



# Animal Products Notice

## Recognised Laboratories

9 May 2022

## **TITLE**

Animal Products Notice: Recognised Laboratories

## **COMMENCEMENT**

This Animal Products Notice comes into force on 1 July 2022

## **ISSUING AUTHORITY**

This Animal Products Notice is issued under section 167(1) for the purposes of section 77H of the Animal Products Act 1999 and under section 167(2) of the Animal Products Act 1999 to supplement Part 9 of the Animal Products Regulations 2021.

Dated at Wellington, 09 May 2022

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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) The purpose of this notice is to supplement the Animal Products Regulations 2021 and set requirements for recognised laboratories.

## Background

- (1) The Animal Products Act 1999 sets the framework for the recognition of agencies.
- (2) The Animal Products Regulations 2021 sets specific requirements for recognised agencies, with additional requirements for recognised laboratories.
- (3) This Notice incorporates some of the information that was previously contained in the Animal Product Notice: Specifications for Laboratories.

## Who should read this Animal Products Notice?

- (1) This Animal Products Notice should be read by:
  - a) laboratories applying to be recognised agencies; and
  - b) recognised laboratories; and
  - c) persons conducting testing in a recognised laboratory or performing any specialist laboratory function or testing activity in connection with such laboratories; and
  - d) animal product exporters, processors and risk management programme operators who contract recognised laboratories to perform testing to satisfy their obligations under the Animal Products Act 1999.

## Why is this important?

- (1) A laboratory that fails to comply with the requirements of this Notice may not be granted, or may not retain, as applicable, recognition.
- (2) A failure to comply with this Notice may be an offence under the Animal Products Act 1999.

## Document History

Version	Date	Section Changed	Change(s) Description
09 May 2022		-	New Notice

## Other information

- (1) Laboratories are also subject to relevant requirements including the following legislation:
  - a) Animal Products Act 1999:
  - b) Animal Products Regulations 2021:

## Part 1: Preliminary

### 1.1 Application

- (1) This Notice applies to a laboratory recognised under section 101 of the Animal Products Act 1999.
- (2) This Notice does not apply to a laboratory recognised under section 102 of the Act.

### 1.2 Definitions

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

**Act** means the Animal Products Act 1999

**designated ILCP** means the designated Inter-Laboratory Comparison Programme, which is a proficiency programme operated on behalf of the Ministry for Primary Industries

**designated ILCP provider** means the person contracted by the Ministry for Primary Industries to operate the designated ILCP

**ISO/IEC 17025** means NZS ISO/IEC 17025:2018 *General requirements for the competence of testing and calibration laboratories*

**Regulations** means the Animal Products Regulations 2021; and a reference to a specific Regulation is a reference to that regulation in those Regulations

- (2) Any term defined in the Act, the Animal Products Regulations 2021 or Animal Products Notice: Production, Supply and Processing that is used in this Notice but not defined has the meaning given in the Act, Regulations, or that Notice.

## Part 2: Recognition requirements

### 2.1 Accreditation

- (1) For the purposes of Regulation 190(1)(b)(i), a recognised laboratory must be accredited to ISO/IEC 17025.

### 2.2 Making documentation available

- (1) A recognised laboratory must provide employees performing tests and other relevant functions with access to:
  - a) the current version of the Act, and all relevant regulations, notices and directions made under it; and
  - b) ISO/IEC 17025 and any other documents or information related to the laboratory's accreditation; and
  - c) relevant parts of the laboratory's own systems, procedures, records, and databases.

### 2.3 Non-compliance reporting

- (1) For the purposes of Regulation 206(2), a report to the Director-General about a non-compliance must include:
  - a) a description of what has occurred; and
  - b) the actions taken or to be taken to ensure integrity of test results; and
  - c) the actions taken or to be taken to address the root cause.

### 2.4 Annual reporting

- (1) A recognised laboratory that performs live animal or germplasm testing must provide an annual report for all export testing carried out on live animals or germplasm for the period 1 July to 30 June, by 31 July of each calendar year.
- (2) The annual reports must include:
  - a) the name of the species of animal that is tested; and
  - b) the number and type of tests performed; and
  - c) the results of those tests; and
  - d) results of ILCP testing, including full ILCP laboratory report; and
  - e) details of non-conformances identified in internal audits; and
  - f) any identified conflicts of interest and any subsequent mitigation strategies.

## Part 3: Testing

### 3.1 Acceptable test methods

- (1) If a test is required under the Act to be done by a specified test method, a recognised laboratory must use the specified test method, without modification.
- (2) If no test method is specified, a recognised laboratory must use a test method suitable for the relevant sample matrix.

