



Animal Products (Recognised Laboratories and Persons Specifications for Conducting Testing of Live Animals and Germplasm for Export) Notice 2010

Pursuant to sections 60(1) (a), 102(4) and 167(l) (m), (o), (p) and (q) of the Animal Products Act 1999, I, Tim Knox, Director (Border Standards) issue the following notice for the purposes of specifying:

- a. functions and activities, in relation to the export of live animals and germplasm, that will only be valid for official assurance purposes where they are performed by recognised laboratories and recognised persons
- b. requirements to be met by persons or bodies wishing to become recognised laboratories
- c. competencies or other requirements to be met by persons wishing to become recognised persons
- d. procedures for the recognition of laboratories and persons under section 102 and 103
- e. performance standards and other matters for the performance of functions and activities by recognised laboratories and persons
- f. records and other information to be kept and returns to be made by recognised laboratories and persons for the purposes of section 159 of the Act.

This notice revokes the notice previously issued on 14 December 2009

Signed at Wellington this 19th day of April 2010.

Signed: Tim Knox
Director (Border Standards)
MAF Biosecurity New Zealand
Ministry of Agriculture and Forestry
(Acting under delegated authority)

Certified in order for signature

Signed: Lin Da Teoh
Solicitor
Legal Services
16/04/2010

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Notice

Title

This notice is the Animal Products (Recognised Laboratories and Persons Specifications for Conducting Testing of Live Animals and Germplasm for Export) Notice 2010.

Commencement

This notice comes into force on 1 May 2010.

Part 1 Preliminary provisions

1.1 Application

- 1.1.1 This notice 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.

1.2 Definitions

- 1.2.1 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 notice, has the same meaning as in those Acts or regulations.
- 1.2.2 In this notice, unless otherwise stated or the context otherwise requires, the following definitions, abbreviations and interpretations are used:

the Act, or APA	the Animal Products Act 1999
antibody/antigen detection systems	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)
ANZSDP	the current edition of the Australia and New Zealand Standard Diagnostic Procedures
closed out	the corrective action for a non-compliance(s) identified in an audit or assessment has been verified as successfully completed
competent authority	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
competence	in relation to a recognised person, means a demonstrated ability to apply that person's knowledge and skills

conflict of interest	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
controlled copy	the correct and latest revised version of a document, which is retrieved and replaced when a change is made
ELP	Export laboratory programme
export requirements	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
export test	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
germplasm	semen, embryos, and ova of animals
ILPT	means inter-laboratory proficiency testing
ISO 17025	AS/NZS ISO/IEC 17025 – General Requirements for the Competence of Testing and Calibration Laboratories
MAF	Ministry of Agriculture and Forestry
MAFBNZ	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
molecular biology diagnostic systems	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
non-compliance	these are rated as follows: <ol style="list-style-type: none">critical non-compliancemajor non-complianceminor non-compliance. <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">negligencenon-disclosure of unfavourable test or examination resultssubstitution of animals or samplesfailure to keep essential recordsfalse 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

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 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
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 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
pathology diagnostic systems	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
propagation-based assays	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
recognised laboratory	in relation to any function or activity set out in this notice 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 notice applies
recognised person	in relation to any function or activity set out in this notice 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 notice applies
relevant function	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
SCAHLs	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
signatory function	one or more of the following specialist laboratory functions that a person may be recognised to perform for the purposes of this notice: <ul style="list-style-type: none">• assessing that the quality control(s) of an export test conducted by a recognised laboratory is or are acceptable• interpreting the results of an export test• providing the signatory for the test report.
technical manager	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
visualisation diagnostic systems	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 <i>Babesia</i> spp., faecal egg counts, parasite identification

Part 2 Requirements for recognised laboratories conducting export testing

2.1 Requirements for recognised laboratories conducting export test 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
 - b. demonstrate to the Director-General a successful assessment, as conducted by the accreditation body, for its compliance with this notice (see section 2.14.1). 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.
 - f. be a New Zealand resident according to the Income Tax Act 2007.
- 2.1.2 A recognised laboratory, as referred to in clause 2.1.1, must meet any other technical requirements as specified 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 A person or agency wishing to become a recognised laboratory must apply to the Director-General using Form 1 in Appendix I, and pay any fees and charges required under the Act.
- 2.2.2 A controlled copy of the recognised laboratory's systems and procedures must be provided to the Director-General as soon as practicable after recognition.

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.

- 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 Temporary closure of a recognised laboratory

- 2.4.1 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.
- 2.4.2 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.
- 2.4.3 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.

2.5 System and facility requirements for recognised laboratories

- 2.5.1 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).
- 2.5.2 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.
- 2.5.3 Recognised laboratories must ensure that:
- at the time any particular export testing is being conducted, they are recognised for the export test being carried out
 - functions for which the laboratory is recognised are carried out only by persons who are themselves recognised for those functions
 - the competency of any recognised persons performing specialist functions in relation to export testing is assessed and maintained.
- 2.5.4 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.
- 2.5.5 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.
- 2.5.6 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 Animal Products (Recognised Laboratories and Persons Specifications for Conducting Testing of Live Animals and Germplasm for Export) Notice 2009, 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.

