Proposed Export Laboratory System

NZFSA Public Discussion Paper; no. 02/08

January 2008
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NZFSA seeks submissions from all interested parties on any aspect of the draft “Animal Products (Export Laboratory System) Notice”.

The following points may be of assistance in preparing comments:

- Wherever possible, comment should be specific to a particular section of the document. All major sections are numbered and these numbers should be used to link comments to the document.
- Omissions should be clearly and separately indicated.
- Comments should be to the point and, where possible, reasons and data to support comment are requested.
- The use of examples to illustrate particular points is encouraged.
- As a number of copies may be made of your comments, please use good quality type, or make sure the comments are clearly hand-written in black or blue ink.

Please include the following information in your submission:

- The title of the discussion document;
- Your name and title (if applicable);
- Your organisation’s name (if applicable);
- Your address;
- The number(s) of the sections you are commenting on.

**Please submit your response by 5:00pm on 14 March 2008**

**Your comments should be sent to:**

Export Standards – Animal Products
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Please note that your submission is public information and subject to the Official Information Act 1982. Therefore if you consider that any or all information in your submission should be treated as confidential or is commercially sensitive, please state this clearly when making your submission.
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1 Introduction

This discussion paper presents a proposed notice under the Animal Products Act 1999 (“the Act”) that will consolidate the requirements for laboratories conducting testing, sampling, and chemical or biological or other analysis for the purposes of supporting official assurances and allowing assessment of compliance with requirements for any animal material or product intended for export.

2 Background

At present there are two principal systems governing laboratories conducting tests to support official assurances under the Act. These are the systems for laboratories testing –

- Dairy products
- Meat, seafood, poultry and other non-dairy animal products (known as the Laboratory Approval System, or “LAS”)

These have been developed independently over 15 to 20 years. During most of this time the industries operated under significantly different legislation. While there are important similarities, there are major differences and associated problems:

- The lack of a common philosophy, and no logical reason for the differences that exists, leaves NZFSA open to criticism by foreign authorities that rely on the official assurances provided to them;
- The existence of two sets of rules means that laboratories involved with both systems are required to duplicate administrative activities with resulting confusion and annoyance;
- The existence of independent systems within NZFSA leads to duplication of administrative effort, and lack of overall accountability.
3 Proposed system

3.1 Scope of the proposed system

The proposed system covers all laboratories conducting tests required to support official assurances and maintain the integrity of the export programme. As such it covers:

- Tests of both dairy and non dairy products;
- Where required by overseas markets, the environment in which these products are handled.

Unless there is a specific requirement to do so to meet an overseas market requirement, it does not cover:

- Tests that are part of the routine quality assurance of a Risk Management Programme;
- Tests conducted to meet customer requirements.

3.2 The default position

The proposed system is designed to provide a common approach which adopts the strengths of the existing systems. At the same time it must ensure maximum flexibility to address the wide range of products and industries covered by the laboratories within the system.

As a basis for this, a default position is proposed which is to be followed for all laboratories, unless there is a specific reason to adopt an alternative. This default is that all laboratories -

- Must be recognised in terms of Part 8 of the Animal Products Act; and
- Must be accredited for specified tests or test methods by International Accreditation New Zealand (IANZ) to New Zealand Standard NZS ISO/IEC 17025:2005 standard "General Requirements for the Competence of Testing and Calibration Laboratories".

While it will be a fundamental requirement that the responsibility for compliance with the system will rest with the laboratory operator, it is also proposed that all laboratories should have a person identified as the “day-to-day manager” who is the person through which NZFSA will normally communicate.
3.3 Additional requirements

For some tests, the default position is all that will be required. In many situations, however, there are additional requirements. In practice, these requirements stem from the specific tests the laboratory wishes to conduct. To provide flexibility, therefore, the proposed system links these additional requirements to the relevant tests by making them conditions for conducting the tests.

Specific issues that will be addressed in this manner include the following:

- Tests which are at present part of the LAS system must be conducted under the responsibility of recognised persons identified as recognised signatories. The acceptance of the LAS system by the authorities in overseas markets means this requirement must be maintained for these tests.

- Tests now presently part of the dairy system will continue to be supervised by persons identified as key technical personnel.

- Laboratories conducting certain tests are required to take part in specified Inter Laboratory Comparison Programmes. This requirement will be continued for the appropriate tests.

- Laboratories at present part of the dairy system are subject to performance based assessment by IANZ. This requirement will be continued for the appropriate tests.

- Many tests have specified methods that must be used. These may be methods set out in New Zealand law, but are more frequently methods required by other countries or established during negotiations on market access. These are designated as “official test methods”, and they must be used without alteration.

