitensis)</i>		CFT	Antibody detection	Antibody/antigen detection
		<i>Brucella canis</i>		RSA	Antibody detection	Antibody/antigen detection
		<i>Brucella ovis</i>		CFT	Antibody detection	Antibody/antigen detection

Appendices

	<i>Brucella ovis</i>	ELISA-Ab	Antibody detection	Antibody/antigen detection
	<i>Campylobacter</i> spp.	Bacterial culture	Propagation	Propagation
	<i>Campylobacter fetus</i> subsp. <i>venerealis</i>	Bacterial culture	Propagation	Propagation
	Canine / feline heartworm	ELISA-Ag	Antigen detection	Antibody/antigen detection
	Caprine arthritis-encephalitis (CAE) virus	ELISA-Ab	Antibody detection	Antibody/antigen detection
	Cervine herpesvirus type-1	VNT	Antibody detection	Antibody/antigen detection
	Cytopathic fish virus	VI	Propagation	Propagation
	EDS 76	HI	Antibody detection	Antibody/antigen detection
	<i>Ehrlichia canis</i>	IFAT	Antibody detection	Antibody/antigen detection
	Enzootic bovine leukosis (EBL)	AGID test	Antibody detection	Antibody/antigen detection
	Enzootic bovine leukosis (EBL)	ELISA-Ab	Antibody detection	Antibody/antigen detection
	Epizootic haemorrhagic disease (EHD)	AGID test	Antibody detection	Antibody/antigen detection
	Equine herpesvirus	VNT	Antibody detection	Antibody/antigen detection
	Equine herpesvirus-1	ELISA-Ab	Antibody detection	Antibody/antigen detection
	Equine herpesvirus-4	ELISA-Ab	Antibody detection	Antibody/antigen detection
	Equine infectious anaemia (EIA)	AGID test	Antibody detection	Antibody/antigen detection
	Equine influenza virus	HI	Antibody detection	Antibody/antigen detection
	Equine influenza virus	PCR	Molecular biology	Molecular biology
	Equine viral arteritis (EVA) virus	VI	Propagation	Propagation
	Equine viral arteritis (EVA) virus	VNT	Antibody detection	Antibody detection

Appendices

	Infectious bovine rhinotracheitis (IBR) virus	VI	Propagation	Propagation
	Infectious bovine rhinotracheitis (IBR) virus	VNT	Antibody detection	Antibody/antigen detection
	Infectious bovine rhinotracheitis (IBR) virus	ELISA-Ab	Antibody detection	Antibody/antigen detection
	Infectious bursal disease (IBD) virus	ELISA-Ab	Antibody detection	Antibody/antigen detection
	Infectious bursal disease (IBD) virus	PCR	Molecular biology	Molecular biology
	Infectious bursal disease (IBD) virus	VNT	Antibody detection	Antibody/antigen detection
	Influenza	PCR	Molecular biology	Molecular biology
	Influenza A+B	LFD	Antigen detection	Antibody/antigen detection
	Johne's disease (JD), paratuberculosis	AGID test	Antibody detection	Antibody/antigen detection
	Johne's disease (JD), paratuberculosis	CFT	Antibody detection	Antibody/antigen detection
	Johne's disease (JD), paratuberculosis	ELISA-Ab	Antibody detection	Antibody/antigen detection
	<i>Leishmania</i> spp.	IFAT	Antibody detection	Antibody/antigen detection
	<i>Leptospira</i> Ballum (1)	MAT	Antibody detection	Antibody/antigen detection
	<i>Leptospira</i> Bratislava (2)	MAT	Antibody detection	Antibody/antigen detection
	<i>Leptospira</i> Canicola (3)	MAT	Antibody detection	Antibody/antigen detection
	<i>Leptospira</i> Copenhagenii (4)	MAT	Antibody detection	Antibody/antigen detection
	<i>Leptospira</i> Gripotyphosa (5)	MAT	Antibody detection	Antibody/antigen detection
	<i>Leptospira</i> Hardjobovis (6)	MAT	Antibody detection	Antibody/antigen detection
	<i>Leptospira</i> Icterohaemorrhagiae (7)	MAT	Antibody detection	Antibody/antigen detection

