

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

MAF Food: Dairy & Plants

Circular number 71
Dairy Industry Regulations 1990

D301.1 MAF-Approved Dairy Test Methods

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301.1	31 January 2002	Promulgated by Circular number 71	Director, MAF Food: Dairy & Plants	

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Issue of Circular and Implementation

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, number 71, containing ‘MAF Standard D301.1, “MAF-Approved Dairy Test Methods,”’ is issued in accordance with that regulation 59.

This Circular, number 71, takes effect on 31 January 2002

From the date of issue by Circular, this Standard will apply to all new test methods used for verifying conformance with regulatory requirements or official assurances. Test methods currently used for verifying conformance with regulatory requirements or official assurances, including those previously approved by MAF, will need to comply with this Standard 18 months from the date of issue by Circular.

This Circular number 71 revokes Circulars 13, 17, 19, 20, 22, and 25.



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

31 January 2002

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

Foreword

MAF provides a range of assurances, including official assurances, relating to the conformance of dairy produce and products to regulatory requirements. Along with laboratory capability and sampling, test methods contribute to the quality of the data and ultimately the conformance decision.

To enable MAF to have confidence, a mechanism is required to ensure that where assurances are required, dairy laboratories testing produce/product use only appropriate test methods. Appropriateness of a test method depends on the method's source, its performance characteristics and also the conformance limits and assurances.

This Standard outlines the mechanism to approve test methods to be used for the provision of data for conformance decision making and the provision of assurances. Test methods approved using the mechanism outlined in this Standard have not necessarily been validated. Dairy laboratories remain responsible for demonstrating that the methods used are appropriate (fit for purpose) in accordance with their accreditation to ISO Standard 17025 "General Requirements for the Competence of Testing and Calibration Laboratories" or recognition to MAF Standard MRD Stan-5, "General Standards for the Competence of Category 2 Laboratories".

The MAF Standard on MAF-approved test methods was developed to:

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

Specifically, this Standard sets out the outcomes that are specified in the *Dairy Industry Regulations 1990* relating to test methods.

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 test method is appropriate; and
- to assist parties to achieve the outcomes described in this Standard.

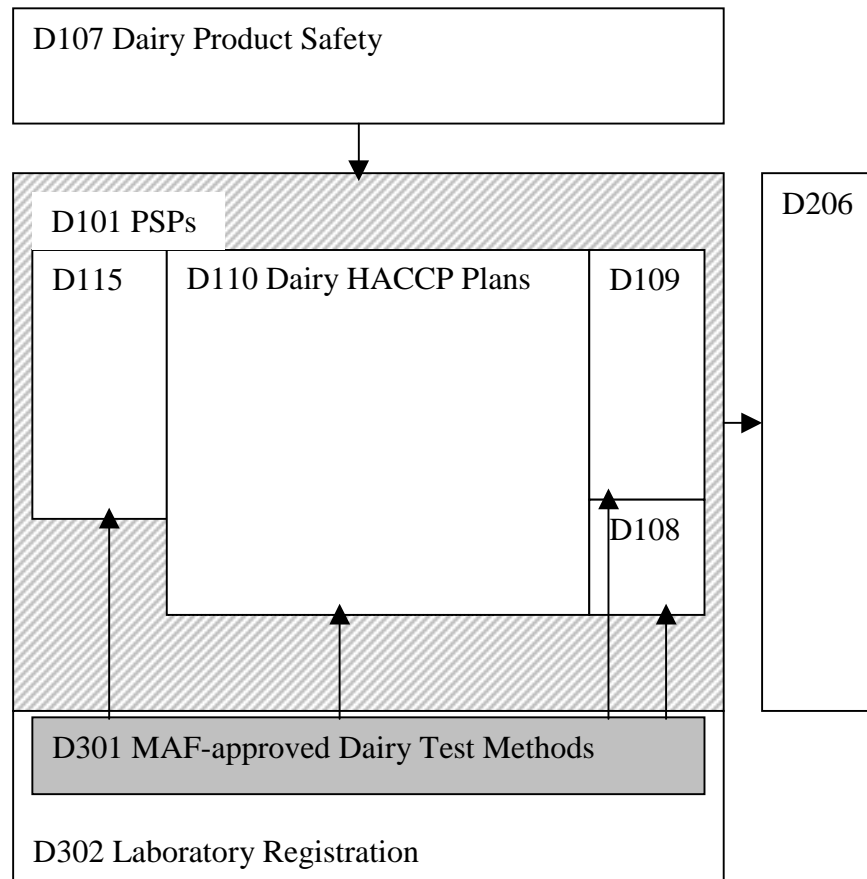
Dairy laboratories and parties seeking approval for test methods may offer proposals to MAF for alternate criteria that deliver the outcomes described in this Standard. Proposals for alternative criteria will be approved by MAF, provided it can be demonstrated to MAF's satisfaction that the required outcomes will be achieved. A guide to the information required in these proposals and the procedures used by MAF to assess proposals can be obtained from MAF Food.