- For a number of tests the persons who conduct them must have specified qualifications.

3.4 Approval of test methods

All tests of concern to the programme become “official tests”. These describe the product (or other item of interest) that is be tested, and the attribute or characteristic to be determined. They do not describe the method – the default position is that the selection of method is up to the laboratory, and no other conditions apply. Where no official method is set out for a test, it is proposed that responsibility for choosing an appropriate method rest with the laboratory, subject to any view that IANZ may have.
Where official methods are specified, laboratories will still be able to seek approval for change. This will be referred to the appropriate experts within NZFSA, but as with the existing systems, any significant change is unlikely to be approved.

In some cases in the present systems, changes of a minor nature are subject to detailed scrutiny. It is possible that this will be relaxed as the new system is put into place.

3.5 The non-standard situation

Some situations do not fit easily into the pattern described above. For this reason provision is made for the Chief Executive to allow alternatives. These are:

- Laboratories may be “authorised” as part of the system, rather than recognised. This will allow laboratories outside New Zealand (and therefore not subject to New Zealand law) to be included within the system.

- It will also allow laboratories within New Zealand to be included where the Chief Executive believes that it is appropriate to do so, and that the integrity of the system can be maintained without the need for recognition.

- Provision may be made for laboratories to operate to a standard other than New Zealand Standard NZS ISO/IEC 17025:2005 standard “General Requirements for the Competence of Testing and Calibration Laboratories”. There is at present one laboratory in this category within the LAS system.
4 Impact of the proposed system

4.1 Market exposure

Many markets have strict requirements for laboratories testing product for assurance purposes, including in some instances, a requirement to use government owned laboratories. In order to justify the approach that New Zealand takes, it must have a robust system in place that will withstand criticism by overseas authorities.

The present operation of dual systems is not considered sufficiently robust to meet such criticism. The proposed system is designed to significantly reduce this exposure to criticism and the possibility of any adverse actions.

4.2 Requirement for recognition

The introduction of a general requirement for recognition under the Act will have minimal impact on existing dairy system laboratories, but will require a significant change for existing LAS laboratories.

LAS laboratories are “approved” under the LAS system. The process of approval is essentially the same as that for recognition, but does not involve the rigour of meeting the specific requirements for recognition set out in the Act. Existing LAS laboratories will therefore be required to apply for recognition. This will require the completion of the details required in the standard application form (AP8: “Recognised Agency Application Form”), but otherwise be handled administratively within NZFSA.

All laboratories would be issued with new conditions of recognition. In the case of dairy system laboratories this will mean the withdrawal of existing conditions as provided for in Section 105 of the Animal Products Act. In the case of LAS laboratories this will mean replacement of the existing conditions of approval.

A draft set of conditions is contained in Appendix 1.
4.3 Conditions applying to tests

The proposal does not change existing conditions for any test or test method. This means there will be no impact on laboratories.

4.4 Laboratories at present within both existing systems

Several laboratories at present operate under both the dairy and LAS systems. They will be able to extend their present recognition (as part of the dairy system) to incorporate their present LAS tests.

This will minimise the impact of the transition, while the introduction of a single system will simplify their ongoing reporting and administration.

4.5 Administrative activities

There will be an initial increase in administrative activities within NZFSA to handle the changes involved. In the longer term there will be reduction in administration.

4.6 Summary of impacts

<table>
<thead>
<tr>
<th>During change over</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>NZFSA exposure to market criticism</td>
<td>Possible reduction</td>
</tr>
<tr>
<td>Dairy Laboratories</td>
<td>May be small impact when the Conditions of Recognition alter (estimated to be less than one person – day)</td>
</tr>
<tr>
<td>LAS Laboratories</td>
<td>New application required to become recognised (estimated to be not more than one person – day)</td>
</tr>
<tr>
<td>Joint Laboratories</td>
<td>Application for extension to existing list of dairy tests to include LAS tests (estimated to be less than one person – day)</td>
</tr>
<tr>
<td>NZFSA</td>
<td>Increased work load (of order of one person for one month)</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>On going</th>
<th>Impact</th>
</tr>
</thead>
<tbody>
<tr>
<td>NZFSA exposure to market criticism</td>
<td>Significant reduction</td>
</tr>
<tr>
<td>Dairy Laboratories</td>
<td>Small reduction over time</td>
</tr>
<tr>
<td>LAS Laboratories</td>
<td>Small reduction over time</td>
</tr>
</tbody>
</table>
Joint Laboratories | Moderate reduction due to single administrative procedure
---|---
NZFSA | Improved efficiency

5 Legislative Framework

5.1 Links to the Animal Products Act 1999

5.1.1 Recognition

The ability to recognise laboratories is included in Part 8 of the Act:

Section 100 (1) allows the Chief Executive to: “recognise that person or body as an agency that may be responsible for the verification functions and activities or other specialist functions and activities for the purposes of this Act.”