Appendices

		<i>Leptospira Pomona</i> (8)		MAT	Antibody detection	Antibody/antigen detection
		<i>Leptospira Tarassovi</i> (9)		MAT	Antibody detection	Antibody/antigen detection
		Lyssa virus	*	IFAT	Antibody detection	Antibody/antigen detection
		Maedi visna (MV) virus		ELISA-Ab	Antibody detection	Antibody/antigen detection
		Malignant catarrhal fever		PCR	Molecular biology	Molecular biology
		Microfilariae		Knotts test	Visualisation	Visualisation
		<i>Mycoplasma</i> spp.		Bacterial culture	Propagation	Propagation
		<i>Mycoplasma agalactiae</i>		ELISA-Ab	Antibody detection	Antibody/antigen detection
		<i>Mycoplasma capricolum</i> subsp. <i>capricolum</i>		CFT	Antibody detection	Antibody/antigen detection
		<i>Mycoplasma gallicepticum</i>		RSA	Antibody detection	Antibody/antigen detection
		<i>Mycoplasma mycoides mycoides</i> Large Colony		CFT	Antibody detection	Antibody/antigen detection
		<i>Mycoplasma synoviae</i>		RSA	Antibody detection	Antibody/antigen detection
		<i>Mycoplasma meleagridis</i>		RSA	Antibody detection	Antibody/antigen detection
		<i>Myxobolus cerebralis</i>		Microscopy	Visualisation	Visualisation
		Newcastle disease virus (NDV)		ELISA-Ab	Antibody detection	Antibody/antigen detection
		Newcastle disease virus (NDV)		HI	Antibody detection	Antibody/antigen detection
		Newcastle disease virus (NDV)		VI	Propagation	Propagation
		Palyam virus		AGID test	Antibody detection	Antibody/antigen detection
		Parainfluenza virus type-3		VI	Propagation	Propagation
		Parasite eggs		Faecal egg count	Visualisation	Visualisation
		Pestivirus / hairy shaker disease virus / Border disease virus		VI	Propagation	Propagation

Appendices

	Hairy shaker disease virus / border disease virus		2 passages	Propagation	Propagation
	<i>Ornithobacterium rhinotracheale</i>		Bacterial culture	Propagation	Propagation
	Porcine parvovirus (PPV)		ELISA-Ab	Antibody detection	Antibody/antigen detection
	Q fever		CFT	Antibody detection	Antibody/antigen detection
	Q fever		ELISA-Ab	Antibody detection	Antibody/antigen detection
	Q fever		PCR	Molecular biology	Molecular biology
	Rabies virus	*	RFFIT	Antibody detection	Antibody/antigen detection
	<i>Renibacterium salmoniarum</i>		PCR	Molecular biology	Molecular biology
	<i>Salmonella</i> spp.		Bacterial culture	Propagation	Propagation
	<i>Salmonella</i> spp.		ELISA	Antibody detection	Antibody/antigen detection
	<i>Salmonella</i> Arizona		Bacterial culture	Propagation	Propagation
	<i>Salmonella</i> Pullorum		SAT	Antibody detection	Antibody/antigen detection
	<i>Salmonella</i> spp. inc <i>S. Typhimurium</i> and <i>S. Enteritidis</i>		Bacterial culture	Propagation	Propagation
	<i>Streptococcus</i> Equi ss. Equi culture		Bacterial culture	Propagation	Propagation
	<i>Taylorella equigenitalis</i>		Bacterial culture	Propagation	Propagation
	Ticks		Identification	Visualisation	Visualisation
	<i>Theileria equi</i>		ELISA-Ab	Antibody detection	Antibody/antigen detection
	<i>Theileria equi</i>	*	IFAT	Antibody detection	Antibody/antigen detection
	<i>Trichinella spiralis</i>		ELISA-Ab	Antibody detection	Antibody/antigen detection
	<i>Trichinella spiralis</i>		Pepsin digestion	Visualisation	Visualisation
	<i>Trichomonas foetus</i>		Bacterial culture	Propagation	Propagation
	<i>Yersinia ruckeri</i>		Bacterial culture	Propagation	Propagation
	West Nile virus	*	ELISA-Ab	Antibody detection	Antibody/antigen



