



Specifications for Laboratories

7 August 2017

TITLE

Animal Products Notice: Specifications for Laboratories

COMMENCEMENT

- (1) This Animal Products Notice comes into force on 8 August 2017
- (2) Despite subclause (1), the Revocation clause below comes into force on 31 August 2017

REVOCATION

This Animal Products Notice revokes and replaces:

- (1) The Animal Products Notice: Specifications for Laboratories 18 June 2015.
- (2) The Animal Products (Recognised Laboratories and Persons Specifications for Conducting Testing of Live Animals and Germplasm for Export) Notice 2015.
- (3) The current edition of the Laboratory Approval Scheme.

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 7th day of August 2017

Paul Dansted
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Ministry for Primary Industries
(acting under delegated authority of the Director-General)

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Introduction

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

Purpose

- (1) This Notice is issued for the purpose of specifying requirements that must be met in relation to a laboratory:
 - a) 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
 - b) 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) The Specifications for Laboratories Notice and was created to combine the three laboratory programmes together and was first issued 18 June 2015.
- (2) Subsequently it was identified that the Laboratory Approval Scheme ILCP needed to be included in the Consolidated List of Tests: for Animal Products: meat, poultry, honey, seafood, dairy, live animals and

germplasm. Clause 2.6 has been altered to reflect this as this has meant a change in the intention of this incorporated by reference list.

Other information

- (1) A transition period of two years is being allowed for the changes in accreditation assessments for the alignment of the 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 and associated documents 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 Notice Contaminant Monitoring and Surveillance 2014; and
 - e) Animal Products (National Microbiological Database Specifications) Notice 2012.

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 as standard works of reference:
 - 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".
- (2) Under section 168 of the Act, the following documents are incorporated into, and form part of this Notice:
 - a) The current edition of the MPI Consolidated List of Tests for Animal Products: meat, poultry, honey, seafood, dairy, live animals and germplasm.

1.2 Definitions

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

accreditation means the accreditation provided by an accreditation body against 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 being chemistry, microbiology, parasitology, molecular biology, or other areas of expertise

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 by the senior management of the laboratory who oversees the accredited laboratory operations in the person's area(s) of expertise

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

MPI means the Ministry for Primary Industries

Quality Manager means a person with overall responsibility for the laboratory's compliance with the requirements of this Notice, and who is the point of contact with MPI in respect of this Notice

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

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 testing. 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

test report means the final result of analysis for a test signed by the appropriate KTP and issued by the laboratory to the client

- (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.

Part 2: Requirements that apply to laboratories

2.1 Application of this Part

- (1) This Part applies to laboratories intending to perform tests, and that seek to be recognised under the Act; and
- (2) This Part specifies requirements for the recognition of laboratories performing tests.

2.2 Laboratories must be recognised

- (1) A laboratory performing a test as defined under clause 1.2 of this Notice must be recognised as a laboratory under section 101 of the Act prior to performing any test.
- (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 or clause 2.4 of this Notice.
- (3) Notwithstanding subclause (1) and (2), under exceptional circumstances the Director-General may, by notice to the laboratory, 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.
- (4) The Director-General may, by notice to the laboratory, revoke the waiver if satisfied that—
 - a) the laboratory no longer operates to a standard equivalent to the requirements set out in this Notice; or
 - b) that it is practicable to require such a laboratory to be recognised.

2.3 General requirements for recognition of laboratories

- (1) The Director-General may grant recognition to a laboratory to perform tests under section 101 of the Act if the Director-General is satisfied that the laboratory—
 - a) is accredited to ISO/IEC 17025 by an accreditation body in accordance with ISO/IEC 17011; or
 - b) is a research laboratory or reference laboratory whose functions include calibration, quality assurance and specific testing parameters and that is not accredited to ISO/IEC 17025 for all tests conducted; and
 - c) 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
 - d) has suitable facilities, equipment, procedures, materials and staff to ensure that all testing and other required functions are carried out properly and competently at all times; and
 - e) makes payment of any fees and charges required by the Act or by Regulations made under the Act; and
 - f) has appointed a Quality Manager.

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 meet all 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 has appointed 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; and
 - e) appoints a Quality Manager.
- (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(1) of this Notice.

2.5 Changes to laboratory recognition

- (1) A recognised laboratory must ensure that no significant changes are made to the Quality Manager, a KTP, premises, equipment, facilities, or to its discipline(s) unless –
- a) the Director General has been informed of the change as soon as practicable; and
 - b) the change is carried out in a manner that ensures that the integrity of analytical testing is maintained.
- (2) If a recognised laboratory informs the Director-General of any significant change described in subclause (1), the Director-General must, where appropriate, record the change in the register of recognised laboratories.

2.6 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 available upon request.
- (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) Where a recognised laboratory conducts tests that are specified in Part 2 (Designated ILCP) of the Consolidated List of Tests for Animal Products: meat, poultry, honey, seafood, dairy, live animals and germplasm, it must comply with the requirements set out in that Part 2.
- (5) 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.
- (6) 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 practices.

2.7 Subcontracting

- (1) Tests may be subcontracted:

- a) to another recognised laboratory that is recognised for conducting the tests concerned under clause 2.2(2) of this Notice, or to a laboratory that is exempt from recognition under clause 2.2(3) of this Notice; or
 - b) to a non-recognised laboratory when circumstances arise where testing cannot be conducted by any current recognised laboratory and the Director-General approves the carrying out of tests by a non-recognised laboratory.
- (2) Before approving the carrying out of tests by a non-recognised laboratory, the Director-General must be satisfied that:
- a) the approval relates to specified testing; and
 - b) the laboratory can demonstrate competence of its systems and staff, and the reliability of test results.

