Ministry for Primary Industries
Manatū Ahu Matua

Animal Products Notice

Specifications for Laboratories

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An animal products notice issued under the Animal Products Act 1999

New Zealand Government

TITLE

Animal Products Notice: Specifications for Laboratories

COMMENCEMENT

This Animal Products Notice comes into force on ..

REVOCATION

This Animal Products Notice revokes and replaces

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

(2) The Laboratory Approval Scheme issued in July 2013.

ISSUING AUTHORITY

This Animal Products Notice is issued under sections 45, 60(1)(a), 159(3) and 167(1)(h), (ja), (m), (maa), (maab) and (o) of the Animal Products Act 1999 -

a) having had regard to the matters specified in section 44(7) of that Act; and
b) being satisfied of the matters specified in section 60(1)(a) of that Act; and
c) after appropriate consultation has been carried out in accordance with section 163 of that Act.

This Animal Products Notice is also issued under regulation 15 of the Animal Products Regulations 2000 and regulation 14 of the Animal Products (Dairy) Regulations 2005.

Dated at Wellington this ... day of 2014

Matthew Stone
Director, Animal and Animal Products
Ministry for Primary Industries
(acting under delegated authority of the Director General)
A copy of the instrument of delegation may be inspected at the Director General's office.

Contact for further information
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Animal Products
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Contents

Introduction

This introduction is not part of the Animal Products Notice, but is intended to indicate its general effect.

Purpose

This Notice is issued for the purpose of specifying requirements that must be met in relation to a laboratory:

(1) To be recognised, to perform tests associated with live animals, animal material or animal product, or the processing of animal material or animal products under the Animal Products Act 1999; and

(2) Carrying out tests for live animals, on animal material or animal product, or on materials associated with the processing of animal material or animal products.

Background

(1) This new Notice brings together and aligns three MPI laboratory programmes under one legal Notice:

a) **Dairy Laboratory System**: The dairy laboratory system specifies the requirements for laboratories that carry out tests associated with dairy products and dairy material to meet New Zealand standards, and to support official assurances.

b) **Laboratory Approval Scheme (LAS)**: The LAS specifies the requirements for laboratories that carry out tests associated with the issuing of official assurances for animal products, and in some cases details test methods that are required to meet specific market access requirements. The scheme applies to meat, poultry, seafood and honey, and also includes potable water testing and food composition.

c) **Export Laboratory Programme Requirements for Laboratories and Persons Conducting the Testing of Live Animals and Germplasm for Export (ELP)**: The ELP consolidates the requirements for laboratories undertaking testing of live animals and germplasm for export.

Who should read this Animal Products Notice?

(1) The following persons should read this Notice:

a) laboratories performing tests associated with live animals, animal material or animal product, or the processing of animal material or animal products, where the test results are intended to be recognised under the Act;

b) persons conducting laboratory testing or any specialist laboratory function or testing activity in connection with such laboratories;

c) animal product exporters, processors and risk management programme operators who contract laboratories to perform testing to satisfy their obligations under the Act; and

d) laboratories performing tests associated with surveillance and residues testing programmes.

Why is this important?

(1) Operating other than in accordance with this Notice is an offence under Part 10 of the Animal Products Act 1999.

Document history

(1) This is the first Laboratory Specifications Notice and was created to combine the three laboratory programmes together.

Other information

(1) A transition period of two years is being allowed for the changes in accreditation assessments for the alignment of laboratory programmes, commencing from the date this Notice comes into force.

(2) The MPI laboratory programme guidance documents will be amended to reflect these changes as a consequence of this Notice, e.g. Dairy National Chemical Contaminants Programme – Operational Criteria.

(3) The following Animal Product Notices will also be amended separately:

a) Animal Products (Recognised Agency and Persons Specifications) Notice 2011;
b) Animal Products (Dairy Recognised Agency and Recognised Persons Specifications) Notice 2011 Number 2;
c) Animal Products (Specifications for Bivalve Molluscan Shellfish) Notice 2006;
d) Animal Products (Dairy) Conditions of Recognition (June 2005);
e) Animal Products (Dairy) Approved Criteria for Recognition of Agencies and Persons (2011);
f) Animal Products Notice Contaminant Monitoring and Surveillance 2014; and
g) Animal Products (National Microbiological Database Specifications) Amendment Notice 2012.