**Table of subcontracted tests:**

Test Name	Subcontractor details	<input checked="" type="checkbox"/> Within NZ	<input checked="" type="checkbox"/> Outside NZ



MAF Biosecurity New Zealand  
 Animal Imports and Exports Group  
 PO Box 2526  
 Wellington 6140  
 Ph: 0800 008 333  
 Fax: (04) 894 0733

## Application Form 2: Recognised Person (Conducting Testing of Live Animals and Germplasm for Export)

This application for initial and annual recognition as a person is made under section 102 of the Animal Products Act 1999.

This application form must be completed annually by applicants requiring recognition under section 101 of the Animal Products Act 1999 for functions associated with the export of live animals and animal germplasm. An application fee will be charged annually, but an annual consent to disclosure of information form is not required.

Recognition of a person is granted under section 101 of the Animal Products Act 1999. Under section 105 of the Animal Products Act 1999, the Director-General can specify, in the notice of recognition, conditions on the grant.

The consent for disclosure of information form must be printed on letterhead paper of the recognised laboratory and completed by **initial** applicants only, and returned with the application form.

Send the completed application and other appropriate documentation to MAFBNZ, attention: Group Manager, Animal Imports and Exports, at the above address.

The application fee and assessment fee will be charged each time new functions and activities are applied for.

Where an applicant is refused recognition as a recognised person, these fees will still be payable as the work they cover must still be undertaken regardless of outcome.

If there are any changes to the contact details provided in this application subsequent to recognition, the recognised laboratory must inform the Group Manager Animal Imports and Exports in writing.

The MAFBNZ conflict of interest policy is available on the MAFBNZ website at <http://www.biosecurity.govt.nz>.

**1. Applicant name:**

Full name of applicant: .....

**2. Organisation name (where appropriate) - (provide registered company name or partnership names (including the trading name) or sole trader name):** .....

The use of initials is not permitted. The name will appear on the Notice of Recognition as stated in the application form, including the use of upper and lower case as provided by the applicant.

**3. Address and contact details of applicant**

Physical address (for service): .....

Postal address (for communication): .....

Phone No: .....

Mobile No: .....

Fax No: .....

Email: .....

**4. Recognised laboratory details**

Recognised laboratory name: .....

Physical address (for service): .....

Postal address (for communication): .....

Phone No: .....

Fax No: .....

Email: .....

**5. Functions management table:**

<b>List of functions</b>		
<ol style="list-style-type: none"> <li>1. Signatory for antibody/antigen detection systems, covering multiple agents</li> <li>2. Signatory for molecular biology diagnostic systems, covering multiple agents</li> <li>3. Signatory for propagation-based assays, covering multiple agents</li> <li>4. Signatory for pathology diagnostic systems, covering multiple agents</li> <li>5. Signatory for visualisation diagnostic systems, covering multiple agents.</li> </ol>		
<b>Names of person to be recognised</b>	<b>Specified functions (list No's as above)</b>	<b>Evidence of competency and date(s) of assessment by the recognised laboratory (refer to section 3.10 of the ELP).</b>
e.g. Mary Smith	e.g. 1	e.g. provide documentation to show that the requirements of 3.10 of the ELP have been met.