2.6 Requirements for a laboratory where a person applies for recognition

2.6.1 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 notice, 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.

2.6.2 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.

2.7 Movement of recognised persons and functions between recognised laboratories

2.7.1 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.

2.7.2 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.

2.8 Communication of status as a recognised laboratory

2.8.1 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*]”.

2.8.2 A recognised laboratory must not, except as provided in clause 2.8.1, make reference to, or use a logo associated with, NZFSA, MAF, or any other department of state.

2.9 Information

- 2.9.1 For the purpose of determining the recognised laboratory’s compliance with this notice, 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.

2.10 Management of consignments for export

- 2.10.1 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.

2.11 Reporting

- 2.11.1 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"> a. significant changes to personnel, facilities and equipment b. results of internal audits c. results of any inter-laboratory quality assurance testing undertaken. 		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 ³	
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 ¹	

Reports	Event	Annual
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 ³ X ¹ where critical	
Technical information of: a. name of species and the commodity (live animals or donors of germplasm, or the germplasm itself, or the group of origin) that is tested b. number and type of tests performed c. the results of those tests (number suspicious, number positive, number negative, equivocal results due to unclear cut offs for positives and negatives).		X summary
Disputes and appeals, identifying: a. background to the issue b. outcome c. legal action and settlements where applicable.		X summary
Potential issues likely to compromise the integrity of export certification.	X ¹	
Pressure from a submitter or any other person to alter test results, or to re-test, without good reason.	X ¹	
Changes to the recognised laboratory's ownership, directorship, management or recognised persons.	X ²	

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

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

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

2.11.2 Any event report must contain the following information:

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

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

2.11.4 A recognised laboratory must submit to the Director-General any report on any such matter relating to the functions and tests for which it is recognised as the Director-General may request.

2.12 Requirements for disclosure of information

2.12.1 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.

2.12.2 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 by the Director-General in writing, to make available a copy of any performance report.

2.13 Records

2.13.1 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 or assessment reports
- j. non-compliances found during internal/external audits or 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.

2.13.2 The records referred to in clause 2.13.1 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.

2.13.3 Copies of all records referred to in clause 2.13.1 must be provided to the Director-General upon request by the Director-General.

2.14 Audit and assessment requirements

2.14.1 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's 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's 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.

2.14.2 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 notice.

2.14.3 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, assessment or audit:

- a. by any agency or person appointed for that purpose by the Director-General
- b. 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.

2.15 ELP Test List (list 1)

2.15.1 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:

- a. the current OIE Manual of Diagnostic Tests and Vaccines for Terrestrial Animals
- b. 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
- c. export requirements for an importing country where an agreement has been reached between MAFBNZ and that country's competent authority
- d. a recognised laboratory's standard operating procedure for the test where the methodology is proven to be at least equivalent to the OIE prescribed test, using the OIE principles for test validation
- e. the recognised laboratory's own standard operating procedure.

2.15.2 Where commercial serological kits are used the following criteria apply:

- a. the current OIE Manual and ANZSDP acknowledge that commercial kits are available
- b. the commercial kits have been validated using the principles for test validation in the OIE Manual and/or ANZSDP
- c. the diagnostic specificity and sensitivity are the same for the kits as for tests prescribed by the OIE Manual and/or ANZSDP.

2.16 Recognised laboratory(s) for undertaking tests (List 2)

2.16.1 A recognised laboratory that wants to undertake a new test must, where required by the Director-General:

- a. obtain accreditation for that test from the accreditation body
- b. apply to Director-General for approval to extend the scope of recognition using Form 1 in Appendix 1.

2.16.2 The recognised laboratory must conduct tests according to the requirements of sections 2.15.1 and 2.15.2.

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- 2.16.3 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.
- 2.16.4 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.
- 2.16.5 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).
- 2.16.6 Every recognised laboratory must ensure that all reports for tests conducted under this notice:
- conform to good laboratory practice and the requirements of this notice
 - are not used in a misleading manner
 - relate only to tests where the requirements of this notice have been met
 - do not make any misleading statement in relation to its recognition
 - 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.
- 2.16.7 The recognised laboratory may subcontract any test for which it is recognised, provided that the subcontracted laboratory is itself recognised to conduct that test.
- 2.16.8 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.

Part 3 Requirements for recognised persons

3.1 Requirements for recognised persons conducting export testing

- 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.
- 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:
- where it is personal information, be managed in accordance with the Privacy Act 1993
 - except where non-disclosure is permitted by law, be made available to the Director-General if requested by the Director-General
 - not be released to a third party without prior approval from the Director-General.
- 3.1.4 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.

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 Functions for which persons may be recognised

- 3.4.1 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:
- signatory for antibody/antigen detection systems, covering multiple agents
 - signatory for molecular biology diagnostic systems, covering multiple agents
 - signatory for propagation-based assays, covering multiple agents
 - signatory for pathology diagnostic systems, covering multiple agents
 - 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.