2.8 Requirements of a recognised laboratory for qualified personnel

- (1) Each recognised laboratory must have personnel with expertise in the disciplines covered by the laboratory accreditation.
- (2) For each test for which the laboratory is recognised the laboratory must have at least one KTP who –
- a) has a relevant tertiary qualification; or
 - b) meets the criteria specified by the accreditation body for dispensation from the requirement for relevant tertiary qualifications such as appropriate practical experience and specific training in that work.

2.8.1 Where sampling criteria are specified

- (1) Where the Act or Regulations, Notices, Specifications or Directions issued under the Act specifies that the laboratory must 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.

2.9 Accreditation body assessment

- (1) Each laboratory must ensure that its performance is assessed by its accreditation body in accordance with the requirements in subclauses (2) and (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 before applying to the Director-General for recognition; and
 - b) the Director-General receives the initial full assessment outcome from the applicant laboratory issued by 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.
- (3) For continuation of recognition:

- a) 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; and
 - b) the Director-General must receive any accreditation body reports on the laboratory.
- (4) The Director-General may require additional assessments by the accreditation body and the laboratory must facilitate any such additional assessment required.

2.10 Audit or investigation 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, equipment, 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.

2.11 Reporting requirements

- (1) Each recognised laboratory must ensure that all test reports:
 - a) conform to the reporting requirements in ISO/IEC 17025 and to any requirements for that test in this Notice; and
 - b) are in a form approved by the Director-General.
- (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:
 - a) testing activities; and
 - b) test method validation; and
 - c) the assessment of test performance including results; and
 - d) any assessment or analysis carried out by the ILCP provider; and
 - e) assessment reports or results from any assessment carried out under clause 2.9 of this Notice; and
 - f) significant changes made under clause 2.5 of this Notice.

2.12 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.

2.13 Disclosure of information and confidentiality

- (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 if that information is not provided under clause 2.11.
- (3) A recognised laboratory or Quality Manager 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, trade, or public health risk; or
 - c) the laboratory or Quality Manager becomes aware of a situation that suggests the laboratory or KTP at the laboratory has a conflict of interest, lacks impartiality in respect of testing activities or of a situation that impacts on the laboratory's credibility; or
 - d) the laboratory knows of any critical non-compliance that relates to testing. 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 accreditation.
- (4) KTPs must maintain confidentiality of all information that comes into their possession as part of their activities as a person having responsibility for testing and reporting.
- (5) KTPs must advise the Director-General within 24 hours, where practicable, of situations that might give rise to a conflict of interest, and must comply with any directions given by the Director-General regarding dealing with the situation.

2.14 Records

- (1) The recognised laboratory must retain records kept for the purposes of this Notice:
- a) for at least four years; and
 - b) must ensure that the records are retrievable within two working days of a request from the Director-General or the accreditation body.

Part 3: Acceptable test methods

3.1 Application of this Part

- (1) This Part specifies 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 is required to be undertaken and the required test method is also specified.
- (3) This Part applies to tests where, under the Act, Regulations, Notices, Specifications or Directions issued or made under the Act, a specified test is required to be undertaken but no test method is specified or approved.

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

- (1) Where clause 3.1(2) applies, a recognised laboratory that conducts a test described in that subclause must use the applicable test method specified or approved without modification.
- (2) Where clause 3.1(3) applies, a recognised laboratory that conducts a test described in that subclause must use the applicable test method (if any) specified in the MPI Consolidated List of Tests for Animal Products: meat, poultry, honey, seafood, dairy, live animals and germplasm, and must use the applicable test method without modification.
- (3) In all cases the recognised laboratories must ensure that –
 - a) The analysis is only undertaken in a laboratory recognised for that test; and
 - b) The test method used is within the scope of the laboratory's accreditation; and
 - c) The test method has been confirmed as suitable for the intended sample matrix.

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 of this Notice.

4.2 Authorisation of results

- (1) The recognised laboratory must ensure that all test reports are only released by the KTP responsible for the tests to which the reports relate.
- (2) If a test has been subcontracted, the original laboratory that subcontracted the test to another laboratory must ensure that the test report is:
 - a) signed by a KTP working for the subcontracted recognised laboratory, or
 - b) where the laboratory is a non-recognised laboratory under clause 2.7 of this Notice, signed by a person qualified in the discipline the test relates to.
- (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, or qualified person as described in subclause (2)(b), at that subcontracted laboratory who released the particular test result(s) to the primary client.

Part 5: Transitional provisions

5.1 Transitional provisions

- (1) Except as required by subclause (2), a laboratory performing tests is not required to comply with this Notice until 31 August 2017.
- (2) If a laboratory's recognition or approval expires at any time during the period prior to the commencement of this notice, and the laboratory wishes to continue to perform tests:
 - a) the laboratory must apply for recognition under the Act and this Notice unless it is otherwise exempted under the Act or this Notice; and
 - b) if an application for recognition is not granted before the end of the transition period (31 August 2017), the laboratory must cease to conduct tests.
- (3) A laboratory that intends to start to perform tests after the commencement of this Notice must apply for, and be granted, recognition under the Act and this Notice before it commences testing unless it is otherwise exempted under the Act or this Notice.
- (4) Once a laboratory performing tests is recognised as a laboratory under section 101 of the Act for the purposes of this Notice, that laboratory must comply with the requirements in this Notice. The Animal Products (Recognised Laboratories and Persons Specifications for Conducting Testing of Live Animals and Germplasm for Export) Notice 2015 and the current edition of the Laboratory Approval Scheme, as the case may be, and any other relevant requirements for recognition in any notice made under the Act, will no longer apply to that laboratory.