If the organisation's name and contact details provided in section 2 are the same as the recognised laboratory, then only provide the recognised laboratory name. If the name and contact details of the recognised laboratory differ from that provided in section 2, then provide the name and contact details of the recognised laboratory.

**6. Applicant declaration:** To be completed by the applicant.

I declare that:

- a. the information supplied in this application is accurate
- b. I am of good character and reputation
- c. in the year between the date of submission of my previous application and the date of submission of this application, I have not been charged with a crime and have no convictions pending
- d. I have read and understood the MAFBNZ conflict of interest policy
- e. I confirm (please tick) that:
  - I do not have any conflict of interest that would prevent me conducting the function of a signatory for the ELP, and
  - I will avoid conflicts of interest with my professional duties under the ELP wherever possible, and where this is not possible I will declare them fully and promptly so that

- they can be effectively managed to the satisfaction of MAFBNZ (please attach signed declaration form provided in ELP Appendix or MAFBNZ website
- f. there is no other information that I am aware of that affects my ability to carry out the function(s) and activities as a recognised person.

Name:

Date:

Designation(s):

Signature:

**7. Recognised laboratory declaration:**

I declare that this recognised laboratory has completed a thorough assessment of the competency of this applicant to perform the functions for which recognition is requested. I am also satisfied that the applicant is of good character and reputation, and should be recognised to perform the functions listed above.

Name:

Date:

Designation(s):

Signature:

This declaration must be completed by a staff member of the recognised laboratory with delegated authority to make declarations on behalf of the laboratory for any person for whom recognition is being sought.
--

## CONSENT TO DISCLOSURE OF INFORMATION

Licensing & Vetting Service Centre

Office of the Commissioner

PO Box 3017

WELLINGTON

I.....

(Surname)

(Fore Names)

.....

(Maiden or any other names used)

Sex.....(M/F)    Date and place of birth.....

Nationality..... Residential Address.....

Suburb..... City.....

NZ Driver Licence number .....

hereby consent to the disclosure by the New Zealand Police of any information they may have pursuant to this application, to MAFBNZ. I understand that any record of criminal convictions I might have will automatically be concealed if I meet the eligibility criteria stipulated in Section 7 of the Criminal Records (Clean Slate) Act 2004.

Signed.....

Date.....

## COMMENTS OF THE NEW ZEALAND POLICE

**NOTE: This page must be printed on letterhead paper**

### **Collection of Personal Information on Individuals**

In regard to any information being collected on this application for recognition as an laboratory or person, pursuant to the Animal Products Act 1999 (that is personal information identifying or being capable of identifying an individual person), notification is provided, in accordance with principle 3 of the Privacy Act 1993, to individuals of the following matters:

1. This information is being collected for purposes relating to the application for recognition and general administration of recognised agencies under the Animal Products Act 1999.
2. The recipient of this information, which is also the laboratory that will collect and hold the information, is the Ministry of Agriculture and Forestry Biosecurity New Zealand (MAFBNZ), PO Box 2526, Wellington.
3. The collection of information is authorised under section 102 of the Animal Products Act 1999. The provision of this information is necessary in order to process this application. Failure to provide information is likely to result in the return of this application form to the applicant.
4. You are reminded that under Principles 6 and 7 of the Privacy Act 1993, you have the right of access to, and correction of, any personal information that has been provided.



MAF Biosecurity New Zealand  
Animal Imports and Exports Group  
PO Box 2526  
Wellington 6140  
Ph: 0800 008 333  
Fax: (04) 894 0733

## Conflict of Interest Declaration Form

Send the completed declaration and other appropriate documentation to the Group Manager, Animal Imports and Exports, MAFBNZ.

If there are any changes to the details provided in this declaration subsequent to approval, the applicant must immediately inform MAFBNZ in writing.

Please obtain the latest copy of the MAFBNZ conflict of interest policy, from the MAFBNZ website at:  
<http://www.biosecurity.govt.nz>

Name: .....

Telephone: .....

Address: .....

Email address: .....