100 (3) states: “Without limiting the generality of subsection (1), the functions and activities for which an agency may be recognised include—

“(d) Functions and activities in relation to the testing, sampling, and chemical or biological or other analysis of animal material or products.”

This is already done for laboratories operating within the dairy system.

A similar provision provides for the recognition of people (Section 101). This covers the situation of “recognised signatories” presently operating within the LAS system, and which is to be carried over into the proposed system.

5.1.2 Export requirements

Specific application of this Notice to export requirement is covered by Section 60. This authorises the Chief Executive to “specify requirements in relation to all or any class or description of animal material or animal product intended for export …” if this is “… necessary or desirable for the purpose of facilitating access to overseas markets”.
5.1.3 Conditions on tests

The Chief Executive is able to impose such conditions as he/she considers appropriate. For instance, Section 105(1) states that recognition "may be subject to such conditions as the Director-General [i.e. Chief Executive] thinks fit and specifies in the notice of recognition."

The Act makes no comment about the range or application of conditions, or the approach to be taken to specifying these. For clarity, Part 3 of the proposed Notice sets out a series of parameters that will be considered as part of the Export Laboratory System.

5.2 Use of schedules

5.2.1 Tests and test conditions

The list of tests, together with the conditions applying to them, is an essential feature of the system. Legal advice is that to make the tests an integral part of the Notice, and to ensure enforceability of the conditions, they must be listed as part of the Notice.

Schedule 1 of the Notice therefore sets out the tests to be covered by the system, while Schedule 2 lists the conditions that apply to the various tests.

Tests and test conditions are subject to change. This means that from time to time changes to Schedules 1 & 2 will be necessary. Experience with the LAS system, which follows a similar approach, suggests that changes will be necessary three to five times per year.

While this will mean issuing amendments to the Notice, it is not expected to lead to an increase in administrative burden.

5.2.2 Sensitive information

Section 60A of the Act, allows "export requirements that are commercially sensitive" to be kept confidential, and access limited to those whose "specific export or processing activities cannot be properly undertaken under this Act unless they have that access".

This applies to much of the information associated with the proposed Schedule 1.

This confidential information is therefore not included within the Schedule, but is available to laboratories and organisations with Overseas Market Access Requirement (OMAR) access.
Any organisation with OMAR access, registered Category 1 dairy laboratory or approved LAS laboratory that is not able to access this should contact NZFSA at http://www.nzfsa.govt.nz/animalproducts/publications/forms/passwd-form.htm

5.2.3 Conditions relating to provision of independent services

The Chief Executive is able to enter into contracts, or negotiate Memoranda of Understanding, for the supply of independent services to any programme that the NZFSA may operate. This authority exists outside the scope of this Notice, and such arrangements are normally confidential commercial arrangements between the parties.

Some aspects of such arrangements, however, may have an impact on third parties. For the proposed system, all laboratories are required to be assessed by IANZ against New Zealand Standard NZS ISO/IEC 17025:2005, or by IANZ or other organisation to an alternative standard. Depending on the tests the laboratory conducts it may also be required to take part in a specified Interlaboratory Comparison Programme (ILCPs).

To cater for this, the aspects of such arrangements that will impact on laboratories are set out in Schedules to the Notice. Schedule 3 relates to the performance of ILCPs. Schedule 4 relates to assessments.

5.3 Other considerations

It is necessary to ensure that the interface is clear between the requirements of the new system and existing requirements. In particular, it is important that any “export laboratory system” laboratory recognised to conduct tests on dairy products is exempted from the requirements that exist at present for Category 1 Dairy laboratories.

It is proposed that this be addressed by a savings clause within the Notice.
6 Appendix 1: Draft Conditions of Recognition

Note: These draft “Conditions of Recognition” refer to the conditions issued under Section 103 “Grant of Recognition” and Section 105 “Conditions of Recognition” of the Animal Products Act 1999.

