Ministry for Primary Industries
Manatū Ahu Matua

Animal Products Notice

Dairy Recognised Agencies and Persons Specifications

[Subtitle]

[Document Date]

Issued under the Animal Products Act 1999

New Zealand Government

TITLE

Animal Products Notice: Dairy Recognised Agencies and Persons Specifications

COMMENCEMENT

This Animal Products Notice comes into force on [Effective Date]

REVOCATION

This Animal Products Notice revokes and replaces the Animal Products Notice: Dairy Recognised Agency and Recognised Persons Specifications dated 26 August 2015.

ISSUING AUTHORITY

This Animal Products Notice is issued pursuant to section 167(1)(m), (maa) and (maab) of the Animal Products Act 1999.

Dated at Wellington this ... day of .....

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

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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 the New Zealand dairy industry for any person or agency to be recognised as any of the following:

a) an evaluator and verifier of risk management programmes;
b) a verifier of regulated control schemes (including a responsible verifier for farm dairy operators and depot operators under the Raw Milk for Sale to Consumers Regulations 2015);
c) a verifier of overseas market access requirements;
d) a raw milk farm dairy assessor operating under the Raw Milk for Sale to Consumers Regulations 2015;
e) a laboratory that tests dairy material and dairy product.

Background

(1) In 2011, the Ministry of Agriculture and Forestry (MAF) issued the 'Animal Products (Dairy Recognised Agency and Recognised Persons Specifications) Notice 2011 Number 2' which specified requirements and procedures for the recognition of agencies and persons.

(2) In 2015, the 'Animal Products Notice: Specifications for Laboratories' came into effect which required consequential changes to the 'Animal Products Notice: Dairy Recognised Agency and Recognised Persons Specifications'. These changes were editorial in nature. At the same time the document was reformatted into MPI's latest format and a number of minor amendments were also made.

(3) On 1 March 2016, the Raw Milk for Sale to Consumers Regulations 2015 came into force. Those regulations impose a regulated control scheme (RCS) under the Animal Products Act 1999 in relation to the production and processing of raw milk intended for sale or delivery to a final consumer (RCS raw milk). The regulations impose certain assessment and verification requirements with respect to RCS raw milk production and processing.

(4) Transitional provisions provided that certain recognised persons and agencies:

a) could perform certain specialist raw milk assessment and verification functions; and
b) would be treated as being recognised persons or agencies with respect to those specialist functions for a time period ending on 28 February 2017.

(5) Changes to the Animal Products Notice: Dairy Recognised Agency and Recognised Persons Specifications were needed to provide for recognition of RCS raw milk assessment and verification functions from 1 March 2017. The Notice was also amended to provide generally for recognition of verifiers of regulated control schemes, and to make minor amendments to apply technical corrections.

Who should read this Animal Products Notice?

A person should read this Notice if, for the purposes of the New Zealand Dairy Industry, they want to apply for or retain recognition as a person or agency as any of the following:

a) an evaluator or verifier of risk management programmes;
b) a verifier of regulated control schemes (including a responsible verifier for farm dairy operators and depot operators under the Raw Milk for Sale to Consumers Regulations 2015);
c) a verifier of overseas market access requirements;
d) a raw milk farm dairy assessor operating under the Raw Milk for Sale to Consumers Regulations 2015;
e) a laboratory that tests dairy material and dairy product.

Why is this important?

(1) A person or agency that fails to comply with the requirements of this Notice may not be granted, or may not retain, as applicable, recognised person or recognised agency status.

(2) In addition, a person who fails to comply with the requirements of this notice may be committing an offence under Part 10 of the Animal Products Act 1999.

Document History

(1) This Notice replaces the Animal Products Notice: Dairy Recognised Agency and Recognised Persons Specifications 2015 dated 26 August 2015.

Other information

(1) The Animal Products Notice: Specifications for Laboratories commenced 31 August 2015 and specifies requirements for laboratories.

(2) The requirements of this Notice that relate to laboratories remain in force until 31 August 2017 but are only relevant for a particular laboratory performing tests until that laboratory is recognised as a laboratory under section 101 of the Act for the purposes of the Animal Products Notice: Specifications for Laboratories.

Part 1: Requirements

1.1 Application of this Part and requirement for recognition

(1) This Part applies to any person or agency applying under section 107 of the Act in relation to the New Zealand Dairy Industry for the purpose of being recognised as any of the following:

a) an evaluator or verifier of risk management programmes;
b) a verifier of regulated control schemes (including a responsible verifier for farm dairy operators and depot operators under the Raw Milk for Sale to Consumers Regulations 2015);
c) a verifier of overseas market access requirements;
d) a raw milk farm dairy assessor operating under the Raw Milk for Sale to Consumers Regulations 2015;
e) a laboratory that tests dairy material and dairy product.

