

**Ministry of Agriculture and Forestry  
P O Box 2526, Wellington, New Zealand**

**MAF Food: Dairy & Plants**

**Circular no. 51**

*Dairy Industry Regulations 1990*

***Registration of Dairy Laboratories***

ISBN: 0-478-07522-7

## Issue of Circular

Regulation 59 of the *Dairy Industry Regulations 1990* allows the Director-General of the Ministry of Agriculture and Forestry to issue Circulars setting out criteria for matters which must be approved by, or done to the satisfaction of, the Director-General, pursuant to the *Dairy Industry Regulations 1990*.

This Circular, no. 51, containing 'MAF Standard D302.1, "Registration of Dairy Laboratories,"' is issued in accordance with that regulation 59.

This Circular, no. 51, takes effect on 23 December 1999.



Tim Knox  
**Director, Dairy and Plant Products**  
**MAF Food Assurance Authority**

23/12/99

*(Signed under authority delegated by the Director-General of MAF, pursuant to regulation 59 of the Dairy Industry Regulations 1990.)*

# Contents

- 1 Background
- 2 Summary
- 3 Outcome
- 4 Effective changes
- 5 Implementation
- 6 Effect on compliance costs

## **MAF Standard D302.1, “Registration of Dairy Laboratories”**

- 1.0 SCOPE
- 2.0 PURPOSE
- 3.0 OUTCOME
- 4.0 INTERRELATED REQUIREMENTS
- 5.0 ADDITIONAL RESOURCES
- 6.0 DEFINITIONS
- 7.0 REQUIREMENTS
- 8.0 VERIFICATION
  - 8.1 Criteria
  - 8.2 Decision
  - 8.3 Result
- 9.0 VERSION CONTROL

## **APPENDICES**

### **One: ACCEPTABLE CRITERIA**

- 1.0 Categories of laboratories
  - 1.1 Category 1 laboratories
  - 1.2 Category 2 laboratories
- 2.0 Additional registration criteria
  - 2.1 General criteria
  - 2.2 ILCP
  - 2.3 Reporting criteria
  - 2.4 Pathogen laboratories

### **Two: IMPORTING COUNTRY REQUIREMENTS**

## **1 Background**

The MAF Standard on Registration of Dairy Laboratories was developed to:

- outline regulatory requirements specified in New Zealand dairy legislation for registration of dairy laboratories,
- describe acceptable criteria (means for satisfying MAF that the requirements are being achieved), and
- outline relevant importing country requirements.

## **2 Summary**

This Standard specifies requirements relating to registration of dairy laboratories to ensure that they perform tests properly and competently.

Appendix One outlines acceptable criteria for demonstrating that the outcomes in the Standard are achieved, including:

- accreditation of Category 1 laboratories to ISO Guide 25/ ISO Standard 17025,
- recognition of Category 2 laboratories as meeting the requirements of MAF Standard MRD-Stan 5, and
- regular reporting concerning the performance of the laboratory.

Proposals for alternative criteria may be approved by MAF, provided it can be demonstrated to MAF's satisfaction that the required outcomes will be achieved.

Appendix Two outlines importing country requirements relating to dairy laboratory registration.

## **3 Outcome**

All dairy laboratories that test dairy products and produce for food safety, truth of labelling and export certification, are registered by MAF Food, in compliance with regulations 25 to 35, 6(a) and 9(k) of the *Dairy Industry Regulations 1990*.

Where MAF provides official assurances to international competent authorities, the relevant importing country requirements are demonstrated to be met.

#### **4 Effective changes**

This Standard will introduce the following changes to the previously existing situation.

- Where the results from an in-process testing laboratory are being used as a basis for rationalised testing, or export certification of finished product for food safety, truth of labelling or importing country required tests, the laboratory must be either an independently registered dairy laboratory or registered as part of a Category 1 laboratory.
- The date of expiry of registration is referred to on the registration certificate and listed on the MAF Food: Dairy & Plants website.
- Only the site manager, or registered signatories authorised by the site manager, may sign test reports.
- The person signing the test report is responsible for ensuring that all tests have been performed in laboratories registered to do those tests.
- Registered dairy laboratories must report specific information concerning their performance to MAF Food.