(4) Any description in this document which is enclosed in a box does not form a part of the requirement. It is guidance which is intended to explain the general intent of the particular requirement and may serve to clarify how compliance with the requirement may be demonstrated.

Part 1: Requirements

1.1 Incorporation of material by reference

(1) Under section 168 of the Act, the following documents are incorporated into, and form part of, this Notice:

a) The current edition of the New Zealand Standard ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories".
b) The current edition of ISO/IEC 17043 "Conformity assessment – General Requirements for Proficiency Testing".
c) The current edition of ISO/IEC 17011 "Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies".

1.2 Definitions

(1) In this Notice, unless the context otherwise requires –

accreditation means the accreditation provided by an accreditation body in accordance with the appropriate ISO standard such as ISO/IEC 17025

accreditation body means an independent organisation operating in accordance with ISO/IEC 17011 that assesses and accredits conformity assessment bodies including laboratories providing testing services

Act means the Animal Products Act 1999

competent authority means any government authority in an overseas importing country that has lawful authority to carry out assessment of compliance with New Zealand's laws

critical non-compliance means personnel, equipment, facilities, working environment or other resources (or lack of) which, in its current state, is not in accordance with requirements and is shown to have an adverse effect on the integrity of test results

discipline means the defined area of expertise; chemical, microbiological, parasitological, molecular biology, or other

ILCP means inter-laboratory comparison programme and is a form of proficiency testing

ISO/IEC 17025 means the current edition of ISO/IEC 17025 "General requirements for the competence of testing and calibration laboratories"; this refers to the latest edition of that standard, together with any additions, amendments, and deletions made to or from that standard up to that time

ISO/IEC 17011 means the current edition of ISO/IEC 17011 "Conformity assessment - General requirements for accreditation bodies accrediting conformity assessment bodies"; this refers to the latest edition of that standard, together with any additions, amendments, and deletions made to or from that standard up to that time

ISO/IEC 17043 means the current edition of ISO/IEC 17043 "Conformity assessment – General Requirements for Proficiency Testing"; this refers to the latest edition of that standard, together with any additions, amendments, and deletions made to or from that standard up to that time

Key Technical Person (KTP) means a laboratory person formally appointed or contracted by the senior management of the laboratory who is employed as a qualified expert to oversee the accredited laboratory operations in the person's area(s) of expertise

ILCP provider means a supplier of proficiency testing services for laboratory testing accredited to ISO/IEC 17043

MPI means the Ministry for Primary Industries

recognised laboratory means a laboratory recognised under section 101 of the Act

relevant function means 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

sample means the –

a) material such as animal product; or
b) live animal material or other material associated with live animals; or
c) material from production and processing of animal material and products;

that is collected for the purpose of analysis. A sample may be split to form multiple test items, or multiple samples may be combined to form a composite sample

sample taker means any person who takes or collects samples

temporary closure means any short term closure for any reason where a laboratory is closed for up to three months

test means any analytical test associated with live animals, animal material or animal product, or the production and processing of animal material or animal products performed by a laboratory under the Act or under Regulations, Notices, Specifications or Directions issued under the Act, and includes the test sample matrix

test item means the sample portion tested by the laboratory for analysis

test method means the method of analysis used to qualitatively or quantitatively test for a parameter in a sample associated with live animals, animal material or animal product, or material associated with the production and processing of animal material or animal product

(2) Any term or expression used in this Notice that is defined in the Act or Regulations made under the Act and used, but not defined, in this Notice has the same meaning as in the Act or Regulations.

Guidance on terms:
KTP: All signatories will continue to be recognised during the transition period until the laboratory is under the scope of this notice and can apply to become KTPs.

Part 2: Requirements that apply to laboratories

2.1 Application of this Part

(1) This Part applies to:

a) laboratories intending to perform tests, and that seek to be recognised under the Act;
b) recognition of laboratories performing tests.