Appendix Two of this Standard outlines importing country requirements relating to official assurances provided by MAF concerning test methods.

Preface

CONTEXT

This standard relates to other MAF standards as shown diagrammatically below.



RESOURCES

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

- MAF Standard D101, “Product Safety Programmes”
- MAF Standard D107, “Dairy Product Safety”
- MAF Standard D108, “Non-conforming Dairy Produce”
- MAF Standard D109, “Dairy Product Conformance”
- MAF Standard D110, “Dairy HACCP Plans”
- MAF Standard D115, “Raw Milk Acceptance”
- MAF Standard D206, “Dairy Sanitary and Related Export Certification”
- MAF Standard D302, “Registration of Dairy Laboratories”.

The following documents are useful resources:

- ISO/IEC Standard 17025, “General Requirements for the Competence of Testing and Calibration Laboratories”. International Standards Organisation 1999.
- MAF Standard MRD Stan-5 “General Standards for the Competence of Category 2 Laboratories”. Regulatory Authority, New Zealand Ministry of Agriculture and Forestry.
- “Parameters/attributes requiring a MAF-approved test method”. MAF Food: Dairy and Plant Products, 2001.

EFFECTIVE CHANGES

From the date of issue by Circular, this Standard will apply to all new test methods used for verifying conformance with regulatory requirements or official assurances. Therefore all new methods will need to be approved in accordance with this Standard from 31 January 2002.

Test methods currently used for verifying conformance with regulatory requirements or official assurances, including those previously approved by MAF, will need to comply with this Standard 18 months from the date of issue by Circular. Therefore all methods currently being used for verifying conformance with regulatory requirements or official assurances will need to be approved in accordance with this Standard from 31 July 2003.

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

- All test methods used for verifying the conformance of dairy produce or produce with regulatory requirements or attestations provided in official assurances are required to be MAF-approved.
- The mechanism to obtain MAF approval, based on application and assessment by an accreditation body, is defined.
- Methods from the following sources are subjected to assessment criteria and are normally approved by MAF provided that they were used within their scope and unmodified:
 - international standards, e.g. ISO, IDF, Codex; or
 - methods published in reputable international texts, e.g. standard methods published by the American Public Health Association, AOAC Official Methods of Analysis, “Pearson’s Chemical Analysis of Foods”; or
 - national or regional standards or legislation, e.g. New Zealand Standards, Australian Standards, British Standards, Euronorm Standards, USA FDA’s “Bacteriological Analytical Manual” (BAM), EU legislation, etc.
- All other methods may be approved by MAF provided they are characterised and meet the assessment criteria.
- A list of MAF-approved methods will be available on the MAF website.
- Test methods’ approvals will be reviewed:
 - every five years; or
 - following changes to regulatory requirements and official assurances; or
 - if there is evidence that a method may not be fit for purpose.

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MAF Standard D301.1, “MAF-Approved Dairy Test Methods”

1. SCOPE

This Standard contains the outcomes for test methods for them to be approved by MAF for verifying conformance of dairy produce or products:

- to regulatory requirements; and/or
- with attestations provided by MAF in official assurances.

This Standard applies to any test method used for verifying conformance of dairy produce or products:

- to regulatory requirements; and/or
- with attestations provided by MAF in official assurances.

All MAF-registered dairy laboratories must comply with this Standard.

2. DEFINITIONS

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).

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

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; and

- (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.