#### **5 Implementation**

The Standard will apply from the date of its issue by Circular. A transition period of twelve months is provided to allow for the orderly review of quality systems. When the accreditation/recognition body does the next routine assessment of the registered laboratory, they will assess the laboratory against this standard, as well as ISO Guide 25/ISO Standard 17025 or MAF Standard MRD-Stan 5.

#### **6 Effect on compliance costs**

No additional compliance costs are anticipated. Category 1 laboratories will continue to be assessed by an accreditation body. Category 2 laboratories will be assessed by an approved accreditation/recognition body.

# MAF Standard D302.1, "Registration of Dairy Laboratories"

## 1.0 SCOPE

This Standard contains the outcomes for registration of dairy laboratories, including registration of:

- Category 1 laboratories that test products for export certification and samples to determine food safety and truth of labelling;
- Category 2 laboratories that test the company's own products for sale in the New Zealand domestic market, and samples (including raw milk) for internal quality control purposes; and
- in-process laboratories that test produce for truth of labelling and food safety, the results of which are used as a basis for reduced testing of finished product for food safety, truth of labelling or importing country required tests.

Category 1, Category 2 and in-process testing laboratories must comply with this Standard.

## 2.0 PURPOSE

This Standard sets out the outcomes that are specified in the *Dairy Industry Regulations 1990* relating to dairy laboratories in order to be registered by MAF Food.

The acceptable criteria outlined in Appendix One of this Standard were developed in consultation with industry to establish clear rules for judging whether or not a proposed PSP is satisfactory, and to assist parties to achieve the outcomes described in the Standard. Proposals for alternative criteria will be approved by MAF, provided it can be demonstrated to MAF's satisfaction that the required outcomes will be achieved.

Appendix Two of this Standard outlines importing country requirements relating to official assurances provided by MAF concerning registration of dairy laboratories.

## 3.0 OUTCOME

All dairy laboratories that test dairy products and produce for food safety, truth of labelling and export certification, are registered by MAF Food, in compliance with regulations 25 to 35, 6(a) and 9(k) of the *Dairy Industry Regulations 1990*.

Where MAF provides official assurances to international competent authorities, the relevant importing country requirements are demonstrated to be met.

#### 4.0 INTERRELATED REQUIREMENTS

The following standards must be read in conjunction with this Standard.

- ISO/IEC Guide 25: 1990 (E) “General requirements for the technical competence of testing laboratories” (to be replaced by ISO Standard 17025). International Standards Organisation, 1990.
- ISO Standard 17025, “General Requirements for the Competence of Testing and Calibration Laboratories.” International Standards Organisation, 1998.
- IANZ Specific Criteria Schedule No 1, “Dairy Testing Laboratories” (will become Schedule No. 9 when this Circular is issued).
- MAF Standard D301, “MAF-Approved Dairy Test Methods” (once promulgated). Dairy and Plant Products Group, Food Assurance Authority, New Zealand Ministry of Agriculture and Forestry.
- MAF Standard D303, “Performance Measurement of Dairy Laboratories” (once promulgated). Dairy and Plant Products Group, Food Assurance Authority, New Zealand Ministry of Agriculture and Forestry.
- MAF Standard DXXX, “Interlaboratory Comparison Programmes” (once promulgated). Dairy and Plant Products Group, Food Assurance Authority, New Zealand Ministry of Agriculture and Forestry.
- MAF Standard MRD-Stan 5, “General Requirements for the Competence of Category 2 Laboratories.” Regulatory Authority, New Zealand Ministry of Agriculture and Forestry, 1993.
- MAF Standard MRD-Stan 17, “Standard for the National Monitoring Programme for Residues in Raw Milk (Draft).” Regulatory Authority, New Zealand Ministry of Agriculture and Forestry.

#### 5.0 ADDITIONAL RESOURCES

The following documents are useful resources.

