Ministry for Primary Industries
Manatū Ahu Matua

Guidance Document

Animal Products Recognised Laboratories

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Te Kāwanatanga o Aotearoa
New Zealand Government

Title

Guidance Document: Animal Products Recognised Laboratories

About this document

This guidance document has been prepared to assist laboratories to meet the requirements for laboratories recognised under the Animal Products Act 1999.

The Animal Products Act 1999, the Animal Products Regulations 2021 and the Animal Products Notice: Recognised Laboratories comprise the legal requirements and should be read and referred to in the first instance.

The guidance provided in this document assists laboratories in the process of application for recognition, assessment, maintenance of recognition, and notification of changes to MPI.

Related Requirements

This document should be read in conjunction with the:

a) Animal Products Act 1999 (called the Act in this guidance);
b) Animal Products Regulations 2021 (called the Regulations in this guidance); and
c) Animal Products Notice: Recognised Laboratories (called the Laboratory Notice in this guidance).

Document history

Version Date	Section Changed	Change(s) Description
31 August 2015		New document
09 February 2021	All	General update
27 June 2022	All	Update resulting from: (a) review of the operation of recognised laboratories; and (b) the new Animal Products Regulations 2021 and Animal Products Notice: Recognised Laboratories.
19 October 2022	6.1.6 6.1.8 6.1.9 10 (new)	Minor wording change for clarity in 6.1.6(1), 6.1.8(1) and 6.1.9 (1) & (2) Addition of new section 10 Additional guidance for reporting screen tests

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Disclaimer

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Background

This guidance document has been prepared by the Ministry for Primary Industries.

It is intended to assist recognised laboratories to comply with the relevant requirements of:

- Animal Products Act 1999;
- Animal Products Regulations 2021; and
- Animal Products Notice: Recognised Laboratories.

The Act, Regulations and Laboratory Notice contain the legal requirements that a laboratory must meet in order to obtain and maintain recognition.

The requirements in the Act, Regulations and Laboratory Notice only apply to the functions and activities (i.e. specific analytical testing) that the laboratory is recognised for. Any testing the laboratory does that it is not recognised for is not covered by these requirements.

This guidance document only applies to laboratories recognised under section 101 of the Act and does not apply to laboratories recognised under section 102 of the Act.

1 Definitions

(1) Refer to the Animal Products Act 1999, Animal Products Regulations 2021 and the Animal Products Notice: Recognised Laboratories for definitions.

(2) In this guidance document, these additional definitions are provided for clarification:

closed out means the corrective action for a non-compliance(s) or defect category identified in an assessment, audit or designated ILCP has been verified as successfully completed

CLT means the Consolidated List of Tests for Animal Products published by MPI

conflict of interest means where the duties or responsibilities of a person could be improperly affected by some other interest or duty the person may have

germplasm means semen, embryos and ova of animals

GREX means General Requirements for Export. GREXs outline the general requirements that must be met in order for a product to be eligible for export. GREXs are notices issued by MPI

IANZ means International Accreditation New Zealand, an accreditation body who accredits laboratories to ISO/IEC 17025

official assurance means a general statement issued to a foreign government (or its agent) attesting that certain conditions apply. Only authorised persons can issue an official assurance

OMAR means Overseas Market Access Requirements. OMARs outline the requirements that exporters need to meet to access markets in different countries. OMARs are legal documents issued by MPI

overseas competent authority means a governmental organisation that is responsible for food safety in its country or territory

person, when used in the Regulations and Laboratory Notice, refers to both corporate persons (e.g. a recognised laboratory) and natural persons (i.e. a human)

scope of accreditation means the list of tests the laboratory is accredited for by the accreditation body (i.e. the schedule to the certificate of accreditation issued by IANZ for the MPI Recognised Laboratories Programme)

scope of recognition means the functions and activities (i.e.: specific analytical testing) the laboratory is recognised for. The functions and activities are listed in the notice of recognition issued by MPI, as well as the Public Register

under the Act means the Animal Products Act and all relevant Regulations and Notices made under it

2 Roles and responsibilities of a recognised laboratory

(1) Recognised agencies perform specialist food safety functions and activities on behalf of the New Zealand Government. A recognised laboratory is a specific type of recognised agency.

