**Proposed new Animal Products (Specifications for Laboratories) Notice Context and Changes**

**Introduction**

**Purpose**

The Ministry for Primary Industries (MPI) has produced a new draft Notice for Animal Product Act (APA) laboratory requirements for your consideration. This is a public consultation on the approach MPI is taking by developing an over-arching legal notice for the three main laboratory schemes discussed here. Responses from interested parties about this proposed approach are being sought.

**Context**

There are two compelling drivers for this new draft Notice: the government move towards regulatory reform, and some of the technical requirements being out of date. For these schemes this translates into the simplification and improved clarity of the core requirements of three laboratory programmes into one legal Notice and to reduce the burden on multi-functional laboratories.

Another driver for the change is also to separate out the different aspects of laboratory schemes, and to focus on achieving outcomes, ensuring that laboratories competently perform tests. Some of the laboratory schemes include a mix of approval of the laboratory, plus approval of the people to perform tests, plus specifying the tests that must be approved. This Notice focuses on the recognition of a laboratory.

This new draft Notice would affect:

* Laboratories which test dairy material and dairy products;
* Laboratory Approval Scheme (LAS); and
* Export Laboratory Programme: Requirements for Laboratories and Persons Conducting the Testing of Live Animals and Germplasm for Export (ELP).

This new Notice also supports MPI and NZ laboratories to meet the Whey Protein Concentrate (WPC) Inquiry recommendations for laboratory accreditation and tests.

MPI is consulting on the proposed changes to requirements being brought about by this new draft Notice.

**History**

The New Zealand regulatory programmes have evolved over time, and in most cases there are no longer government laboratories carrying out the testing. A number of the requirements in MPI’s schemes are also now adequately covered by a robust framework of accreditation requirements and international standards. There is also substantial Crown oversight of accredited laboratories, for example under the Testing Laboratory Registration Act 1972. This Act provides for International Accreditation New Zealand (IANZ) to act as the accreditation body to accredit laboratories to ISO/IEC 17025.

MPI considers that accreditation of a laboratory to the international standard for conformity assessment is sufficient for laboratories to be able to validate their own test methods. This is with the exception of testing that is specified for the purposes of market access or other regulatory assurances provided by MPI.

There are three main MPI laboratory schemes currently maintained under the *Animal Products Act 1999*:

**Dairy Laboratory Programme**

The dairy laboratory system specifies the requirements for laboratories that carry out tests on dairy products and dairy material to meet New Zealand standards, and to support official assurances. The system has its origins under the Dairy Industry Act 1952 and the Dairy Industry Regulations 1990. Minimal changes were made to the dairy laboratory systems following the transition from the Dairy Industry Act to the APA in 2005. Laboratories are recognised by MPI (either Category 1 or 2) and test methods (where required) are also approved.

**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. The LAS has been in place since 2004, originally as the MILAB Approval Scheme, and includes a detailed system for the approval of signatories.

**Export Laboratory Programme (ELP)**

The ELP was developed to support official assurances for live animals and germplasm when testing for export was required. The aim was to maintain the integrity of the export programme by requiring the health testing of live animals or donor animals (of germplasm, hatching eggs and day old chicks) to be done by an approved laboratory that was accredited for specific tests. Since June 2008 the ELP has undergone several iterations.

**Scope**

The three laboratory schemes covered by the *Animal Products Act 1999* (Dairy, LAS and ELP).

Out of scope would be some testing obligations (e.g. what tests are needed on which products) and other laboratory regimes under other Acts administered by MPI (e.g. Food Act 1981, Biosecurity Act 1993, Wine Act 2003) and plant laboratory functions.

**Process**

An initial targeted consultation with Animal Product laboratories was undertaken to canvas stakeholder support for streamlining the requirements in 2013.

MPI has met with IANZ to discuss the re-drafted Notice in 2014, but has not yet sought wider feedback on the draft notice attached. That said, the direction towards an over-arching Notice has already had some consultation with support for this approach through industry forums.

**Description of changes**

1. Implementation of the proposed notice would bring about the following changes to current legal documents:
* amend the Animal Products (Recognised Agency and Persons Specifications) Notice 2011; the Animal Products (Dairy Recognised Agency and Recognised Persons Specifications) Notice 2011 Number 2: the Animal Products (Animal Products (Specifications for Bivalve Molluscan Shellfish) Notice 2006; the Animal Products (Dairy) Conditions of Recognition (June 2005); Animal Products (Dairy) Approved Criteria for Recognition of Agencies and Persons (2011): and Animal Products Notice Contaminant Monitoring and Surveillance 2014.
* revoke the Animal Products (Recognised Laboratories and Persons Specifications for Conducting Testing of Live Animals and Germplasm for Export) Notice 2011 and the Laboratory Approval Scheme document.
1. Minimum requirements have been defined in the proposed Notice, e.g. competencies. Whilst this may appear to be a duplication of some of the IANZ requirements, the approach has been taken that providing a legal basis for such requirements does add robustness to the laboratory schemes that the Notice supports.

**Dairy Changes**

The main changes would involve removal of the text relating to laboratories and test methods in the existing dairy Recognised Agency and Persons Notice. Also it would involve the removal of the Category 2 laboratory requirements. The assessment of dairy laboratories would align with other laboratories such that there is a full routine re-assessment every three years, with two surveillance assessments in the intervening years.

**LAS Changes**

MPI is planning to progressively move away from having additional signatory requirements. There is a process to go through in order to do this e.g. where OMARs need updating, international discussions with trading partners would be required and this would be addressed progressively over time.

**ELP Changes**

The changes would include removing signatory requirements and streamlining obligations e.g. for annual reporting, providing controlled copies of laboratory procedures to MPI for applications, etc.

**Implementation of the Laboratory Specifications Notice**

Initially there would be no changes to the administration of each programme. Laboratories would continue to work through the persons they would normally communicate with for dairy, LAS and ELP.

A two year transition period has been proposed to ensure:

* the registration of laboratories under the new Notice;
* MPI listings of laboratories;
* any changes to the scope of tests requiring signatories;
* the expected reduction in ISO 17025 audit schedules;

such that the deliverables of the current laboratory programmes would be maintained.

Depending on stakeholder feedback, one or more guidance documents would be developed to support the Notice to assist in the interpretation of requirements.

A proposed combined test list is also provided as part of this consultation and includes a number of changes particularly for the numbering of tests. MPI is seeking feedback on whether the test list should be combined in this manner as any such list will have immediate impact for IANZ. Currently the LAS schedule of tests exists at: <http://www.foodsafety.govt.nz/elibrary/industry/laboratory-approval-scheme/las-schedule-tests-lab-signatories-recognised-persons.pdf> and the ELP tests are an appendix in: <http://www.biosecurity.govt.nz/files/regs/exports/animals/elp-requirements.pdf>.

**Having Your Say**

MPI invites responses on the change in focus by the new draft Notice as well as the content, and welcomes stakeholders comments and feedback. Submissions can be made using the accompanying document ‘Consultation on Proposed new Animal Products (Specifications for Laboratories) Notice’. A number of questions have been asked to seek direction on some areas of implementation. It is appreciated if feedback was made in an electronic form such as a Word document to assist in the analysis of your submissions.

A summary of responses will be made available in due course. It is anticipated that once feedback is analysed the new Notice will be progressed with the aim of gazetting it as soon as practicable.