- *Dairy Products Safe and True.* Dairy and Plant Products Group, Food Assurance Authority, New Zealand Ministry of Agriculture and Forestry, 1999. World Wide Web address: [www.maf.govt.nz/Dairy/](http://www.maf.govt.nz/Dairy/)
- *Proficiency Programmes Information Manual.* AgriQuality New Zealand Ltd, 1999.

## 6.0 DEFINITIONS

These definitions must be read in conjunction with the interpretations in the *Dairy Industry Act 1952* and the *Dairy Industry Regulations 1990*.

MAF Food: Dairy & Plant Products Group definitions of terms can be found in their “Glossary of Terms,” available on the Dairy & Plants website ([www.maf.govt.nz/Dairy/](http://www.maf.govt.nz/Dairy/)).

**Accreditation** - Formal granting of recognition of competence for specified categories, following assessment against a standard, by an accreditation body.

**Accreditation body** – An internationally recognised, independent organisation which is authorised to accredit organisations to certain ISO standards. Currently, only IANZ and JAS-ANZ are accreditation bodies in New Zealand.

**Assessment** – Systematic examination of an individual, organisation, plan, programme, or system against regulatory requirements.

**Authorised signatory** – Person within an organisation who is authorised by an accreditation body to sign endorsed reports on behalf of that organisation.

**Certification** - Provision of a written statement(s) confirming that the product described complies with relevant New Zealand legislation or importing country official requirements or both.

**Dairy produce** – Milk, cream, butter, cheese, and any other product of milk or cream.

**Dairy product** - Dairy produce intended for sale in, or export from, New Zealand for human consumption;

- (a) includes raw milk or cream intended for sale in New Zealand for human consumption as raw milk or cream; but
- (b) does not include raw milk or cream intended to be processed before sale in New Zealand for human consumption.

**FDA BAM** – *Bacteriological Analytical Manual for Foods* published by the FDA.

**IANZ** – International Accreditation New Zealand. An accreditation body.

**ILCP** – Inter-laboratory Comparison Programme.

**ISO Guide 25** – ISO/IEC Guide 25: 1990 (E) entitled “General requirements for the technical competence of testing laboratories” (to be replaced by ISO Standard 17025).

**ISO Standard 17025** – ISO Standard entitled, “General requirements for the competence of testing and calibration laboratories” (will replace ISO Guide 25:1990).

**MAF Compliance** – The Compliance and Investigation Group of MAF Food, reporting to the Director, Compliance and Investigation Group.

**MAF Food** – The Food Assurance Authority of the Ministry of Agriculture and Forestry.

**MAF Food: Dairy & Plants** – The Dairy and Plant Products Group of MAF Food, reporting to the Director, Dairy and Plant Products.

**Non-compliance** - Any failure to comply with regulatory requirements.

**Occupier** – In relation to a farm dairy, includes every person for the time being managing or controlling it. In relation to any other premises, includes every person for the time being carrying on business there.

**Pathogens** –Disease-causing organisms.

**Rationalised testing** – A scheme for product certification that uses knowledge of process capability, process control and product test information to give assurance of product quality.

**Recognition** – In relation to an individual or organisation, written confirmation from MAF that they have been assessed against MAF Standards as competent to provide evaluation or verification services to the dairy industry in specified categories. In relation to a Category 2 dairy laboratory, written confirmation from an accreditation or recognition body that it is has been assessed against MAF Standards as competent to provide verification services to the dairy industry.

**Recognition body** – An organisation approved by MAF to recognise Category 2 dairy laboratories.

**Registered laboratory** – A laboratory that is registered by MAF for the purposes of the *Dairy Industry Regulations 1990* or for the performance of other tests required for MAF certification.

**Registration** – The official process whereby MAF formally confirms approval by the Director-General pursuant to the *Dairy Industry Regulations 1990*. Applies to individuals, organisations, laboratories, and premises; includes adding those to its records, and other administrative aspects.

**Regulatory Verification Sampling Programme** – An independent check of all systems required for export certification.

**Sanction** – Official response to regulatory non-compliance.

**Significant change** – Any change made to key staff, environment, premises, equipment, facilities, process or product which has the potential to affect food safety.

## 7.0 REQUIREMENTS

All tests required by MAF must be carried out in a registered dairy laboratory.