General Conditions

1. The laboratory must adhere strictly to the requirements of the Animal Products (Export Laboratory System) Notice 2008; including
   i. continuing to meet the conditions for recognition, including the payment of any fees that may be due;
   ii. ensuring that the staff of the laboratory have an appropriate understanding, and comply with the requirements, of the system;
   iii. documenting the proficiency and performance of each key technical person, competent person and recognised signatory (where recognised signatories are required), and replacing any person judged not competent to perform a test for which that person was appointed; and
   iv. documenting the circumstances and any corrective action arising from participation of any person in any proficiency testing programme; and
   v. making available any reports on such matter as the Chief Executive or his agent or a representative of IANZ may request.

2. The laboratory must ensure that it meets the requirements of ISO 17025 and that it holds current accreditation from IANZ for each of the tests listed in the Schedule to this Notice of Recognition; and that
   i. it does not conduct any official test or official test method for the purposes of this system unless accredited for that test or test method by IANZ;
   ii. it makes adequate arrangements with IANZ to be assessed by IANZ -
      • according to the conditions for assessment where these are a condition of any test for which the laboratory is recognised; or
• according to the IANZ programme for routine reassessments, and annual surveillance assessments, where no test for which the laboratory is recognised contains any condition relating to assessment or audit; and

iii. it authorises IANZ to report to the Chief Executive or his/her appointee on any critical non-compliance found, and when requested by the Chief Executive or his/her appointee in writing, to make available a copy of any audit report.

3. The laboratory must comply with all conditions associated with each of the tests listed in the Schedule to this Notice of Recognition; including –

i. ensuring that all persons who conduct or supervise or sign-off the test reports of any test are competent, and in particular –

• by appointing one or more signatories who must be recognised signatories as set out in clause 15 of the Animal Products (Export Laboratory Recognition Programme) Notice 2008, for each test for which this is a requirement; and

• by appointing one or more persons (who may be recognised signatories) with the specified qualifications to conduct or supervise any test for which special qualifications are required; and

ii. taking part in any designated proficiency programme required for any test for which this is a condition; and

iii. authorising the provider of any proficiency programme to report to, and make available copies of any reports to, the Chief Executive or his/her appointee; and

iv. adhering to the test methods for which the laboratory is recognised without change unless and until –

• the laboratory shall have been accredited by IANZ for the new method; and

• in the case of any test having a condition that approval for change must be made by NZFSA, that formal approval shall have been granted by NZFSA and advised to the laboratory.

4. The laboratory must ensure that no test report or test certificate is used in a misleading manner, nor make any statement relevant to its recognition which may be considered misleading or unauthorised; in particular
i. it must not issue any test report for NZ official assurances purposes except for those tests listed in the Schedule to this Notice;

ii. it must not issue any test report for the purposes of this System during any time that it is closed.

5. The laboratory must advise the Chief Executive or his/her appointee of –

i. any temporary closure,

ii. any matter that may indicate a critical non compliance,

iii. emerging trends that have the potential to affect test results,

iv. any pressure from a client to alter test results, or to re-test, without good reason;

v. any significant changes of the circumstances of the laboratory including changes in –

- legal, commercial or organisational status;
- organisation or management structure, including any changes involving the day-to-day manager and other key managerial staff;
- Policies or procedures;
- Premises;
- Personnel, equipment, facilities, working environment or other resources which have the potential to have an adverse effect on test results;
- Signatories;
- Any other matters which may affect the capability of the laboratory to meet the requirements for recognition.

6. The laboratory must make itself available for audit –

i. by any agency or person appointed for that purpose by the Chief Executive; or

ii. by the representatives of any other country as part of an assessment of compliance of the Export Laboratory System with market access requirements.
7. The laboratory has the right to identify itself, and the tests listed in the Schedule attached to this Notice, as recognised under this System by:

- making the statement “NZFSA Recognised” on any test report or test certificate which relates solely to a test or tests for which recognition has been granted;
- making in any document the statement “NZFSA Recognised” followed by an appropriate reference to any one or a combination of tests for which recognition is held.

i. The laboratory must never make or imply that its recognition is an approval of any animal product.

Special Conditions

[anything special that may have limited application to this laboratory, or a few laboratories, or which will apply for a limited period.]

Term of Recognition

1. Provided that the laboratory continues to comply with the conditions above, this recognition will remain valid until [12 months from date of issue, or any earlier date the Chief Executive may advise].

2. If the laboratory is closed for a period of more than three months, it will remain recognised, but the schedule of recognised tests will be cancelled.

Note: When applying for renewal of recognition, it is the responsibility of the laboratory to provide evidence of –

i. current accreditation by IANZ; or

ii. progress toward completion of an assessment by IANZ.

Schedule of Tests and Test Methods [to be attached as a separate Schedule that can be easily replaced]

The laboratory is recognised for the following tests / test methods as at [date]:

[test / test methods to be listed here]