Fitness for purpose (of a test method) – The suitability of a test method for a particular application. Fitness for purpose examines the effect of the test method’s characteristics on assessments made using the results generated by that method, e.g. in a sampling plan used to determine whether a lot is acceptable.

Method characteristics – The characteristics of a test method determined in the validation process. These performance characteristics are used to assess the suitability of a test method for its intended purpose, i.e. whether it is fit for purpose.

Modification (of test methods) – Any change to a test method which changes the method’s characteristics and/or fitness for purpose.

Official assurance – Statement made by MAF to a foreign government, or an agent of a foreign government, attesting that, as appropriate, any one or more of the following applies in respect of any product:

- (a) any specified process has been completed under the relevant legislation with respect to the product concerned;
- (b) the product concerned meets the standards set under the legislation for that product;
- (c) any market access requirements of the importing country, which New Zealand has agreed to meet, that are stated in the assurance have been met by the system under which the product was produced or processed; and/or
- (d) the situation in New Zealand, in relation to any matter concerning animal material or animal products, is as stated in the assurance.

Regulatory requirements – Requirements described in or derived from legislation and/or importing country requirements, which must be met by regulated parties; found in legislation, MAF Standards, and MAF-approved documents (e.g. PSPs, MAF-approved standards).

Test method – A procedure describing a sequence of operations to measure the value of a certain attribute or parameter in the sample being tested.

Validation (of a test method) – The process of establishing the performance characteristics and limitations of a test method. This includes the identification of factors that may affect these characteristics as well as the extent the method can determine the analyte in a range of matrices and the effect of interferences.

Verification – Application of methods, procedures, tests and other checks, in addition to monitoring, to determine compliance with MAF-approved plans, programmes and systems, and to confirm the ongoing applicability of those.

3. OUTCOME

All test methods used to verify conformance of dairy produce or products to regulatory requirements, and/or with attestations provided by MAF in official assurances, are approved by MAF in accordance with the regulations for the registration of laboratories, regulations 27 (1), 30, 31 and 32 of the *Dairy Industry Regulations 1990*.

3.1 Methods requiring MAF approval

MAF approval is required for any test method used for testing dairy produce or products' conformance with:

- *Dairy Industry Act 1952*;
- *Dairy Industry Regulations 1990*;
- MAF Standards; or
- official assurances provided by MAF.

3.2 International, national or regional test methods

Test methods from the following sources are usually approved by MAF provided they are used within their scope and are unmodified:

- international standards;
- methods published in reputable international texts; or
- national or regional standards or legislation.

3.3 Other test methods

Test methods from the other sources may be approved by MAF subject to an assessment of the method.

4. VERIFICATION

As part of the assessment of a registered laboratory, the accreditation/recognition body verifies compliance with the outcomes described in section 3 of this Standard.

4.1 Compliance

The laboratory is compliant with the outcomes described in section 3 of this Standard if:

- MAF-approved test methods are used for testing dairy produce and products to verify conformance of dairy produce or products with regulatory requirements; and/or with attestations provided by MAF in official assurances.
- MAF Food's written approval to use an unapproved test method, has been obtained prior to the testing commencing and that the testing and test reporting has been done in accordance with the scope and restrictions specified in the approval.

Laboratories operating in compliance with the outcomes described in section 3 of this Standard are entitled to:

- Test dairy produce and products for the purposes of verifying conformance with regulatory requirements; and/or with attestations provided by MAF in official assurances.

4.2 Non-compliance

Non-compliance with the outcomes described in section 3 of this Standard constitutes an offence under regulation 47 of the *Dairy Industry Regulations 1990*.

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

If a dairy laboratory does not operate in accordance with the requirements in this Standard:

- an Order may be issued by a MAF Inspector to remedy any defects;
- export certification and/or use of any MAF marks may be suspended;
- registration of the laboratory may be cancelled or conditions varied or imposed; and/or
- prosecution for offences may occur.

Appendix One: Acceptable Criteria

Following are criteria by which a test method used by a MAF-registered dairy laboratory may be judged to satisfactorily achieve the outcomes described in section 3 of this Standard. Where each of these criteria are satisfied, MAF will approve a test method and accept test reports from registered laboratories using that test method.