Registered dairy laboratories must have suitable:

- premises,
- equipment,
- procedures, and
- staff

to ensure that all testing is carried out properly and competently, at all times.

Registered dairy laboratories must keep appropriate records to demonstrate that testing is carried out properly and competently.

Registered dairy laboratories are issued with a registration number and certificate of registration by MAF Food. Registration may be for a specified period. The occupier of a registered laboratory must ensure that the certificate of registration is prominently displayed in the laboratory at all times.

The occupier of a registered dairy laboratory must ensure that no significant changes are made to the premises, equipment or facilities unless:

- the change has been approved by the Director-General, following a written application;
- 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
- work on the change is started within 12 months of the Director-General's approval.

The occupier of a registered dairy laboratory must advise the Director-General, in writing, when:

- they stop operating the laboratory, or
- the ownership or right of possession of all or part of the laboratory changes.

Every person who acquires any interest in the ownership or possession of a registered dairy laboratory must advise the Director-General, in writing, without delay.

## **8.0 VERIFICATION**

Verification of compliance with this Standard is undertaken by the accreditation/recognition body during the annual assessments.

### **Registration of laboratories, including approved tests**

MAF Food maintains a register of registered laboratories and the tests for which it is registered. This register is available on the MAF Food: Dairy & Plants website at [www.maf.govt.nz/Dairy](http://www.maf.govt.nz/Dairy). This register is used to verify that:

- the laboratory displaying a registration certificate is currently registered (that is, registration has not expired), and
- the laboratory is currently registered for the tests it is reporting.

### **Categories of laboratories**

The accreditation/recognition body issues a certificate to the laboratory specifying its accreditation or recognition status.

- Category 1 dairy laboratories must be accredited by an accreditation body under the dairy testing programme.
- Category 2 dairy laboratories must be recognised by a MAF-approved recognition body under the dairy testing programme.

### **Accreditation status and approved signatories**

Accredited Category 1 laboratories are issued with a certificate by the accreditation body, stating that they comply with the Standards. This is accompanied by a schedule detailing the tests, test methods and products for which they are accredited, and listing the authorised signatories for those tests. This schedule is updated following the assessments.

### **Recognition status**

Recognised Category 2 laboratories are issued with a certificate of recognition by the accreditation/recognition body, stating that they comply with the Standards. This is accompanied by a schedule detailing the tests, test methods and products for which they are recognised. This schedule is updated following the assessments.

## **8.1 Criteria**

The criteria for assessing compliance with this Standard are as follows.

- The laboratory is assessed by competent assessors in the categories Lc (laboratory audit – chemistry), Lm (laboratory audit – microbiology), and/or Ll (laboratory audit – lead auditor), as appropriate, employed by a MAF-approved accreditation or recognition body.
- has documented procedures that address the requirements of this Standard.
- The procedures documented to meet the requirements of this Standard are being followed.
- The laboratory is currently accredited to ISO Guide 25/ISO Standard 17025 by an recognition/accreditation body, or recognised to MAF Standard MRD-Stan 5 by a MAF-approved body, to perform specified tests on specified products.
- Registered laboratories that perform tests, use test methods or test products which do not comply with their registration criteria, notify MAF Food, in writing, before the event.
- For registration to continue, laboratories must:
  - demonstrate to the accreditation/recognition body that they are continually following these requirements, and
  - address non-compliances issued by their accreditation/recognition body within the agreed time.

## **8.2 Decision**

The dairy laboratory is non-compliant if one or more of the criteria for assessing compliance is not met.

## **8.3 Result**

### **8.3.1 Compliant laboratories**

Laboratories which meet the requirements are accredited/recognised by their accreditation/recognition body. The accreditation/recognition body recommends to MAF Food that they be registered.

Laboratories which are accredited/recognised are registered by MAF Food and issued with a registration number and certificate. They are able to conduct tests for food safety, truth of labelling and, where appropriate, export certification of product from registered premises.

### 8.3.2 Non-compliant laboratories

Laboratories which do not meet the requirements are not accredited/recognised by their accreditation/recognition body.