Veterinary Council registration number (where applicable): .....

I declare that:

- a. I have read and understood the MAFBNZ conflict of interest policy
- b. I have identified the following conflicts of interest in my role/proposed role as a recognised person for a signatory function:

c. I propose to manage my conflict of interest in the following manner:

d. I undertake to inform MAFBNZ if any details provided on this form change.

Signature: ..... Date: .....

---

MAFBNZ use only

The conflict of interest has been managed to the satisfaction of MAFBNZ

Group Manager Animal Imports and Exports: ..... Name

..... Signature

..... Date

## Appendix II

<b>ELP Test List (List 1)</b>			
Recognised Laboratories and Persons Specifications for Conducting Testing of Live Animals and Germplasm for Export			
<b>Organism / disease tested</b>	<b>Test method</b>	<b>Type of test method</b>	<b>Function for which person may be recognised</b>
Aerobic bacteria	Bacterial culture	Propagation	Propagation
<i>Aeromonas salmonicida</i>	Bacterial culture	Propagation	Propagation
Akabane virus	VNT	Antibody detection	Antibody/antigen detection
Anaplasmosis	* CFT	Antibody detection	Antibody/antigen detection
Avian influenza virus	AGID test	Antibody detection	Antibody/antigen detection
Avian influenza virus	ELISA-Ab	Antibody detection	Antibody/antigen detection
Avian influenza virus	HI	Antibody detection	Antibody/antigen detection
Avian influenza virus	VI	Propagation	Propagation
Avian paramyxovirus serotype 1 (APMV-1) / NDV	PCR	Molecular biology	Molecular biology
Avian paramyxovirus serotype 2 (APMV-2) Yucaipa	HI	Antibody detection	Antibody/antigen detection
Avian paramyxovirus serotype 2 (APMV-2) Yucaipa	PCR	Molecular biology	Molecular biology
Avian paramyxovirus serotype 3 (APMV-3)	HI	Antibody detection	Antibody/antigen detection
Avian paramyxovirus serotype 3 (APMV-3)	PCR	Molecular biology	Molecular biology
Avian pneumovirus (referred to as turkey rhinotracheitis in turkeys)	ELISA-Ab	Antibody detection	Antibody/antigen detection
Avian virus	VI	Propagation	Propagation
<i>Babesia</i>	Blood smear	Visualisation	Visualisation
<i>Babesia caballi</i>	ELISA-Ab	Antibody detection	Antibody/antigen detection
<i>Babesia caballi</i>	* IFAT	Antibody detection	Antibody/antigen detection
<i>Babesia gibsoni</i>	* IFAT	Antibody detection	Antibody/antigen detection

Appendices

<i>Babesia gibsoni</i>	*	PCR	Molecular biology	Molecular biology
Blood parasites ( <i>Babesia spp.</i> )	*	Blood smear	Visualisation	Visualisation
Bluetongue virus		AGIDT	Antibody detection	Antibody/antigen detection
Bluetongue virus		ELISA-Ab	Antibody detection	Antibody/antigen detection
Bovine herpesvirus 1		PCR	Molecular biology	Molecular biology
Bovine viral diarrhoea virus (BVDV)		ELISA-Ab	Antibody detection	Antibody/antigen detection
Bovine viral diarrhoea virus (BVDV)		ELISA-Ag	Antigen detection	Antibody/antigen detection
Bovine viral diarrhoea virus (BVDV)		PCR	Molecular biology	Molecular biology
Bovine viral diarrhoea virus (BVDV)		VI	Propagation	Propagation
Bovine viral diarrhoea virus (BVDV)		VNT	Antibody detection	Antibody/antigen detection
Bovine viral diarrhoea virus (BVDV)		2 passages	Propagation	Propagation
<i>Brucella abortus</i>		SAT AM	Antibody detection	Antibody/antigen detection
<i>Brucella abortus</i>		SAT EU	Antibody detection	Antibody/antigen detection
<i>Brucella spp. (B. melitensis; B. suis)</i>		ELISA-Ab	Antibody detection	Antibody/antigen detection
<i>Brucella spp. (B. melitensis)</i>		CFT	Antibody detection	Antibody/antigen detection
<i>Brucella canis</i>		RSA	Antibody detection	Antibody/antigen detection
<i>Brucella ovis</i>		CFT	Antibody detection	Antibody/antigen detection
<i>Brucella ovis</i>		ELISA-Ab	Antibody detection	Antibody/antigen detection
<i>Campylobacter spp.</i>		Bacterial culture	Propagation	Propagation
<i>Campylobacter fetus</i> subsp. <i>venerealis</i>		Bacterial culture	Propagation	Propagation
Canine / feline heartworm		ELISA-Ag	Antigen detection	Antibody/antigen detection
Caprine arthritis-encephalitis (CAE) virus		ELISA-Ab	Antibody detection	Antibody/antigen detection
Cervine herpesvirus type-1		VNT	Antibody detection	Antibody/antigen detection
Cytopathic fish virus		VI	Propagation	Propagation