(2) A recognised laboratory is a laboratory that MPI has recognised under the Act to carry out laboratory functions and activities (i.e. specific analytical testing) that relates to animal material or animal product.

(3) **A recognised laboratory performs specific testing on behalf of the New Zealand Government.**

(4) This testing demonstrates that animal material or animal product is fit for its intended purpose.

(5) Recognition of laboratories allows the New Zealand Government to have oversight of and confidence in the results of this testing, and to demonstrate this to overseas competent authorities.

(6) In the Act (section 112G), the main duties of a recognised laboratory (as a recognised agency) are to:

a) only perform testing (as a recognised laboratory) for those tests that are within their scope of recognition;
b) ensure they are adequately resourced with qualified staff and facilities;
c) have suitable systems to carry out tests;
d) report matters to MPI as required; and
e) ensure any identified conflicts of interest are managed.

(7) These duties are expanded on in Part 9 Subpart 1 of the Regulations and the Laboratory Notice.

(8) Recognised laboratories must ensure that the person responsible for its day-to-day management and other appropriate people employed by the laboratory:

a) understand the laboratories role as a recognised agency; and
b) understand why laboratories are recognised to perform certain tests; and
c) are familiar with the general responsibilities of being a recognised agency and the specific responsibilities of being a recognised laboratory.

3 Requirements that apply to recognised laboratories

(1) The requirements that recognised laboratories must follow are in the Act, the Regulations and the Laboratory Notice.

(2) For a full understanding of the requirements, all three documents should be read together.

3.1 Animal Products Act 1999

(1) The Act establishes a procedure for the recognition of agencies and sets out the duties of recognised agencies. It also set out when recognition can be suspended or withdrawn.

(2) The most relevant sections for recognised laboratories are listed below, however, this does not mean that other sections of the Act are not applicable:

- 81 Director-General may give directions
- 101 Recognition of agencies
- 107 Application for recognition
- 108 Director-General may require further information
- 109 Proposal to refuse application to recognise agency, person, or class of persons
- 111 Director-General may impose or vary conditions of recognition
- 112 Grant of recognition
- 112A Scope, effect, and transfer of recognition
- 112B Duration of recognition

- 112C Renewal of recognition before expiry
- 112D Application for renewal of recognition
- 112E Substituted notice of recognition
- 112F Ongoing recognition fees, charges, or levies
- 112G Duties of recognised agencies
- 112I Recognised agency or person may act in other capacities
- 112IA Recognised agency and recognised person accountable to Director-General
- 112J Suspension of recognition of recognised agency, recognised person, or recognised class
- 112K Director-General may extend suspension of recognition
- 112L Method of suspension of recognition
- 112M Suspension does not limit other actions
- 112N Withdrawal of recognition of recognised agency or recognised person
- 112P Method of withdrawal of recognition
- 112Q Surrender of recognition
- 112R Effective date of surrender of recognition
- 112S Public register of recognised agencies, recognised persons, and recognised classes to be kept
- 112T Contents of public register

3.2 Animal Products Regulations 2021

(1) The Regulations set out requirements for the recognition, and maintenance of recognition, of agencies that have been recognised under section 101 of the Act, as well as some specific requirements that only apply to recognised laboratories.

(2) The requirements are all in *Part 9 Subpart 1 - Recognised Agencies,* regulations 188 to 206. No other regulations apply.

3.3 Animal Products Notice: Recognised Laboratories

(1) The Laboratory Notice supplements the Regulations and provides additional technical details.

3.4 Consolidated List of Tests

(1) MPI requires certain tests to be performed by a recognised laboratory. Where a test is required to be done by a recognised laboratory, this is written in a legal document issued under the Act (for example, in Regulations, Notices, OMARs, and GREXs).

(2) A document summarising the tests that are required to be performed by a recognised laboratory has been created, called the Consolidated List of Tests (CLT). Where the CLT differs from the legal document, follow the requirements in the legal document.

(3) The CLT assigns a reference number for each test for ease of reference.

4 Contacting MPI

(1) A common email inbox is available as a contact point for any questions or information related to recognised laboratories: RLP@mpi.govt.nz. This inbox is checked every working day.

