

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

MAF Food: Dairy & Plants

Circular no. 54

Dairy Industry Regulations 1990

Third Party Agencies' Responsibilities

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Issue of Circular

This Circular, no. 54, containing 'MAF Standard D503.1, "Third Party Agencies' Responsibilities,"' is issued to set out requirements for Third Party Agencies providing evaluation and verification services to the New Zealand dairy industry under the Optimal Regulatory Model (ORM).

This Circular, no. 54, takes effect on 23 December 1999.

A handwritten signature in blue ink that reads "Tim Knox". The signature is written in a cursive style with a long horizontal stroke above the name.

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

23/12/99

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1 Background

The MAF Standard on Third Party Agencies' Responsibilities was developed to describe acceptable criteria (means for satisfying MAF) for the responsibilities of TPAs, which provide evaluation and verification services to the New Zealand dairy industry under the Optimal Regulatory Model (ORM).

Upon the introduction of the ORM-based regulatory system, TPAs will assume responsibilities for assessing regulated parties for compliance with Product Safety Programme requirements and reporting on their assessments.

2 Summary

This Standard specifies requirements relating to the responsibilities of TPAs approved by MAF Food to provide evaluation and verification services to the dairy industry.

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

- evaluation and verification of industry compliance with approved Product Safety Programmes (PSPs) and regulatory standards prior to MAF approval, and recommending assessment frequency to MAF Food;
- management of resolution of client non-compliances, including follow-up of corrective actions with persons accountable for PSPs and notifying MAF Compliance of critical non-compliances;
- regular reporting of selected information concerning clients operating under PSPs;
- verification of manufacturing clients' compliance with the Regulatory Verification Sampling Programme;
- regular reporting of selected information concerning their own operations;
- management of approved individuals providing assessment services in accordance with a management system based upon ISO Standard 17020 and approved by the accreditation body.

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.

3 Outcome

Approved TPAs and MAF Food monitor the performance of all parties operating under Product Safety Programmes and manage all events of regulatory non-compliance, providing MAF Food with confidence that the New Zealand dairy industry regulatory system is providing the food safety and truth of labelling outcomes described in section 15B of the *Dairy Industry Act 1952* and regulation 3 of the *Dairy Industry Regulations 1990*.

4 Effective changes

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

- TPAs will verify industry compliance with Product Safety Programmes (PSPs) and regulatory standards, and make recommendations for their assessment frequency, to MAF Food.
- TPAs will manage non-compliances and critical non-compliances by regulated parties, unless they are critical situations, when MAF Compliance will take responsibility.
- TPAs will report information concerning the performance of regulated parties to MAF Compliance.
- TPAs will verify that manufacturing clients are complying with the Regulatory Verification Sampling Programme.
- TPAs will report information concerning their own performance to MAF Compliance.
- TPAs will manage approved individuals providing assessment services in accordance with a management system based upon ISO Standard 17020 and approved by the accreditation body.

5 Implementation

This Standard will apply from the date of its issue by Circular.

6 Effect on compliance costs

Costs incurred in managing non-compliances, the reporting function and approved individuals will move from MAF Compliance to TPAs. Recovery of these costs will be part of the contractual agreement between regulated parties and TPAs.

MAF Standard D503.1, "Third Party Agencies' Responsibilities"

1.0 SCOPE

This Standard contains the outcomes for the operating requirements for Third Party Agencies (TPAs) that provide evaluation and verification services to the New Zealand dairy industry.

All TPAs approved by MAF Food to provide assessment services to the dairy industry must comply with this Standard.

2.0 PURPOSE

This Standard specifies the outcomes relating to the responsibilities of TPAs servicing the New Zealand dairy industry, and how these must be discharged.

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 Third Party Agency should gain or maintain MAF approval, and to assist parties to achieve the outcomes described in the Standard.

3.0 OUTCOME

Approved TPAs and MAF Food monitor the performance of all parties operating under Product Safety Programmes and manage all events of regulatory non-compliance, providing MAF Food with confidence that the New Zealand dairy industry regulatory system is providing the food safety and truth of labelling outcomes described in section 15B of the *Dairy Industry Act 1952* and regulation 3 of the *Dairy Industry Regulations 1990*.