(2) This Part also applies to any person or agency recognised under section 112 of the Act in relation to the New Zealand Dairy Industry as any of the following:

a) an evaluator or verifier of risk management programmes;
b) a verifier of regulated control schemes (including a responsible verifier for farm dairy operators and depot operators under the Raw Milk for Sale to Consumers Regulations 2015);
c) a verifier of overseas market access requirements;
d) a raw milk farm dairy assessor operating under the Raw Milk for Sale to Consumers Regulations 2015;
e) a laboratory that tests dairy material and dairy product.

1.2 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 ISO/IEC Standard 17020 Conformity assessment - Requirements for the operation of various types of bodies performing inspection; and
b) the current edition of ISO/IEC Standard 17025 General requirements for the competence of testing and calibration laboratories.

1.3 Definitions

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

accreditation body refers to IANZ or JAS-ANZ which are independent organisations of international standing that accredit organisations to ISO standards

Act means the Animal Products Act 1999

Category 1 laboratory means a recognised dairy laboratory that tests dairy product for export certification and tests samples to determine whether dairy product is fit for intended purpose or to meet overseas market access requirements. This definition expires on 31 August 2017

Category 2 laboratory means a recognised dairy laboratory belonging to an animal product business that tests its dairy product that is intended for sale in the New Zealand domestic market and tests samples (including raw milk) for internal quality control purposes. This definition expires on 31 August 2017

in-process laboratory means a recognised dairy laboratory that tests dairy material, the results of which are used as a basis for reduced testing of finished product to determine whether dairy product is fit for intended purpose or to meet overseas market access requirements. This definition expires on 31 August 2017

MPI is the Ministry for Primary Industries

raw milk farm dairy assessor has the meaning defined under the Raw Milk for Sale to Consumers Regulations 2015

recognised dairy laboratory means a laboratory that is a recognised agency for testing of dairy material or product. This definition expires on 31 August 2017

(2) Any term or expression defined in the Act, or in any regulations made under the Act (including, but not limited to, the Raw Milk for Sale to Consumers Regulations 2015), that is used but not defined in this Notice, has the same meaning as in the Act or regulations (as the case may be).

Part 2: Applications for Recognition

2.1 Application of this Part

(1) This Part applies to any person or agency applying under section 107 of the Act in relation to the New Zealand Dairy Industry for the purpose of being recognised as any of the following:

a) an evaluator or verifier of risk management programmes;
b) a verifier of regulated control schemes (including a responsible verifier for farm dairy operators and depot operators under the Raw Milk for Sale to Consumers Regulations 2015);
c) a verifier of overseas market access requirements;
d) a raw milk farm dairy assessor operating under the Raw Milk for Sale to Consumers Regulations 2015;
e) a laboratory that tests dairy material and dairy product.

2.2 General requirements

(1) Clause 2.2(4) expires on 31 August 2017.

(2) A person or agency applying for recognition as an evaluator or verifier must be accredited, by an accreditation body, to ISO/IEC Standard 17020.

(3) The Director-General may determine that not all persons within an agency need to have their competency assessed for the purposes of gaining accreditation.

(4) A laboratory (including a Category 1 laboratory, Category 2 laboratory and an in-process laboratory) applying for recognition to provide testing of dairy material, dairy product or samples must:

a) be accredited, by an accreditation body, to ISO/IEC 17025; and
b) have suitable premises, equipment, procedures and staff to ensure that all testing is carried out properly and competently at all times.

2.3 Category 2 laboratories

(1) Clause 2.3(2) expires on 31 August 2017.

(2) A laboratory applying for recognition to perform Category 2 laboratory functions and activities must have:

a) suitable premises, equipment, procedures, and staff to ensure that all testing is carried out properly and competently, at all times; and
b) documented procedures and systems in place to manage all of the following areas:

i) organisation and management;
ii) quality system, audit and review;
iii) personnel;
iv) accommodation and environment;
v) equipment and reference material;
vi) measurement, traceability and calibration;
vii) calibration methods and test methods;
viii) handling of test items;
ix) records; and
x) certificates and reports.

Part 3: Recognised Agency Requirements

3.1 Application of this Part

(1) This Part applies to any person or agency applying under section 107 of the Act in relation to the New Zealand Dairy Industry for the purpose of being recognised as any of the following:

a) an evaluator or verifier of risk management programmes;
b) a verifier of regulated control schemes (including a responsible verifier for farm dairy operators and depot operators under the Raw Milk for Sale to Consumers Regulations 2015);
c) a verifier of overseas market access requirements;
d) a raw milk farm dairy assessor operating under the Raw Milk for Sale to Consumers Regulations 2015;
e) a laboratory that tests dairy material and dairy product.