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. 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 METHODS REQUIRING APPROVAL

MAF approval is required for any test method used for testing dairy produce or products' conformances with:

- *Dairy Industry Act 1952*;
- *Dairy Industry Regulations 1990*;
- MAF Standards; or
- official assurances provided by MAF.

MAF only accepts results from an approved method when assessing conformance. Where the manufacturing/customer specification specifies an unapproved test method then a MAF-approved test method is also used to test the produce/product and these results are used for assessing conformance.

Commentary

The laboratory manager is responsible for demonstrating that the test method is fit for purpose and this will be assessed during laboratory accreditation/recognition.

Where there is no MAF-approved method that is suitable, e.g. for testing a new product, MAF's written approval to use an unapproved test method is required. This approval is obtained prior to the testing commencing. Letters to MAF applying for interim approval of a method:

- are accompanied by as much of the information required in section 4.1 as is currently available;
- outline the process and plan to have the method fully approved; and
- provide the date by which the method will be fully approved in accordance with this Standard.

Interim approvals have an expiry date after which the method must be fully approved if it is to be used. Testing and test reporting using the method is done in accordance with the scope and restrictions specified in the interim approval.

Where results from in-process testing are used to verify conformance with regulatory requirements or official assurances provided by MAF, the methods used for in-process testing are required to be MAF-approved.

Commentary

A list of the tests (parameters/attributes) requiring a MAF-approved test method is provided on the MAF Food: Dairy and Plant Products website (www.maf.govt.nz/dairy/) under “Importing Country Requirements”.

2 TEST METHOD APPROVAL

2.1 Generally approved methods

Test methods from the following sources are usually approved by MAF provided they are used within their scope and are unmodified:

- international standards, e.g. ISO, IDF, Codex; or
- methods published in reputable international texts, e.g. Standard methods published by the American Public Health Association, AOAC Official Methods of Analysis, “Pearson's Chemical Analysis of Foods”; or
- national or regional standards or legislation, e.g. New Zealand Standards, Australian Standards, British Standards, Euronorm Standards, USA FDA’s “Bacteriological Analytical Manual” (BAM), EU legislation.

These methods are subjected to the assessment criteria outlined in Section 4.2 and approval is based on the recommendation of the accreditation body.

2.2 Other methods

Test methods from the following sources may be approved by MAF. These methods are characterised (refer Section 2.2.1 below) and subjected to the assessment criteria outlined in Section 3.2 and approval is based on the accreditation body’s recommendation:

- refereed scientific journals;
- in-house methods;
- other sources, e.g. test methods involving new technology. These methods normally come from instrument manufacturers instructions and technical publications.
- generally approved methods (refer section 2.1 above) used outside their scope and/or modified; and
- MAF-approved methods used outside their scope and/or modified.

2.2.1 Characterisation of a test method

The party undertaking the work nominates and uses a suitable standard or code to characterise the method. The nominated standard or code specifies the principles and process being used and is demonstrated to be appropriate for the purpose.

The standard or code may be obtained from:

- international standards and guidelines;
- national and regional standards;
- reputable scientific publications or organisations; or
- a MAF-approved code of practice.

In the absence of a suitable standard or code, then the method is characterised using acceptable scientific principles and practices.

Commentary

As method characterisation can involve considerable time and resources and is a specialist area, it is recommended that advice be obtained from an expert before commencing.

The following characteristics are determined. In some situations, e.g. residue analyses, additional characteristics may be required.

A Method performance characteristics required for continuous methods

Continuous methods produce results that are expressed as numbers. Examples of continuous methods are butter moisture (example of result: 15.5% moisture), and aerobic plate count (example of result: 150 colony forming units per ml).

The following characteristics are required for continuous methods, where applicable (if not applicable, please include a reason why):

- bias;
- precision (reproducibility or intermediate precision);
- limit of detection; and
- range.

The method is characterised across the testing range.

Bias is the average difference between the test results and the accepted reference value.

Precision is an assessment of the closeness of agreement between independent test results on the same sample obtained under specified conditions. *Reproducibility* (R) is the precision of a method where test results are obtained with the same method on identical samples in different laboratories with different operators using different equipment. In situations where only one laboratory uses the method, intermediate precision can be provided. *Intermediate precision* is a measure of method precision due to changes in one or more of time, calibration, equipment, and operator in a single laboratory. Intermediate precision lies between the two extreme measures of precision, repeatability and reproducibility.