(2) Where recognised laboratories are required to notify or report to the Director-General, emailing RLP@mpi.govt.nz or approvals@mpi.govt.nz (where appropriate) meets this requirement.

5 Becoming a recognised laboratory

5.1 When is laboratory recognition required?

(1) Laboratories are required to be recognised by MPI before carrying out any testing that must be performed by a recognised laboratory.

5.2 Steps to become recognised

See also Flowchart 1: Steps to Become a Recognised Laboratory.

(1) Identify which tests the laboratory wants to be recognised for. The CLT may assist in determining these tests.

(2) Determine if any of the tests identified in 5.2 (1) require a designated ILCP to be undertaken. Check Schedule 1: Designated ILCP tests in the Laboratory Notice. If the numerical reference for the specific test is listed, then the laboratory is required to participate in the designated ILCP listed. See 6.1.2 Designated ILCP for more information.

(3) Appoint a person to be responsible for the day-to-day management of the recognised laboratory. This person will be the main contact person for MPI with regards to the recognised laboratory. This person:

a) should be responsible for the laboratory's day-to-day compliance with the Act, Regulations and Laboratory Notice;
b) should have appropriate technical, quality and compliance knowledge;
c) must have an understanding of the role of the recognised laboratory and the relevant regulatory requirements;
d) does not have to be a manager;
e) may also be an appointed key technical person (KTP); and
f) may also be the IANZ authorised representative.

(4) Contact IANZ to apply for accreditation under the MPI Recognised Laboratory Programme for the tests identified in 5.2(1).

Note: Receiving IANZ accreditation under the MPI Recognised Laboratory Programme is not equivalent to recognition by MPI.

(5) Once IANZ has issued accreditation, apply for recognition from MPI.

a) Complete the Recognised Laboratory Application Form AP18:

i) clearly indicate which tests the laboratory is requesting recognition for;
ii) include the most recent IANZ RLP assessment report and close out report;
iii) include the most recent IANZ RLP accreditation scope;
iv) ensure the email address on Section 4 of the AP18 is the email address of the person responsible for the day-to-day management. This email address is used by MPI to communicate with the laboratory, so it is important to make sure it is kept up to date;
v) make payment of any fees and charges required. Fees and charges are set by regulation and are subject to change;

b) send the completed AP18 form and attachments to MPI using the email address given on the form, approvals@mpi.govt.nz.

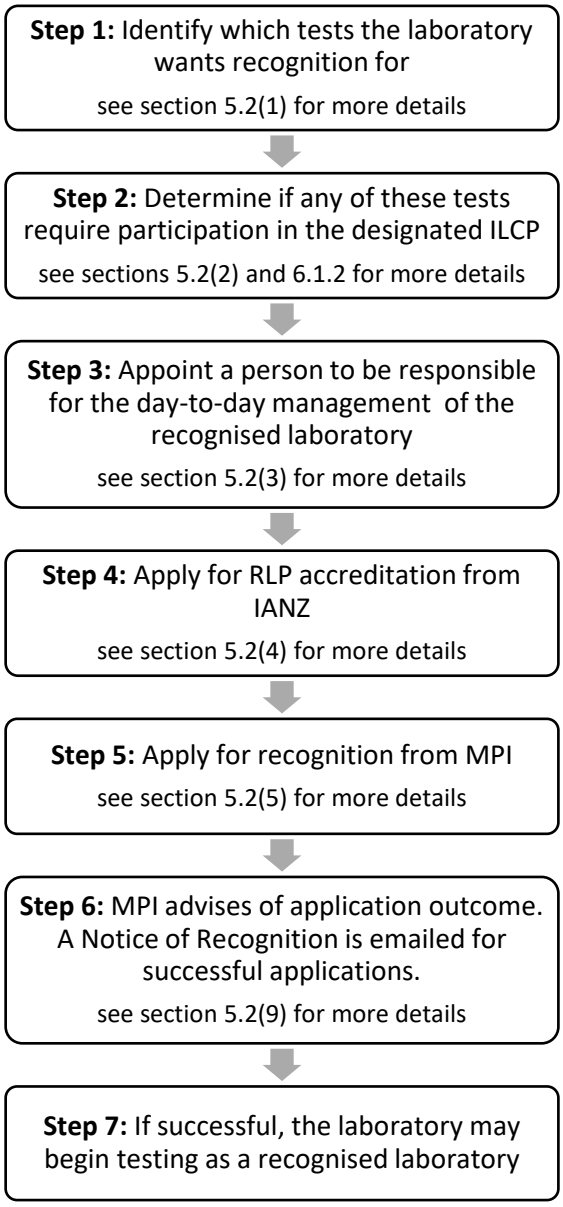
(6) MPI may request additional information from the laboratory, such as ILCP results, staff training records, evidence of suitable facilities and/or equipment, and evidence of business purpose.