Appendices

EDS 76	HI	Antibody detection	Antibody/antigen detection
<i>Ehrlichia canis</i>	IFAT	Antibody detection	Antibody/antigen detection
Enzootic bovine leukosis (EBL)	AGID test	Antibody detection	Antibody/antigen detection
Enzootic bovine leukosis (EBL)	ELISA-Ab	Antibody detection	Antibody/antigen detection
Epizootic haemorrhagic disease (EHD)	AGID test	Antibody detection	Antibody/antigen detection
Equine herpesvirus	VNT	Antibody detection	Antibody/antigen detection
Equine herpesvirus-1	ELISA-Ab	Antibody detection	Antibody/antigen detection
Equine herpesvirus-4	ELISA-Ab	Antibody detection	Antibody/antigen detection
Equine infectious anaemia (EIA)	AGID test	Antibody detection	Antibody/antigen detection
Equine influenza virus	HI	Antibody detection	Antibody/antigen detection
Equine influenza virus	PCR	Molecular biology	Molecular biology
Equine viral arteritis (EVA) virus	VI	Propagation	Propagation
Equine viral arteritis (EVA) virus	VNT	Antibody detection	Antibody detection
Infectious bovine rhinotracheitis (IBR) virus	VI	Propagation	Propagation
Infectious bovine rhinotracheitis (IBR) virus	VNT	Antibody detection	Antibody/antigen detection
Infectious bovine rhinotracheitis (IBR) virus	ELISA-Ab	Antibody detection	Antibody/antigen detection
Infectious bursal disease (IBD) virus	ELISA-Ab	Antibody detection	Antibody/antigen detection
Infectious bursal disease (IBD) virus	PCR	Molecular biology	Molecular biology
Infectious bursal disease (IBD) virus	VNT	Antibody detection	Antibody/antigen detection
Influenza	PCR	Molecular biology	Molecular biology
Influenza A+B	LFD	Antigen detection	Antibody/antigen detection
Johne's disease (JD), paratuberculosis	AGID test	Antibody detection	Antibody/antigen detection
Johne's disease (JD), paratuberculosis	CFT	Antibody detection	Antibody/antigen detection
Johne's disease (JD), paratuberculosis	ELISA-Ab	Antibody detection	Antibody/antigen detection