(2) This Part also applies to any person or agency recognised under section 112 of the Act in relation to the New Zealand Dairy Industry as any of the following:

a) an evaluator or verifier of risk management programmes;
b) a verifier of regulated control schemes (including a responsible verifier for farm dairy operators and depot operators under the Raw Milk for Sale to Consumers Regulations 2015);
c) a verifier of overseas market access requirements;
d) a raw milk farm dairy assessor operating under the Raw Milk for Sale to Consumers Regulations 2015;
e) a laboratory that tests dairy material and dairy product.

(3) A raw milk farm dairy assessor under 3.1(1) d) or 3.1(2) d) is not required to be employed or managed by a recognised agency.

3.2 General requirements

(1) A recognised agency, other than a laboratory, must have documented procedures and systems in place to manage all of the following areas:

a) documenting the applicable contractual conditions with its clients;
b) client confidentiality;
c) workload;
d) confirming ongoing competency of recognised persons and other key staff, and providing training as required;
e) any potential conflicts of interest;
f) recognised persons providing assessment services on its behalf;
g) relevant documents;
h) internal non-compliance;
i) management review of its quality system at appropriate times;
j) participation in industry standardisation sessions;
k) recommending assessment frequency to MPI;
l) resolution of client non-compliance and critical non-compliance, including (if relevant) follow-up of corrective actions with persons accountable for Risk Management Programmes;
m) notifying MPI of critical non-compliance;
n) immediate advice to MPI of potential critical situations;
o) reporting information, as required, concerning clients operating under Risk Management Programmes, to MPI;
p) overseeing the collection of samples from manufacturing clients as advised by MPI under the Independent Verification Programme; and
q) reporting information, as required, concerning their own operations, to MPI.

3.3 Laboratory requirements

(1) Clause 3.3 expires on 31 August 2017.

(2) A recognised dairy laboratory must ensure that the certificate of recognition issued by MPI is prominently displayed in the laboratory at all times.

(3) A recognised dairy laboratory must keep appropriate records to demonstrate that testing is carried out properly and competently.

(4) A recognised dairy laboratory must ensure that no significant changes are made to the premises, equipment, facilities or scope of operations unless:

a) the change has been approved by the Director-General, following a written application;
b) the change is carried out in a manner that, in the opinion of the Director-General, ensures that tests continue to be carried out properly and competently during and subsequent to the change; and
c) work on the change is started within 12 months of the Director-General's approval.

(5) A recognised dairy laboratory must advise MPI, in writing, if:

a) it ceases operating as a laboratory; or
b) the ownership or right of possession of all or part of the laboratory changes.

(6) Every person who acquires any interest in the ownership or possession of a recognised dairy laboratory must advise MPI, in writing, without delay.

3.4 Approval of test methods

(1) Clause 3.4 expires on 31 August 2017.

(2) The prior approval of the Director-General must be obtained for test methods intended to measure the following parameters:

a) inhibitory substances;
b) residues and contaminants in raw milk;
c) farm dairy water clarity; and
d) foreign matter.

(3) With the exception of those test methods covered under clause 3.4(2), Director General approval of test methods is not required provided:

a) analysis is undertaken in a dairy laboratory that is recognised by MPI in the appropriate category for the required test; and
b) the test methodology used is specified within the scope of the laboratory accreditation/assessment and has been validated for the intended product type(s).

(4) The exception in clause 3.4(3) does not apply where a particular method has been specified by way of Notice under the Act.

(5) In situations where approval is required, the Director-General may approve test methods from the following sources provided they are used within their scope and are not modified significantly:

a) international standards;
b) methods published in reputable international texts;
c) national or regional standards or legislation; or
d) any other sources that the Director-General considers acceptable.

(6) For a test method to be approved as an acceptable alternative to a specified method under clause 3.4(2):

a) the method must be shown to be at least equivalent to the specified method in terms of performance characteristics; and
b) the Director-General must have the freedom to accept an alternative.

3.5 Category 2 laboratory requirements

(1) Clause 3.5 expires on 31 August 2017.

(2) A Category 2 laboratory must have documented procedures and systems in place to manage all of the following areas:

a) organisation and management;
b) quality systems, audit and review;
c) personnel;
d) accommodation and environment;
e) equipment and reference material;
f) measurement, traceability and calibration;
g) calibration methods and test methods;
h) handling of test items;
i) records; and
j) certificates and reports.