### 3.2 Composite samples

- (3) A recognised laboratory may combine samples into a composite sample only:
  - a) if requested by the client; and
  - b) for the purpose of microbiological or chemical testing; and
  - c) where discrete testing of a specified quantity of representative samples is not required under the Act.
- (4) A recognised laboratory may combine samples of animal material, or of animal product, or environmental samples into a composite sample.
- (5) A recognised laboratory must have records that link:
  - a) the information supplied with the original samples to the composite sample; and
  - b) the information about the composite sample to the original samples.
- (6) A recognised laboratory that combines samples into a composite sample for microbiological or chemical testing must:
  - a) have defined procedures for combining samples to form a composite sample and the aliquot of the composite sample selected; and
  - b) determine and record that the use of a composite sample is appropriate for the test method, including:
    - i) the maximum sample size that is suitable for the test; and
    - ii) the maximum number of individual samples that can be included in a composite sample; and
    - iii) the level of sensitivity that will be achieved by testing a composite sample compared to discrete sample testing.
- (7) Microbiological testing of a composite sample may be used to determine presence or absence of particular pathogens but may only be used for enumeration of a pathogen if the laboratory has considered the limitations of composite testing for enumeration, such as reduced sensitivity.
- (8) Any report providing test results for a composite sample must clearly identify the individual samples used to create the composite sample.

### 3.3 Test reports for sub-contracted tests

- (1) Any report providing test results where the testing has been subcontracted to another recognised laboratory (see Regulation 204) or to an overseas laboratory (see Regulation 205), must contain information that enables the following to be identified:
  - a) the subcontracted laboratory; and
  - b) the individual or individuals who authorised the results.

## Part 4: Designated Inter-Laboratory Comparison Programme

### 4.1 When to participate

- (1) A recognised laboratory that has any of the tests set out in [Schedule 1: Designated ILCP Tests](#) in its scope of recognition must participate in the designated ILCP (see Regulation 200(2)).

### 4.2 Procedure for participation

- (1) Every participating laboratory must advise the designated ILCP provider of:
  - a) the designated ILCP tests that are in its scope of recognition when first recognised; and
  - b) any subsequent addition to, or removal from designated ILCP tests in its scope of recognition; and
  - c) any suspension of all or part of its recognition where that suspension includes designated ILCP tests.
- (2) For each designated ILCP test that a participating laboratory has in its scope of recognition, the laboratory must perform at least the number of rounds of that test specified in [Schedule 1: Designated ILCP Tests](#).
- (3) On receipt of a set of proficiency samples from the designated ILCP provider for a round of tests, the laboratory must begin testing:
  - a) within 48 hours of receipt or the round opening, in the case of microbiological tests; and
  - b) as soon as practicable after receipt or the round opening, in the case of chemical tests.
- (4) The laboratory must return the results of tests to the designated ILCP provider by the date specified by the designated ILCP provider as the date on which the round closes.
- (5) The laboratory is liable for the cost of all samples (including samples provided for re-tests) provided by the designated ILCP provider.

### 4.3 Defect categories

- (1) The designated ILCP provider may categorise performance that is below expectations as one of the following:
  - a) minor defect category;
  - b) major defect category;
  - c) critical defect category.

### 4.4 Minor and major defect categories

- (1) If the designated ILCP provider notifies a participating laboratory of a minor or major defect category, the laboratory must:
  - a) request a re-test sample within 2 days after receipt of the notification; and
  - b) complete testing of the re-test samples within 5 days after receipt of the samples and return the results to the designated ILCP provider; and
  - c) carry out and document an investigation into the cause; and
  - d) take any necessary corrective action.

## 4.5 Critical defect category

- (1) If the designated ILCP provider notifies a participating laboratory of a critical defect category, the laboratory must:
  - a) continue participation in the minimum number of rounds specified in the Tables in [Schedule 1: Designated ILCP Tests](#) for the tests it does; and
  - b) demonstrate its capability by:
    - i) identifying and undertaking appropriate corrective actions to regain testing proficiency; and
    - ii) undertaking any repeat testing required by the designated ILCP provider and report back to the designated ILCP provider on results obtained.

## 4.6 Resumption of designated ILCP testing

- (1) Sub-clause 4.6(2) applies when a participating laboratory recommences performing designated ILCP tests after a laboratory has been closed temporarily or all or part of its recognition is suspended and that suspension includes designated ILCP tests.
- (2) For the purpose of calculating how many rounds of designated ILCP tests have been done by the participating laboratory in a year, the round immediately preceding the closure or suspension of all or part of its recognition must be treated as its most recent designated ILCP round.