2.2 Laboratories must be recognised

(1) A laboratory performing a test as defined under clause 1.3 must be recognised as a laboratory under section 101 of the Act prior to performing any tests.

(2) The Director-General may grant recognition to a laboratory under section 101 of the Act if the laboratory complies with either the requirements of clause 2.3 of this Notice or the requirements of clause 2.4 of this Notice.

(3) Notwithstanding subclause 2 and 3, under exceptional circumstances the Director-General may waive the requirement for a laboratory to be recognised if satisfied that–

a) the laboratory operates to a standard equivalent to the requirements set out in this Notice; and
b) it is not practicable to require such a laboratory to be recognised.

Guidance on waivers:
Instances where a laboratory may be given a waiver from recognition include overseas laboratories where tests are contracted. The contract may include elements of this Notice as appropriate.

2.3 General requirements for recognition of laboratories

(1) The Director-General may grant recognition to a laboratory under section 101 of the Act if the laboratory–

a) is accredited by an accreditation body in accordance with ISO/IEC 17025; and
b) meets any other technical requirements as specified by the Director-General under the Act, this Notice, or by Regulations, Notices, Specifications or in Directions made or issued under the Act; and
c) has suitable premises, equipment, procedures, materials and staff to ensure that all testing and other required functions are carried out properly and competently at all times; and
d) makes payment of any fees and charges required by the Act or by Regulations made under the Act.

(2) A recognised laboratory must ensure that no significant changes are made to the premises, equipment, facilities or to its discipline(s) unless –

a) the Director General has been advised of the change; and
b) the change is carried out in a manner that, in the opinion of the Director General, ensures that the integrity of analytical testing is maintained.

2.4 Requirements for limited recognition of laboratories

(1) If the Director-General considers that urgent circumstances have arisen that require a laboratory to be able to carry out certain tests and the laboratory does not comply in full with the requirements of clause 2.3 of this Notice, the Director-General may grant recognition to the laboratory for a specified test under section 101 of the Act if –

a) the laboratory is currently accredited to ISO/IEC 17025 for at least one other test of a similar discipline; and
b) where a KTP is required for the specified test, the laboratory nominates one or more KTPs for the test; and
c) the Director-General specifies a period during which the recognition applies; and
d) the laboratory makes payment of any fees and charges required by the Act or by Regulations made under the Act.

(2) Any laboratory granted recognition under this clause to conduct specified tests must as soon as practicable be in full compliance with all requirements for those specified tests under clause 2.3.

Guidance on terms:
Interim approval: The term 'limited recognition' has the same purpose as the term 'interim approval' that was used in some laboratory programmes.

2.5 Requirements of a recognised laboratory for qualified personnel

(1) Each recognised laboratory must have personnel with expertise in the technical areas covered by the laboratory accreditation such as chemistry, microbiology, parasitology, or molecular biology.

(2) For each area of expertise the laboratory must have at least one KTP who has –

a) a relevant tertiary qualification; or
b) been granted a dispensation by the accreditation body from the requirements in paragraph (a) based on appropriate practical experience in the technical area the KTP will be overseeing.

2.5.1 Where sampling criteria are specified

(1) Where the Act or Regulations, Notices, Specifications or Directions issued under the Act require the laboratory to be responsible for sampling requirements and the qualification and status of sample takers for the test concerned it must:

a) ensure samples are taken by sample takers in the manner specified in the Act or Regulations, Notices, Specifications or Directions issued under the Act; and
b) ensure sample takers comply with any requirements issued under the Act or Regulations, Notices, Specifications or Directions issued under the Act; and
c) maintain records of sample takers proficiency and qualifications; and
d) undertake reviews of sampling and sample takers at least annually.

2.6 Assessment

(1) Each laboratory must ensure that its performance is assessed by its accreditation body in accordance with the requirements in subclauses (2) or (3).