Laboratories which are not accredited/recognised are not registered by MAF Food. MAF Food does not accept test results performed by unregistered laboratories.

If the accreditation/recognition body withdraws, suspends or changes the accreditation/recognition status of the registered laboratory, the accreditation/recognition body advises MAF Compliance of the change in status, and MAF Food may:

- cancel registration,
- vary any conditions subject to which a laboratory is registered, or
- impose any new or additional conditions subject to which a laboratory is registered.

The registration of a laboratory may be cancelled or amended if:

- the occupier of the laboratory concerned asks the Director-General to do so;
- the Director-General is satisfied that the laboratory no longer has the premises, equipment, procedures and staff necessary to ensure that the testing carried out there for the purposes of these regulations will be carried out properly and competently;
- the Director-General is satisfied during the past 6 months there has been a breach of any conditions subject to which the laboratory was registered; or
- the Director-General is satisfied that the occupier has failed to comply with any order under section 6 or section 7 of the Act.

## 9.0 VERSION CONTROL

Version	Date	Status	By	Approved
302.1	23 December 1999	Promulgated by Circular no. 51	Director, MAF Food: Dairy & Plants	

This copy may not be the most recent version of this document. It was current at the date in the footer of each page of the document. It is recommended that anyone intending to use this document should contact the Dairy & Plant Products Group of MAF Food or check its website ([www.maf.govt.nz/Dairy/](http://www.maf.govt.nz/Dairy/)) to confirm that this is the current version.

# Appendix One

## ACCEPTABLE CRITERIA

Following are criteria by which a dairy laboratory may be judged to satisfactorily achieve the requirements described in section 7 of this Standard. A dairy laboratory which meets these criteria will be registered by MAF.

Proposals for alternative criteria may be approved by MAF, provided it can be demonstrated to MAF's satisfaction that the required outcomes will be achieved. A guide to the information required in these proposals and the procedures used by MAF to assess proposals can be obtained from MAF Food.

### 1.0 Categories of laboratories

Registered dairy laboratories are registered as Category 1 or Category 2 laboratories.

#### 1.1 Category 1 laboratories

Category 1 laboratories are registered to test:

- for food safety, as required by the *Dairy Industry Regulations 1990* and subsequent amendments,
- for truth of labelling of dairy products, as required by the *Dairy Industry Act 1952*, and
- finished product for export to meet importing country specified tests.

They:

- are accredited under the dairy testing programme by a MAF-approved accreditation body, to ISO Guide 25/ISO Standard 17025,
- maintain a standard in Inter-laboratory Comparison Programmes, or equivalent, for the tests concerned, such that MAF has confidence in their testing ability,
- meet the requirements of all relevant MAF Food standards.

#### 1.2 Category 2 laboratories

Category 2 laboratories are registered by MAF Food to test only the company's own produce for food safety and truth of labelling:

- for the purposes of internal quality control (including raw milk testing), and
- for sale in the New Zealand domestic market.

Category 2 laboratories:

- are recognised under the dairy testing programme, by a MAF-approved recognition body, as meeting the requirements of MAF Standard MRD-Stan 5, and
- maintain a standard in inter-laboratory comparison programmes, or equivalent, for the tests concerned, such that MAF has confidence in their testing ability,
- meet the relevant requirements of all relevant MAF Food Standards.

## **2.0 Additional registration criteria**

### **2.1 General criteria**

Laboratories are registered for specific tests, test methods and products. This information is in the schedule issued by the accreditation/recognition body. Conditions may be applied to laboratory registration; for instance, it may be registered for a limited range of tests or for a fixed period of time.

Registered laboratories continuously meet the registration requirements during the registration period.

If the results from an in-process laboratory are being used to justify rationalised testing of finished product for food safety and/or truth of labelling, it is registered either as an independent laboratory, or as part of a Category 1 or 2 dairy laboratory.

### **2.2 ILCP**

Registered Category 1 and 2 laboratories participate in an inter-laboratory comparison programme (ILCP), if one is available for the tests and products for which they are accredited/recognised, to assure competence and demonstrate reliability of analytical results. The ILCP meets the requirements of MAF Standard DXX, “Interlaboratory Comparison Programmes,” and ISO Guide 43, part 1.