## Schedule 1: Designated ILCP tests

**Table 1: Potable/Suitable Water Microbiology Comparative Programme (meat, poultry and fish)**

Numerical reference	Test name	Designated ILCP	
		Designated ILCP test name	Minimum number of rounds per year
1.3	Colony count 22°C	Standard plate count SPC22	6
1.1.1	Total coliforms (coliform bacteria),	Total coliforms, <i>E. coli</i>	6
11.1.2	<i>Escherichia coli</i>		
1.2	Faecal coliforms	Faecal coliforms	6
11.1.1			
1.6.1	<i>Clostridium perfringens</i> (including spores when available but no less than 2 rounds)	<i>Clostridium perfringens</i>	6
11.6.1	Faecal coliforms (growing water)	Faecal coliforms	4

**Table 2: Meat and Poultry Microbiology Comparative Programme**

Numerical reference	Test name	Designated ILCP	
		Designated ILCP test name	Minimum number of rounds per year
2.1.1	Aerobic Plate Count (APC)	APC 30 (SPC)	11
2.1.2	APC spread plate		
2.1.3	APC Petrifilm		
2.1.4	APC spiral plater		
2.2.1	<i>Escherichia coli</i> , direct plate or Petrifilm	<i>E. coli</i>	11
2.2.2	<i>Escherichia coli</i> , Petrifilm		
2.3	<i>Staphylococcus aureus</i>	<i>Staphylococcus aureus</i>	2
2.8 & 2.8.1	<i>Clostridium perfringens</i>	<i>Clostridium perfringens</i>	2
2.9	Enterobacteriaceae	Enterobacteriaceae	2
2.10	Faecal coliforms	Faecal coliforms	2

**Table 3: Fish Microbiology Comparative Programme**

Numerical reference	Test name	Designated ILCP	
		Designated ILCP test name	Minimum number of rounds per year
11.5.3	Total Plate Count (TPC) or Aerobic Plate Count (APC)	APC (SPC)	4
11.6.7	APC, TPC		
11.8.6	APC		
11.5.10	<i>Escherichia coli</i>	<i>E. coli</i>	4
11.6.2			
11.8.1			
11.5.4	<i>Staphylococcus aureus</i>	<i>Staphylococcus aureus</i>	4

**Table 4: Pathogen Microbiology Comparative Programme (meat, poultry and fish)**

Numerical reference	Test name	Designated ILCP	
		Designated ILCP test name	Minimum number of rounds per year
2.4.1	<i>Salmonella</i>	<i>Salmonella</i>	2 rounds per year for each <i>Salmonella</i> method the laboratory is recognised for
2.4.2	<i>Salmonella</i>		
2.4.3	<i>Salmonella</i>		
11.5.11	<i>Salmonella</i>		
11.6.3	<i>Salmonella</i>		
11.8.2	<i>Salmonella</i>		
2.6	<i>Listeria monocytogenes</i>	<i>Listeria monocytogenes</i> presence/absence and enumeration	2 rounds per year for each <i>Listeria monocytogenes</i> method the laboratory is recognised for
11.8.5	<i>Listeria monocytogenes</i>		
22.1	<i>Campylobacter</i>	<i>Campylobacter</i> enumeration	2
23.1	<i>Escherichia coli</i> O157:H7	<i>Escherichia coli</i> O157:H7 and Top 6 nSTECs	2
23.3	Top 7 Shiga Toxin-producing <i>Escherichia coli</i>		
11.5.12	<i>Vibrio cholerae</i>	<i>Vibrio</i> species	2 rounds per year for each <i>Vibrio</i> species and matrix the laboratory is recognised for
11.6.9	<i>Vibrio cholerae</i>		
11.5.6	<i>Vibrio parahaemolyticus</i>		
11.6.4	<i>Vibrio parahaemolyticus</i>		

**Table 5: Potable/Suitable Water Chemistry Comparative Programme; all markets – surveillance of potable water in meat & game export premises**

Numerical reference	Test name	Designated ILCP	
		Designated ILCP test name	Minimum number of rounds per year
5.02	Conductivity	Conductivity	2
5.03	pH (hydrogen ion concentration)	pH	2
5.04	Turbidity	Turbidity	2
5.10	Ammoniacal nitrogen (ammonium)	Ammoniacal nitrogen (ammonium)	2
5.13	Nitrate	Nitrate	2
5.14	Nitrite	Nitrite	2