(7) The turn-around time for new applications is 20 working days once the application has been determined to be complete.

(8) Recognition may include specific conditions, for example regular reporting requirements. Recognition is granted for 3 years, except under specific circumstances.

(9) MPI will notify the laboratory of the outcome of its application (successful or unsuccessful) via the email address given on the AP18 form. If successful, MPI will also email the Notice of Recognition. The Notice of Recognition includes a list of the functions and activities (i.e. specific analytical testing) that the laboratory is recognised for. The laboratory will be listed on the MPI Public Register, a publicly available list of recognised laboratories which includes the tests each laboratory is recognised for.

Flowchart 1: Steps to Become a Recognised Laboratory



5.3 Recognition in particular circumstances

(1) MPI may grant recognition for a specific test even if not all the requirements of the Regulations are met (e.g. the laboratory does not have the specific test on its scope of accreditation).

(2) MPI needs to have confidence in the integrity of the laboratory's processes and be satisfied that the laboratory is competent and its test results reliable.

(3) Recognition under particular circumstances may only be granted when no other laboratory is recognised for the specific test and at least 1 of the following circumstances exist:

a) there is an urgent need for the particular test to be carried out;
b) there is limited commercial value in providing the test; or
c) the laboratory holds accreditation that includes another test of a similar discipline.

(4) When granting recognition under particular circumstances, MPI may grant the recognition for a shorter time period and may require the laboratory to work towards IANZ accreditation.

6 Maintaining recognition

6.1 General requirements

6.1.1 Access to Documents

(1) Laboratory personnel are expected to have access to the Act, Regulations and Laboratory Notice and other applicable legislation, such as specifications, GREXs, and particularly OMARs.

(2) Laboratories are expected to keep current with changes or updates to relevant documents.

(3) MPI has a subscription facility for updates to information covering various categories.

(4) OMAR notifications provide updates to product or country-specific requirements for animal products. The notifications should be read in conjunction with any OMAR for the related destination markets.

(5) To request or amend access to OMARs, go to this webpage.

6.1.2 Designated ILCP

(1) Participation in the designated ILCP provides MPI with further assurance of a laboratory's capabilities to conduct selected tests to ensure accuracy and integrity of laboratory reports. The designated ILCP provider sends a monthly performance summary to MPI.

(2) For information on participating in the designated ILCP, contact the current designated ILCP provider Global Proficiency Ltd on enquiries@global-proficiency.com.

(3) The designated ILCP provider categorises performance that is below expectations into minor, major or critical defect categories. Laboratories are required to perform certain actions, such as retests, investigation and corrective actions in order to demonstrate its testing proficiency and close out the defect category.

(4) A minor defect category is assigned when a second 'warning' rating is given in the following round for the same designated ILCP type of test, or where individual results in any round are assigned an 'action' rating.

(5) A major defect category is assigned when a 'warning' or 'action' rating is reported on a retest sample.

(6) A critical defect category is assigned when:

a) a further 'warning' or 'action' rating is reported on a retest sample carried out for a major defect category;
b) non-participation by a laboratory in the next round following a major defect category reported on that laboratory;
c) failure by the laboratory to follow-up and report back to the designated ILCP provider on a major defect category; or
d) failure by the laboratory to participate in the required number of designated ILCP rounds for the specified tests for which the laboratory is recognised.

6.1.3 KTPs

(1) A recognised laboratory is required to have a person in its laboratory who is responsible for each test within the scope of its recognition. This is the Key Technical Person (KTP) for each test.