Appendices

<i>Leishmania</i> spp.		IFAT	Antibody detection	Antibody/antigen detection
<i>Leptospira</i> Ballum (1)		MAT	Antibody detection	Antibody/antigen detection
<i>Leptospira</i> Bratislava (2)		MAT	Antibody detection	Antibody/antigen detection
<i>Leptospira</i> Canicola (3)		MAT	Antibody detection	Antibody/antigen detection
<i>Leptospira</i> Copenhagenii (4)		MAT	Antibody detection	Antibody/antigen detection
<i>Leptospira</i> Gripotyphosa (5)		MAT	Antibody detection	Antibody/antigen detection
<i>Leptospira</i> Hardjobovis (6)		MAT	Antibody detection	Antibody/antigen detection
<i>Leptospira</i> Icterohaemorrhagiae (7)		MAT	Antibody detection	Antibody/antigen detection
<i>Leptospira</i> Pomona (8)		MAT	Antibody detection	Antibody/antigen detection
<i>Leptospira</i> Tarassovi (9)		MAT	Antibody detection	Antibody/antigen detection
Lyssa virus	*	IFAT	Antibody detection	Antibody/antigen detection
Maedi visna (MV) virus		ELISA-Ab	Antibody detection	Antibody/antigen detection
Malignant catarrhal fever		PCR	Molecular biology	Molecular biology
Microfilariae		Knotts test	Visualisation	Visualisation
<i>Mycoplasma</i> spp.		Bacterial culture	Propagation	Propagation
<i>Mycoplasma agalactiae</i>		ELISA-Ab	Antibody detection	Antibody/antigen detection
<i>Mycoplasma capricolum</i> subsp. <i>capricolum</i>		CFT	Antibody detection	Antibody/antigen detection
<i>Mycoplasma gallicepticum</i>		RSA	Antibody detection	Antibody/antigen detection
<i>Mycoplasma mycoides mycoides</i> Large Colony		CFT	Antibody detection	Antibody/antigen detection
<i>Mycoplasma synoviae</i>		RSA	Antibody detection	Antibody/antigen detection
<i>Mycoplasma meleagridis</i>		RSA	Antibody detection	Antibody/antigen detection
<i>Myxobolus cerebralis</i>		Microscopy	Visualisation	Visualisation
Newcastle disease virus (NDV)		ELISA-Ab	Antibody detection	Antibody/antigen detection
Newcastle disease virus (NDV)		HI	Antibody detection	Antibody/antigen detection

Appendices

Newcastle disease virus (NDV)		VI	Propagation	Propagation
Palyam virus		AGID test	Antibody detection	Antibody/antigen detection
Parainfluenza virus type-3		VI	Propagation	Propagation
Parasite eggs		Faecal egg count	Visualisation	Visualisation
Pestivirus / hairy shaker disease virus / Border disease virus		VI	Propagation	Propagation
Hairy shaker disease virus / border disease virus		2 passages	Propagation	Propagation
<i>Ornithobacterium rhinotracheale</i>		Bacterial culture	Propagation	Propagation
Porcine parvovirus (PPV)		ELISA-Ab	Antibody detection	Antibody/antigen detection
Q fever		CFT	Antibody detection	Antibody/antigen detection
Q fever		ELISA-Ab	Antibody detection	Antibody/antigen detection
Q fever		PCR	Molecular biology	Molecular biology
Rabies virus	*	RFFIT	Antibody detection	Antibody/antigen detection
<i>Renibacterium salmoniarum</i>		PCR	Molecular biology	Molecular biology
<i>Salmonella</i> spp.		Bacterial culture	Propagation	Propagation
<i>Salmonella</i> spp.		ELISA	Antibody detection	Antibody/antigen detection
<i>Salmonella</i> Arizona		Bacterial culture	Propagation	Propagation
<i>Salmonella</i> Pullorum		SAT	Antibody detection	Antibody/antigen detection
<i>Salmonella</i> spp. inc <i>S. Typhimurium</i> and <i>S. Enteritidis</i>		Bacterial culture	Propagation	Propagation
<i>Streptococcus</i> Equi ss. Equi culture		Bacterial culture	Propagation	Propagation
<i>Taylorella equigenitalis</i>		Bacterial culture	Propagation	Propagation
Ticks		Identification	Visualisation	Visualisation
<i>Theileria equi</i>		ELISA-Ab	Antibody detection	Antibody/antigen detection
<i>Theileria equi</i>	*	IFAT	Antibody detection	Antibody/antigen detection
<i>Trichinella spiralis</i>		ELISA-Ab	Antibody detection	Antibody/antigen detection
<i>Trichinella spiralis</i>		Pepsin digestion	Visualisation	Visualisation