(2) Each laboratory must ensure that the assessment by its accreditation body is undertaken in the following manner:

a) an initial full assessment to ISO/IEC 17025 requirements after applying for recognition to the Director-General; and

b) the Director-General receives the initial full assessment outcome from the accreditation body to determine that the laboratory meets ISO/IEC 17025 requirements for the scope of testing applied for; and
c) following the laboratory being granted recognition by the Director General, the accreditation body carries out a surveillance visit each year for two years in succession; and
d) in the third year after being granted recognition by the Director-General, the accreditation body undertakes a full routine reassessment involving a full review of quality system documentation and a full on-site technical assessment.

Guidance:
An application of intention to seek laboratory recognition can be made using the form supplied by MPI.

(3) The three yearly assessment accreditation cycle as described in subclauses (2)(c) and (2)(d) must be repeated for the duration of the laboratory's recognition.

Guidance:
The laboratory is expected to facilitate any additional assessment that might be required by the accreditation body at the request of the Director General.

2.7 System and facility requirements of recognised laboratories

(1) A recognised laboratory must establish, document and maintain systems and procedures that comply with the Act, and any associated Regulations, Notices, Specifications and Directions made or issued under the Act, and any conditions imposed on the laboratory's recognition by the Director-General in accordance with section 111 of the Act.

(2) If the Director-General has issued the laboratory with one or more Notices of recognition, the laboratory must ensure that each such Notice is prominently displayed in the laboratory at all times.

(3) A recognised laboratory must comply with all directions from the Director-General issued under the Act and which relate to the functions or activities for which the laboratory is recognised.

(4) A recognised laboratory must ensure that its employees and contractors performing testing and other relevant functions and activities, have access to -

a) an up-to-date version of the Act, relevant Regulations and Notices, ISO/IEC 17025, and all other relevant documents; and
b) the laboratory's own systems and procedures and appropriate records and databases.

(5) A recognised laboratory must ensure that its employees and contractors performing testing and other relevant functions and activities are able to demonstrate sound knowledge of the relevant industry operational processes.

Guidance re clause 2.7 subclause (2):
A laboratory notice of recognition can be issued in the form of a certificate by MPI.

2.8 Other audit assessment requirements

(1) 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 the Act, this Notice, or Regulations, Notices, Specifications or Directions issued or made under the Act.

(2) The recognised laboratory must make its facilities, personnel involved in testing, and records relating to testing, readily available to –

a) a person appointed by the Director-General to undertake audits or investigations for the purposes of subclause (1); and
b) the representatives of any other competent authority as part of an assessment of compliance with the Act or Regulations, Notices, Specifications or Directions issued or made under the Act.

2.9 No misleading statements

(1) Each recognised laboratory must not make any –

a) statement either directly or by implication, to the effect that the laboratory's recognition is in itself an approval or assurance in relation to any animal product; or
b) other misleading statement in relation to its recognition.

2.10 Reporting requirements

(1) Each recognised laboratory must ensure that all reports for tests conform to the reporting requirements in ISO/IEC 17025 and to any requirements for that test in this Notice.

(2) If requested by the Director-General, each recognised laboratory must, as soon as practicable, provide the Director-General with any information requested in relation to testing activities, test method validation, and the assessment of test performance including ILCP results and any assessment or analysis carried out by the ILCP provider.

Guidance re clause 2.10 subclause (2):
ILCP requirements for recognised laboratories include:

a) what must be undertaken to meet ISO/IEC 17025 requirements; and
b) specific programmes where MPI contracts an ILCP provider.

2.11 Disclosure of information

(1) A recognised laboratory must notify the Director-General in writing at least five working days prior to -

a) any planned temporary closures; or
b) any change to organisational management or legal ownership; or
c) loss of KTP coverage for any or all of the tests in the laboratory's scope of accreditation; or
d) any other significant change or event which may have the potential to have an adverse effect on test results or operations.

(2) If requested by the Director-General, a recognised laboratory must, as soon as practicable, submit to the Director-General information requested relating to tests carried out.