(2) Only inform MPI when there is a loss of KTP coverage for any or all tests within its scope of recognition. Addition and removal of KTPs is not required to be notified to MPI, as long as coverage is maintained. Email RLP@mpi.govt.nz.

6.1.4 Overseas Laboratories

(1) Overseas laboratories cannot become a recognised laboratory.

(2) MPI may approve a particular recognised laboratory to contract out a particular test within its scope of recognition to a specific laboratory overseas. MPI will need to be satisfied that the overseas laboratory is sufficiently qualified to carry out the test, and that the particular recognised laboratory will have sufficient oversight of the overseas laboratory, including accreditation, testing methods used and reporting of non-conformances. Email RLP@mpi.govt.nz to request approval to contract to an overseas laboratory.

6.1.5 Assessment reports

(1) Recognised laboratories must supply assessment reports to MPI upon request. Accreditation reports are not required to be sent to MPI when received.

6.1.6 Temporary Closure

(1) Temporary closure occurs when the testing services of the laboratory are not able to be delivered for a period of time, usually for a maximum of 3 months.

(2) For planned temporary closures, the laboratory should notify MPI (by emailing RLP@mpi.govt.nz) at least 5 working days prior.

(3) A laboratory should not issue test reports during the period of closure, unless the testing was completed before the temporary closure began.

6.1.7 Non-compliance

(1) A laboratory needs to report any non-compliance (NC) to MPI when an incident that **affects or is likely to affect the integrity of test results occurs.**

(2) Previously, this was called a critical non-compliance. Only the name has been changed, the concept is unchanged.

(3) An NC may include, but is not limited to:

a) testing not performed as per procedure;
b) testing did not occur in the specified time frame;
c) broken, incorrectly working or out of calibration equipment was used;
d) the wrong equipment was used; or
e) reissue of a test report due to incorrect results being originally supplied (this includes where the incorrect result was due to a typo).

(4) Contact RLP@mpi.govt.nz for clarification if it is unclear if an issue is an NC.

(5) **A laboratory is to notify an NC to MPI within 1 working day of it being identified.** You do not have to have full information on the issue before notifying MPI.

(6) A laboratory should notify an NC to MPI via the Non-compliance Form. **Initial notification can be via phone or email to RLP@mpi.govt.nz and may use a partially completed NC form.**

(7) The laboratory should inform MPI of the circumstances of an NC and the actions taken to either restore capability or withdraw from testing under the Laboratory Notice. **Initial corrective actions must be notified to MPI within 5 working days after the notification of an NC.**

(8) MPI expects that all NCs will be investigated by the laboratory and include root cause analysis to ensure that the corrective actions taken are appropriate to address the NC.

(9) Information supplied by the laboratory is reviewed and evaluated by MPI, involving relevant subject matter experts and other parties according to the nature of the NC. This provides additional assurance to MPI that test results are robust. When MPI is satisfied that the corrective actions have been successful, the NC will be closed out, and the laboratory notified.

(10) A critical non-compliance, as defined in the Regulations, does not apply to recognised laboratories.

6.1.8 Tests and Test methods

(1) Where a sample submitter informs the laboratory that a test is required by MPI to be done by a recognised laboratory, the laboratory should ensure that the test:

a) is listed in the laboratory's Notice of Recognition; and
b) that the laboratory's method complies with any regulatory requirements.

(2) Where a recognised laboratory wishes to undertake a new test, the laboratory needs to get the new test added to the laboratory's accreditation scope, and then apply to MPI for recognition to undertake the test. The laboratory may also apply to MPI for recognition in particular circumstances. See Flowchart 2: Adding a Test to a Laboratory's Recognition, 5.3 Recognition in Particular Circumstances and 6.2 Changes to Recognition for more information.