- 3.4.2 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.

- 3.4.3 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.

3.5 Competencies for recognised persons

- 3.5.1 Any person applying to be recognised for any of the functions in 3.4.1 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 notice
 - 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
 - vii. the recognised laboratory's own Standard Operating Procedures.
- b. provide evidence of the relevant competencies (see section 3.5.2).

- 3.5.2 In addition to meeting the requirements of clause 3.5.1, 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.

3.6 Reporting

- 3.6.1 Where in the course of performing his/her function(s), a recognised person detects any non-compliance with any requirement of the Act, this notice, 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.

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

Appendix II: ELP Test List (List 1)



MAF Biosecurity New Zealand
Animal Imports and Exports Group
PO Box 2526
Wellington 6011
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 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:

List of functions	
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.	
Names of persons to be recognised	Specified functions (list No's as above)
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.



20 April 2010

Animal Products (Recognised Laboratories and
Persons Specifications for Conducting Testing of
Live Animals and Germplasm for Export) Notice
2010

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Appendix 1: Application and
Declaration forms

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
	<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</i> spp. (<i>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</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
	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 Canicola</i> (3)		MAT	Antibody detection	Antibody/antigen detection
		<i>Leptospira Copenhagenii</i> (4)		MAT	Antibody detection	Antibody/antigen detection
		<i>Leptospira Gripotyphosa</i> (5)		MAT	Antibody detection	Antibody/antigen detection
		<i>Leptospira Hardjobovis</i> (6)		MAT	Antibody detection	Antibody/antigen detection
		<i>Leptospira Icterohaemorrhagiae</i> (7)		MAT	Antibody detection	Antibody/antigen detection
		<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
	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 detection
		<i>Note: tests with * are not available in New Zealand</i>				

Abbreviations:

Agar-gel immunodiffusion test - antibody detection

American

Complement fixation test - antibody detection

Enzyme-linked immunosorbent assay - antibody detection

Enzyme-linked immunosorbent assay - antigen detection

European

Hemagglutination inhibition test

AGID test

AM

CFT

ELISA-Ab

ELISA-Ag

EU

HI



**MAF Biosecurity New Zealand
Animal Imports and Exports Group
PO Box 2526
Wellington 6011
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:

List of functions		
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 assays, covering multiple agents 4. Signatory for pathology diagnostic systems, covering multiple agents 5. Signatory for visualisation diagnostic systems, covering multiple agents.		
Names of person to be recognised	Specified functions (list No's as above)	Evidence of competency and date(s) of assessment by the recognised laboratory (refer to section 3.5 of this notice or 3.10 of the ELP).
e.g. Mary Smith	e.g. 1	e.g. provide documentation to show that the requirements of 3.5 of this notice, or 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
- 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 6011
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

ELP Test List (List 1)			
Recognised Laboratories and Persons Specifications for Conducting Testing of Live Animals and Germplasm for Export			
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
<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
<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
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
<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
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
<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>				
Abbreviations:				
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 by reference

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
- c. OIE Code the Aquatic Animal Health Code:
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
- e. OIE Manual of Diagnostic Tests for Aquatic Animals:
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
- 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 or
 - b. phoning 0800 00 83 33.

Part 6 **Revocation**

- 6.1.1 The Animal Products (Recognised Laboratories and Persons Specifications for Conducting Testing of Live Animals and Germplasm for Export) Notice 2009 issued on the 14th day of December 2009 is revoked.
- 6.1.2 Despite the revocation of the Animal Products (Recognised Laboratories and Persons Specifications for Conducting Testing of Live Animals and Germplasm for Export) Notice 2009, any eligibility document or official assurance provided under and in accordance with that notice continues to be valid under this notice.
- 6.1.3 The revocation of the Animal Products (Recognised Laboratories and Persons Specifications for Conducting Testing of Live Animals and Germplasm for Export) Notice 2009 does not affect —
- a. the validity, invalidity, effect, or consequences of anything done or suffered;
 - b. an existing right, interest, title, immunity, or duty;
 - c. an existing status or capacity;
 - d. the previous operation of the notice revoked or anything done or suffered under it.
- 6.1.4 The revocation of the Animal Products (Recognised Laboratories and Persons Specifications for Conducting Testing of Live Animals and Germplasm for Export) Notice 2009 does not revive —
- a. a notice that has been revoked;
 - b. any other thing that is not in force or existing at the time the revocation takes effect.
- 6.1.5 The revocation of the Animal Products (Recognised Laboratories and Persons Specifications for Conducting Testing of Live Animals and Germplasm for Export) Notice 2009 does not affect a liability to a penalty for an offence or for a breach of the notice revoked, committed before the revocation.
- 6.1.6 The revoked notice continues to have effect as if it had not been revoked for the purpose of —
- a. investigating the offence or breach;
 - b. commencing or completing proceedings for the offence or breach;
 - c. imposing a penalty for the offence or breach.