The *limit of detection* is the concentration of analyte that leads to the conclusion, with a given probability of error, that the sample concentration exceeds the concentration in a blank.

The *range* is the range of concentrations of analyte lying beyond the limit of detection, within which the method demonstrates a satisfactory relationship with the reference method or samples of known concentration.

B *Method characteristics required for nominal methods*

Nominal methods only report the presence or absence of something. Examples of nominal methods are *Salmonella* detection (example of result: not detected per ml) and leakage of UHT containers (example of result: container leaks).

The following characteristics are required for nominal methods, where applicable (if not applicable, please include a reason why):

- specificity rate (this may vary according to the level of analyte present);
- sensitivity rate (this may vary according to the level of analyte present); and
- limit of detection.

The method is characterised across the testing range.

The *sensitivity rate* (the true-positive detection rate) is the probability that the method will classify a test sample as positive, given that the sample is a “known” positive.

The *specificity rate* (the true-negative detection rate) is the probability that the method will classify a test sample as negative, given that the sample is a “known” negative.

The *limit of detection* is the concentration of analyte that leads to the conclusion, with a given probability of error, that the sample concentration exceeds the concentration in a blank.

3 PROCESS FOR TEST METHOD APPROVAL

3.1 Application

Where approval is sought for a test method, the party seeking approval:

- completes the application form (refer in Annex A);
- attaches the required information (refer below); and
- submits it to the relevant accreditation body.

3.1.1 Information required for generally approved methods

For generally approved methods (refer section 2.1 above), the following information is provided with the completed application form:

- a copy of the published test method;
- a clear statement as to the proposed scope of application for the products i.e. products tested, manufacturing/customer specifications, specification limits etc;
- a copy of the laboratory's test procedure with commentary highlighting any modifications from published procedures;
- copies of any relevant validation report publications; and
- copies of any method approval/recognition by other agencies.

3.1.2 Information required for other methods (characterisation)

For other methods (refer section 2.2) above, the following information is provided with the completed application form:

- a copy of the published test method (where relevant);
- a clear statement as to the proposed scope of application for the products i.e. products tested, manufacturing/customer specifications, specification limits etc;
- a copy of the laboratory's test procedure with commentary highlighting any modifications from published procedures;
- report(s) summarising the findings of the work to characterise the method;
- copies of any other method(s) used in the report;
- all base data, i.e. test results etc;
- statistical analysis and calculations; and
- any other documentation necessary to support the application.

3.2 Assessment

The accreditation body receives applications for test method approval accompanied by the supporting information listed above. The accreditation body assesses the application using the following criteria:

- All required information is provided.
- All references (source material), support the application
- For generally approved methods (international/national) methods:
 - the method provided is the same as the published method;
 - the method is adequately documented;
 - the method is current (not obsolete);
 - the method is based on sound scientific principles and procedures; and
 - there are no reports that suggest this method should not be approved. Where reports exist, there is sound scientific data that alleviates the reported concerns.
- For “other” methods;
 - the method provided is the same as the published method;
 - the method is adequately documented;
 - the method is current (not obsolete);
 - the method is based on sound scientific principles and procedures;
 - there are no reports that suggest this method should not be approved. Where reports exist, there is sound scientific data that alleviates the reported concerns; and
 - the method characteristics are determined correctly (this requires checking of the design, the raw data and the calculations of the characteristics).

On completion of the assessment the accreditation body provides the application, the assessment data and its recommendations, including conditions or restrictions on method use, to MAF.

3.3 Approval

MAF reviews this information and where satisfied that the method is suitable, approves the method including its scope and any appropriate restrictions. MAF advises the applicant the outcome of the application. When the test method is approved, MAF adds the test method to the register (database) of MAF-approved test methods. A list of the MAF-approved test methods, the scope of the approval and any restrictions is published on the MAF Food: Dairy and Plant Products website (www.maf.govt.nz/dairy)

3.4 Review

MAF, in consultation with the accreditation bodies, reviews test methods' approvals:

- once every five years; or
- when there is evidence that the method may no longer be fit for purpose; or
- when there are changes to regulatory requirements or official assurances.