The laboratory manager monitors the performance of the laboratory in the ILCP and ensures that appropriate actions are taken in response to ILCP results, in accordance with MAF Standard DXX, “Interlaboratory Comparison Programmes.”

If ILCP is not available, other means are used to establish analytical capability, e.g. split verification samples or other split samples.

### 2.3 Reporting criteria

Registered laboratories report the following information concerning their performance of tests required by MAF Food, to MAF Compliance.

The following is reported before the event occurs:

- request to use non-approved test methods.

The following exception reports are reported as soon as practicable, but not later than 24 hours after the event:

- critical non-compliances and proposed corrective actions e.g. loss of critical equipment;
- resolution of critical non-compliances;
- poor performance in an ILCP, as defined by with MAF Standard DXX, “Interlaboratory Comparison Programmes;”
- emerging trends that have the potential to affect test results; or
- a client is exerting influence on the laboratory to alter test results or re-test, without good reason.

The laboratory reports to MAF within 10 working days of month end, a summary of its own performance. The frequency of regular reporting depends on the performance assessment category to which the laboratory is allocated. Refer to Draft MAF Standard D303 “Performance Measurement of Dairy Laboratories“. These regular reports concerning laboratory performance include notification of:

- occurrence of internal or external reviews of the quality system,
- participation in an ILCP,
- number of complaints received and resolution status,
- whether any retesting was required as a result of laboratory failures, and
- any other information that would give MAF a more complete picture of the laboratory’s performance.

## 2.4 Pathogen laboratories

In addition to being registered Category 1 laboratories, laboratories testing for pathogens do the following.

- Liaise directly with the client dairy companies on all quality and logistical problems.
- Always assign priority to the testing of dairy traceback samples.

The pathogen laboratory has in place suitable contingency plans to enable it to carry out Salmonella and Listeria testing in the event of a sudden, major increase in workload arising from a dairy company in a traceback situation. The contingency plans conform to the management, operational, technical and quality assurance requirements of ISO Guide 25/ISO Standard 17025, and ensure that the increased workload does not adversely affect the validity of the test results.

- Where circumstances arise that result in delays in testing samples, MAF Food and the affected dairy company are informed.

In case of a major breakdown in the pathogen laboratory which would result in excessive delays in testing, the laboratory informs the affected client dairy companies, and arranges to send the samples to another laboratory facility registered by MAF Food.

- Use only test methods currently approved by MAF Food, unless with the prior written consent of MAF Food and the affected client dairy company. A pathogen laboratory wishing to employ a test method other than one currently approved by MAF Food, seeks written approval from MAF Food for the proposed method prior to use.

## Appendix Two

### IMPORTING COUNTRY REQUIREMENTS

It is the responsibility of exporters to identify and comply with all importing country requirements; non-compliance is at their commercial risk.

Where MAF provides official assurances to competent authorities of importing countries, the statements to which MAF attests must be verifiable. Relevant requirements are described in the MAF Standard on dairy export certification.

#### 1.0 Testing dry milk products intended for export to the USA

Laboratories testing dry milk products intended for export to the USA must have a special approval from MAF Food.

In addition to being registered Category 1 laboratories, these laboratories must:

- be registered to test dry milk products using the FDA BAM method, or an accepted equivalent;
- accept FDA assessments and comply with the requirements of these assessments;
- store and retain the following information for each sample tested, for at least 7 years from the date of manufacture:
  - product type,
  - New Zealand Dairy Board specification number,
  - manufacturer's name and address,
  - factory registration number,
  - batch or lot number,
  - bag size,
  - number of bags per batch or lot,
  - test results for each test,
  - date of test; and

the laboratory must make an attested statement of this information available to the Director-General, on request;

- provide a monthly report to MAF Compliance covering:
  - a summary of internal and external quality control checks,
  - external assessment reports, action taken on non-conformances and corrective actions, and
  - changes to procedures, changes to personnel and changes to facilities; and
- comply with the requirements for pathogen laboratories listed in Appendix One.