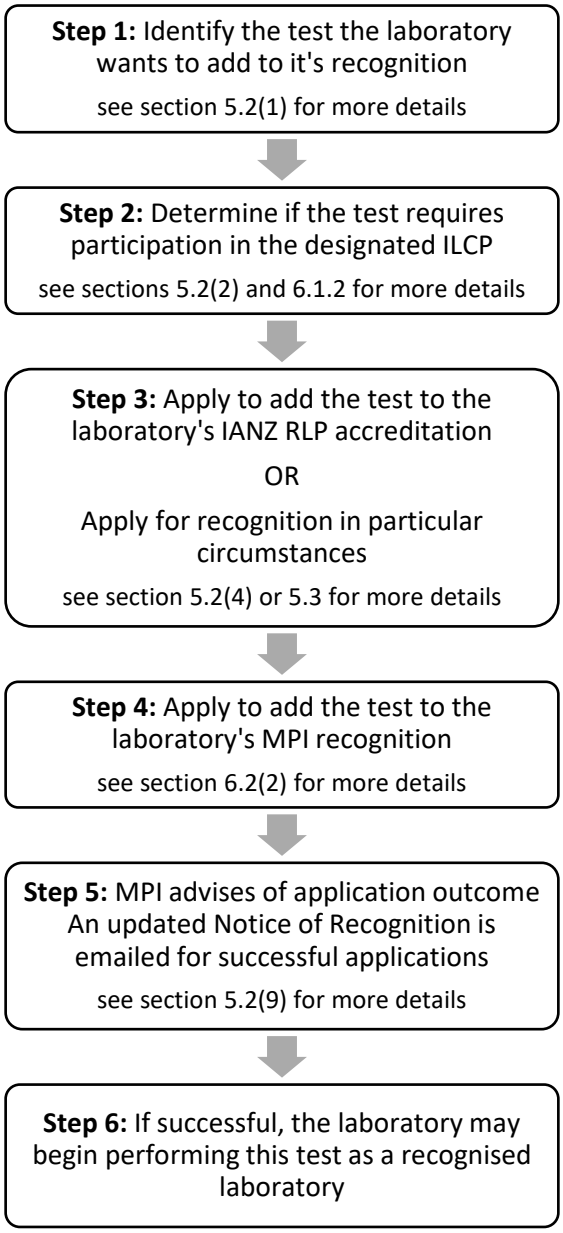
(3) **A recognised laboratory must not report a test until it is recognised for that test.** Recognition for testing is given by listing the test in the laboratory's Notice of Recognition and the MPI Public Register. Listing of a test on the laboratory's accreditation scope is not equivalent to recognition by MPI.

(4) The analytical test method used needs to be:

a) identical to any test method specified (test methods may be specified in OMARs and other notices);
b) suitable for the sample matrix; and
c) listed on the laboratory's accreditation scope, unless the test concerned was recognised by MPI in relation to Regulation 201 *Requirements for recognition as recognised laboratory in particular circumstances*.

(5) Tests that are required to be done by a recognised laboratory are summarised in the CLT. See 3.4 Consolidated List of Tests for more information.

Flowchart 2: Adding a Test to a Laboratory's Recognition



6.1.9 Reporting to MPI

See also sections 6.1.3 KTPs, 6.1.6 Temporary Closure, 6.1.7 Non-compliance and 6.2 Changes to Recognition

(1) Laboratories must report to MPI certain matters that may affect recognition, including:

a) matters that affect its accreditation status (such as suspension or withdrawal of accreditation) must be reported within 1 working day, and MPI notified of corrective actions within 5 working days after initial report;
b) any planned temporary closure must be reported at least 5 working days beforehand;
c) permanent closure must be reported as soon as reasonably practicable but with 5 working days of closing;
d) any change in legal ownership must be reported at least 5 working days beforehand;
e) within 30 days after a proposed change in directorship, management, or control;
f) any significant change to:

i) the person responsible for its day-to-day management (report using an AP18 form as per 6.2 Changes to Recognition);
ii) the person responsible for each test within its scope of recognition (significant change here is considered to be the loss of all KTPs for a particular test, NOT addition or removal of KTPs);
iii) the premises;
iv) the equipment;
v) the facilities;
vi) its disciplines.

g) ability to comply with the Regulations and Laboratory Notice.

(2) Report to MPI via email (RLP@mpi.govt.nz), unless indicated otherwise in 6.1.9(1).