4. RECORDS

Records are kept, for as long as is necessary for traceback purposes, of all aspects of the test method, including its origin, characteristics, assessment and approval, demonstration of fitness for purpose and use.

Signature boxes

Party seeking approval:

Name of person:

Organisation:

Date:

Phone:

Fax:

Signature:

Address:

Email:

Accreditation Body:

Name of person:

Recommendation for approval: Yes/No. If no, reason/If yes any restrictions:.....

.....

.....

Date:

Phone:

Fax:

Signature:

Address:

Email:

MAF Food:

Name of person:

Decision: Approval/not. If not reason/ If approval, are any restrictions required:.....

.....

.....

Date:

Party advised

Database entry

Signature:

Date:

Date:

ANNEX B: EXAMPLE OF A COMPLETED APPLICATION FORM

Method title:	<i>e.g. Milk and Milk Products. Enumeration of Presumptive <u>Escherichia coli</u>, Part 1: Most Probable Number Technique.</i>	
Reference (method source):	<i>e.g. IDF Standard 170A: 1999. IDF Brussels.</i>	
From the MAF list of “Parameters/attributes requiring a MAF-approved test method” (if more than one assurance, provide this information as a attachment to this form):		
• Source of the assurance:	<i>e.g. MAF Standard D107, “Dairy Product Safety”</i>	
• Assurance:	<i>e.g. “The level of micro organisms in a dairy product at the end of processing does not exceed the limits specified in Table A1.1 for that micro organism in that product.”</i>	
• Parameter/attribute:	<i>e.g. <u>E.coli</u></i>	
• Specification:	<i>e.g. 100/g</i>	
• Produce/product (scope):	<i>e.g. Soft and semi soft cheese, firm and hard cheese, processed cheese, cottage cheese, cream cheese</i>	
Category of approval(tick box):	<input checked="" type="checkbox"/> generally approved (international/national) method <input type="checkbox"/> other method	
For generally approved methods, attach the following and complete signature box below: <input checked="" type="checkbox"/> copy of the method <input type="checkbox"/> copy of validation report, if applicable. <input type="checkbox"/> copies of existing approvals by other agencies, if applicable.		
Other methods continue:		
Method type (tick box):	<input type="checkbox"/> continuous <input type="checkbox"/> nominal	
Standard or code used:	<i>e.g. IDF 135B:1991, Milk and Milk Products, “Precision Characteristics of Analytical Methods. Outline of Collaborative Study Procedure”. IDF Brussels.</i>	
For other methods, attach the following: <input type="checkbox"/> report summarising the findings of the characterisation work <input type="checkbox"/> copies of any standards or codes used to determine characteristics		
Method characteristics (complete table below):		
Characteristic	Continuous method	Nominal method
Bias		
Precision as (tickbox): <input type="checkbox"/> Reproducibility <input type="checkbox"/> Intermediate precision		
Range		
Limit of Detection		
Sensitivity rate		
Specificity rate		

Signature boxes

Party seeking approval:

Name of person: *John Analyst*
Organisation: *Method Development Company Limited*
Date: *31 Jan 02* Signature: *J Analyst*
Phone: *09 123 4567* Address: *PO Box 123, Auckland*
Fax: *09 123 4569* Email: *janalyst@methoddev.co.nz*

Accreditation Body:

Name of person: *Ann Assessor*
Organisation: *An Accreditation Body*
Recommendation for approval: Yes/~~No~~. If no, reason/If yes any restrictions:.....
.....
Date: *14 Feb 02* Signature: *A Assessor*
Phone: Address:
Fax: Email:

MAF Food: Dairy and Plant Products

Name of person: *Theodore Director*
Decision: Approval/~~not~~. If not reason/ If approval, are any restrictions required:...*None*
.....
Date: *28 Feb 02* Signature: *T Director*
Party advised Date: *1 Mar 02*
Database entry Date: *1 Mar 02*

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.

Importing country requirements, which have been officially confirmed, can be obtained from the Dairy and Plant Product Group of MAF or its website (www.maf.govt.nz/Dairy).

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 MAF Standard D206, “Dairy Sanitary and Related Export Certification”.