Part 4: Recognised Persons

4.1 Application of this Part

(1) This Part applies to natural persons applying under section 107 of the Act in relation to the New Zealand Dairy Industry for the purpose of being recognised as any of the following:

a) an evaluator or verifier of risk management programmes;
b) a verifier of regulated control schemes (including a responsible verifier for farm dairy operators and depot operators under the Raw Milk for Sale to Consumers Regulations 2015);
c) a verifier of overseas market access requirements;
d) a raw milk farm dairy assessor operating under the Raw Milk for Sale to Consumers Regulations 2015.

(2) This Part also applies to any natural person recognised under section 112 of the Act in relation to the New Zealand Dairy Industry as any of the following:

a) an evaluator or verifier of risk management programmes;
b) a verifier of regulated control schemes (including a responsible verifier for farm dairy operators and depot operators under the Raw Milk for Sale to Consumers Regulations 2015);
c) a verifier of overseas market access requirements;
d) a raw milk farm dairy assessor operating under the Raw Milk for Sale to Consumers Regulations 2015.

4.2 Applications for recognition

(1) A person applying to the Director-General for recognition must have been assessed and recommended for recognition by:

a) the recognised agency by which the person is employed; or
b) in the case of a raw milk farm dairy assessor, the organisation that employs the person.

(2) The Director-General may determine that a person applying to the Director-General for recognition does not need to be individually assessed by the accreditation body.

(3) A person applying to the Director-General for recognition must:

a) be competent in the skills of assessment;
b) have relevant knowledge of, and experience in, the specific aspect of the dairy industry in which they provide assessment services;
c) demonstrate an understanding of dairy industry legislation and MPI Specifications relevant to their activity; and
d) for persons performing evaluation or verification functions:

i) be part of a recognised agency; and
ii) demonstrate an understanding of, and the ability to effectively apply, the quality system and procedures of the recognised agency.

(4) Any person intending to perform verification of dairy heat treatments must:

a) be recognised for risk management programme verification in the appropriate product group; and
b) have successfully completed one of the following courses and been assessed as competent:

i) Dairy Heat Treatment Verification, AsureQuality Ltd., New Zealand; or
ii) any other course that the Director-General accepts as equivalent to the course specified in clause 4.2(4)(b)i)

4.3 Maintaining Recognition

(1) In order to maintain recognition, recognised persons must:

a) demonstrate continued competency in all areas specified in clause 4.2(3); and
b) have annual internal management reviews and peer reviews.

(2) Persons, other than responsible verifiers operating under the Raw Milk for Sale to Consumers Regulations 2015, that are recognised for evaluation and verification functions must be assessed:

a) by an accreditation body and a technical expert acceptable to MPI for compliance with the criteria stated in clause 4.2(3); and
b) at the frequency provided in Part 5 of this Notice.

(3) The assessment in clause 4.3(2) must include an assessment of the ongoing consistency of the work of recognised persons.

Part 5: Performance Based Verification

5.1 Application of this Part

(1) This Part applies to any person or agency recognised under section 112 of the Act in relation to the New Zealand Dairy Industry as any of the following:

a) an evaluator or verifier of risk management programmes;
b) a verifier of overseas market access requirements;
c) a laboratory that tests dairy material and dairy product.

5.2 Performance based verification of recognised agencies and persons

(1) The performance of a recognised agency and recognised person providing evaluation and verification services to the New Zealand dairy industry, must be assessed:

a) by their accreditation body and MPI; and
b) at the frequency specified by MPI.

(2) For a recognised agency, the following performance standards must all be assessed:

a) history of compliance with ISO/IEC Standard 17020 and MPI requirements or conditions imposed on recognition;
b) history of effective management of client non-compliance;
c) history of effective management of own non-compliance;
d) history of effective management of recognised persons; and
e) history of complete, accurate and timely reporting to the accreditation body and MPI.

5.3 Laboratory performance based verification

(1) Clause 5.3 expires on 31 August 2017.

(2) The performance of a recognised dairy laboratory must be assessed by its accreditation body at the frequency specified by the MPI.

(3) In addition to the matters specified in clause 5.2(2), the following performance standards must be assessed:

a) for Category 1 laboratories, the history of compliance with this Notice, ISO Standard 17025 and with conditions imposed on recognition;
b) for Category 2 laboratories, the history of compliance with this Notice and with conditions imposed on recognition;
c) performance, as indicated by the regular and exception reports sent to MPI; and
d) management and resolution of non-compliance identified in the regular and exception reports.