(3) A recognised laboratory or KTP at the laboratory must inform the Director-General within one working day, if –

a) the laboratory is unable to comply with any of the requirements of this Notice; or
b) as a result of its activities, the laboratory becomes aware of a situation which may pose a significant biosecurity or public health risk; or

c) the laboratory or KTP becomes aware of a situation that suggests the laboratory or KTP has a conflict of interest, lacks impartiality in respect of testing activities or of a situation that impacts on the laboratory's, or KTP's credibility; or
d) any critical non-compliance that relates to testing, whether the critical non-compliance was found by an accreditation body or otherwise became known to the laboratory. The laboratory must provide the Director-General with information related to the critical non-compliance (such as a copy of the accreditation assessment report); or
e) the recognised laboratory is notified by the accreditation body of suspension or withdrawal of accreditaton.

Guidance:
The laboratory has an obligation to maintain all competency requirements applicable to their recognition under the Act (see section 112H). Where a laboratory seeks to change a significant part of its operations, the Director-General may seek to use his/her powers to impose additional conditions on, or revoke the recognition of, a laboratory under section 111 of the Act.

2.12 Subcontracting

(1) Tests may be subcontracted to another recognised laboratory that is recognised for conducting the tests concerned under clause 2.2(2), or to a laboratory that is exempt from recognition under clause 2.2(3).

Guidance:
An example would be where a laboratory is contracted by the Director General to conduct tests on rare contaminants..

2.13 Records

(1) The recognised laboratory must retain technical records (such as maintaining original test observations, copies of reports issued and other information necessary to maintain an audit trail) for four years.

Part 3: Acceptable test methods

3.1 Application of this Part

(1) This Part clarifies the requirements to be met by a recognised laboratory when the test result is intended to be recognised as valid under the Act.

(2) This Part applies to tests where, under the Act, Regulations, Notices, Specifications or Directions issued or made under the Act, a specified test method or approved test methods must be used to satisfy any conditions.

Guidance:
Results are intended to be recognised as valid under the Act when the test or result is required to assess material, product or processing conformance or non conformance. Typically the laboratory will require the client to indicate the nature of testing required.

3.2 Recognised Laboratories to use specified or approved test method for certain tests

(1) If specified or approved test methods are required to be undertaken as described in clause 3.1, each recognised laboratory undertaking tests associated with live animals, animal material or animal product, or the processing of animal material or animal products must use the method specified under the Act for tests, without modification.

(2) Recognised laboratories must ensure that –

a) The analysis is only undertaken in a laboratory recognised in the appropriate category for the test; and
b) The test method used is specified within the scope of the laboratory's accreditation; and
c) The test method has been confirmed as suitable for the intended sample matrix in accordance with clause 3.3.

Guidance:
Recognition for e.g. process control, environmental monitoring, would not be expected to have specified or approved methods.

3.3 Confirmation of suitable test methods

(1) The recognised laboratory must confirm that each test method is suitable for the intended sample matrices.

Guidance:
For example manufacturers appropriate validation information would need to be obtained for a test kit to confirm suitability.
Ongoing validity of test results can be achieved by using positive control material as an independent control.

Part 4: Authorisation of test results

4.1 Application of this Part

(1) This Part applies to results issued for all tests to ensure that the authorisation of each test result and signing or authorisation of each test report –

a) complies with the requirements of accreditation for accredited tests; and
b) is consistent with ISO/IEC 17025 for any test where the laboratory has been granted limited recognition under clause 2.4

4.2 Authorisation of results

(1) The recognised laboratory must ensure that all test reports relating to that test are signed and issued (or, if in electronic form, are authorised for release) by the KTP responsible for those tests. Another KTP can release results at the discretion of the KTP responsible for those tests.

(2) If a test has been subcontracted, the laboratory releasing the report to the client who requested the test must ensure that the test report is signed by a KTP at the subcontracted laboratory that supervised the test.

(3) Any report containing subcontracted test results must be traceable to the original report(s) and must contain information that enables tracing of the subcontracted laboratory and the KTP at that subcontracted laboratory who released the particular test result(s) to the primary client.

Guidance:
Reports, and their approval, can be in electronic format.
Where a (multiple disciplinary) report has more than one KTP involved, the report should nominate a contact KTP for the recognised laboratory.