Appendices

<i>Trichomonas foetus</i>		Bacterial culture	Propagation	Propagation
<i>Yersinia ruckeri</i>		Bacterial culture	Propagation	Propagation
West Nile virus	*	ELISA-Ab	Antibody detection	Antibody/antigen detection
<i>Note: tests with * are not available in New Zealand</i>				
<b>Abbreviations:</b>				
Agar-gel immunodiffusion test - antibody detection		AGID test		
American		AM		
Complement fixation test - antibody detection		CFT		
Enzyme-linked immunosorbent assay - antibody detection		ELISA-Ab		
Enzyme-linked immunosorbent assay - antigen detection		ELISA-Ag		
European		EU		
Hemagglutination inhibition test		HI		
Immunofluorescence antibody test - antibody detection		IFAT		
Lateral flow device		LFD		
Microscopic agglutination test - antibody detection		MAT		
Polymerase chain reaction - RNA, DNA detection		PCR		
Rapid fluorescent focus inhibition test - antibody detection		RFFIT		
Rapid slide agglutination - antibody detection		RSA		
Serum agglutination test - antibody detection		SAT		
Virus isolation		VI		
Virus neutralisation test - antibody detection		VNT		

## Part 5 Documents incorporated

### 5.1 Documents incorporated

5.1.1 The following documents are incorporated by reference, under section 168 of the APA, into this notice:

- a. MAFBNZ conflict of interest policy “Policy for managing conflicts of interest when providing official assurances for export of live animals and germplasm”:  
<http://www.biosecurity.govt.nz/files/regs/exports/>
- b. OIE Code the Terrestrial Animal Health Code:  
[http://www.oie.int/eng/normes/mcode/A\\_summry.htm](http://www.oie.int/eng/normes/mcode/A_summry.htm)
- c. OIE Code the Aquatic Animal Health Code:  
[http://www.oie.int/eng/normes/en\\_amanual.htm](http://www.oie.int/eng/normes/en_amanual.htm)
- d. OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals:  
[http://www.oie.int/eng/normes/mmanual/a\\_summry.htm](http://www.oie.int/eng/normes/mmanual/a_summry.htm)
- e. OIE Manual of Diagnostic Tests for Aquatic Animals:  
[http://www.oie.int/eng/normes/en\\_amanual.htm](http://www.oie.int/eng/normes/en_amanual.htm)
- f. AS/NZS ISO/IEC 17025 – General Requirements for the Competence of Testing and Calibration Laboratories  
[http://www.iso.org/iso/iso\\_catalogue/catalogue\\_tc/catalogue\\_detail.htm?csnumber=39883](http://www.iso.org/iso/iso_catalogue/catalogue_tc/catalogue_detail.htm?csnumber=39883)
- g. Safety in laboratories: Part 3: Microbiological aspects and containment facilities: AS/NZS 2243.3.  
<http://shop.standards.co.nz/scope/ASNZS2243.3-2002.scope.scope.pdf>
- h. Australia and New Zealand Standard Diagnostic Procedures (ANZSDP)  
<http://www.scahls.org.au/standardprocedures/standards.htm>
- i. International Laboratory Accreditation Cooperation (ILAC) Guidelines for the Requirements for the Competence of Providers of Proficiency Testing (ILAC-G13: current version  
<http://www.ilac.org/publicationslist.html>

### 5.2 Location of documents

- 5.2.1 Copies of the MAFBNZ conflict of interest policy can be obtained by:
- a. emailing [animalexports@maf.govt.nz](mailto:animalexports@maf.govt.nz) or
  - b. phoning 0800 00 83 33.