6.2 Changes to recognition

(1) A laboratory needs to complete an AP18 form to advise MPI of the following:

a) removal or addition of tests or disciplines to the laboratory's Notice of Recognition and the MPI Public Register:

i) the CLT reference numbers of the tests and whether they are to be added and/or removed should be clearly indicated on the form (where a test has been removed from the CLT, MPI will remove these tests from the Public Register and an AP18 is not required);
ii) the IANZ RLP assessment report, close out report and accreditation scope should be attached.

b) a change to the person responsible for the day-to-day management; or
c) a change to the email address MPI will use to communicate with the laboratory, this is usually the email address of the person responsible for the day-to-day management; or
d) a change in the legal company name; or
e) a change to the site address; or
f) any changes to fitness and properness criteria, such as any new specified convictions or changes to the character or reputation in relation to directors/persons who are legally responsible for the laboratory.

(2) A laboratory should email the completed AP18 form plus payment to approvals@mpi.govt.nz

(3) Other significant changes should be reported to MPI via email (RLP@mpi.govt.nz). See section 6.1.9 Reporting to MPI for more details.

7 Renewal of recognition

(1) Laboratory recognition is generally granted for a 3-year period.

(2) Renewal of recognition allows MPI to review the recognised laboratory's details and ensure all details are up to date.

(3) Six weeks in advance of the recognition expiry date, MPI will email renewal reminders to the laboratory email address provided. If no response is received, the reminder will again be sent 2 weeks in advance of the expiry date. Despite MPI sending these renewal reminders, the laboratory remains responsible for ensuring that the recognition is maintained and active, so should monitor recognition expiry dates and contact approvals@mpi.govt.nz if reminders have not been received.

(4) The reminder email includes instructions on how to renew. Renewal applications should be received by MPI prior to the expiry date (the expiry date is on the laboratory's Notice of Recognition and on the MPI Public Register). It is the laboratory's responsibility to apply for renewal prior to expiry.

(5) Processing time for renewals is 10 working days.

8 Refusal, removal, suspension, or conditions of recognition

(1) If MPI refuses to grant recognition, suspends or withdraws the recognition, or imposes or varies conditions, the laboratory will be notified, along with the reasons. The laboratory will usually be given a reasonable opportunity to make written or oral submissions prior to a final decision being made.

(2) A laboratory may request suspension of its recognition:

a) if it is temporarily unable to meet the requirements of the Act, Regulations and Laboratory Notice; and
b) while the laboratory works to fix the issue(s).

(3) A laboratory should surrender their recognition if:

a) the laboratory is closing permanently;
b) the laboratory is no longer performing testing required to be done by a recognised laboratory; or
c) the laboratory is unable to meet the requirements of the Act, Regulations and Laboratory Notice and is unable to advise a timeframe when this will be fixed.

(4) A laboratory's recognition will be suspended if the laboratory has failed to pay an ongoing recognition fee, charge, or levy within 30 days after the date on which it was due or if it has not met any of the other specific conditions.

(5) A laboratory's recognition will be withdrawn if the laboratory has failed to renew the recognition despite attempts by MPI to contact the laboratory.

9 Additional guidance for Live Animals and Germplasm

(1) Requirements in the Laboratory Notice for testing live animals and germplasm do not apply to export testing in the following situations:

a) where the test is an intradermal test; or
b) surveillance testing that is conducted on populations to determine the disease status of those populations.

(2) Where potential issues with live animal and germplasm testing are likely to compromise the integrity of export certification, the recognised laboratory should notify the Animal Exports team within 48 hours of the event.

10 Additional guidance for reporting screen tests

(1) Where a screen test is undertaken to detect the presence of a microorganism or other parameter in a sample, the results can be either negative or positive. When a positive result occurs, confirmatory testing may then be done. If a confirmation test will be performed, then the positive screen test result may be reported as a presumptive positive. If a confirmation test will not be performed, then the positive screen test result must be reported as a positive. See Flowchart 3: Reporting Screen Tests

(2) Negative results sourced from any other type of analysis undertaken on the sample (other than a confirmation test) or by retesting of the sample, or by resampling are not valid. The original positive result is the result that must be reported.

(3) If the laboratory withdraws a positive result because the result has been deemed invalid (following all appropriate processes), sampling and testing may be repeated.

Flowchart 3: Reporting Screen Tests