4.0 INTERRELATED REQUIREMENTS

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

- MAF Standard D101, "Product Safety Programmes." Dairy and Plant Products Group, Food Assurance Authority, Ministry of Agriculture and Forestry.
- MAF Standard D102, "Product Safety Programme Reporting Requirements." Dairy and Plant Products Group, Food Assurance Authority, New Zealand Ministry of Agriculture and Forestry.
- MAF Standard D201, "Performance Measurement of Dairy Manufacturers" (for manufacturers operating under ORM only). Dairy and Plant Products Group, Food Assurance Authority, New Zealand Ministry of Agriculture and Forestry.
- MAF Standard D205, "Regulatory Verification Sampling Programme" (once promulgated). Dairy and Plant Products Group, Food Assurance Authority, New Zealand Ministry of Agriculture and Forestry.

- MAF Standard D501, “Technical Competency of Third Party Agency Individuals.” Dairy and Plant Products Group, Food Assurance Authority, New Zealand Ministry of Agriculture and Forestry.
- MAF Standard D502, “Accreditation and Approval of Third Party Agencies.” Dairy and Plant Products Group, Food Assurance Authority, Ministry of Agriculture and Forestry.
- MAF Standard D504, “Performance Measurement of TPAs and Approved Individuals” (once promulgated). Dairy and Plant Products Group, Food Assurance Authority, Ministry of Agriculture and Forestry.

5.0 ADDITIONAL RESOURCES

The following document is a useful resource.

- *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/

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/).

Accountable person – The person named in a MAF-approved PSP who is responsible for all operations covered by the PSP, and for ensuring that those operations comply with regulatory requirements.

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.

Approval - Written confirmation from MAF pursuant to the *Dairy Industry Regulations 1990* where action or participation is dependent on the Director-General of MAF’s formal acceptance or permission.

Approved individual - A person who has demonstrated that they meet MAF competency standards for qualifications and experience, and has subsequently been formally approved by the Director-General of MAF pursuant to the *Dairy Industry Regulations 1990*.

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

Critical non-compliance – An action, event or omission which may result in:

- failure of dairy produce to comply with regulatory requirements;
- failure to follow the lawful direction of an Inspector;
- an alleged offence against the *Dairy Industry Act 1952* or *Dairy Industry Regulations 1990*;
- a critical situation;
- failure of a critical control point within a MAF-approved programme or plan;
- failure to identify when dairy produce is non-conforming;
- failure to stop a non-compliance;
- failure to keep accurate and complete records;
- failure to provide accurate, complete, and timely reports;
- failure to dispose of non-conforming dairy produce in compliance with regulatory requirements;
- failure to prevent recurrence of a non-compliance; and/or
- failure to rectify a non-compliance within the specified timeframe.

Critical situation – Any situation which, in the professional judgement of the Inspector, places public health, animal welfare, market access, official assurances, national good or MAF's credibility at risk, or where an offence is suspected.

Evaluation – Assessment of an individual, plan, programme, or system to determine compliance with regulatory requirements. This will involve review of documentation and, in some cases, review of operations or observation of practice. It is undertaken by a competent individual contracted to an impartial agency (e.g. TPA or National Assessor, MAF Compliance Group).

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 & Plant Products.

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

Product Safety Programme (PSP) – A programme of conditions, processes, procedures, measures, and standards to be complied with, performed, undertaken, taken, or met in relation to:

- (a) any process or activity related to dairy produce, ingredients used in the manufacture of dairy products, or both; and
 - (b) sampling, examination, inspection, and testing, or any of those actions, relating to any such process or activity; and
 - (c) the recording and inspection(by persons with qualifications and experience approved by the Director-General for the purpose) of information relating to any such action;
- and (without limiting the generality of the foregoing) may include conditions, processes, procedures, measures, or standards relating to the production, manufacture, storage, or transport of dairy produce.

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.

Sanction – Official response to regulatory non-compliance.

Third Party Agency (TPA) - Organisation approved by MAF to carry out evaluation and/or verification services.

Truth of labelling - Labelling of dairy produce for export in compliance with a MAF Standard.

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.

7.0 REQUIREMENTS

Approved TPAs must:

- verify compliance with Product Safety Programmes (PSPs) and regulatory standards, and recommend assessment frequency to MAF Food;
- manage resolution of client non-compliances and critical non-compliances, including follow-up of corrective actions with persons accountable for PSPs;
- notify MAF Compliance of critical non-compliances;
- immediately advise MAF Compliance of critical situations;
- report selected information concerning clients operating under PSPs, to MAF Compliance;
- verify that manufacturing clients are complying with the Regulatory Verification Sampling Programme in accordance with MAF Standard D205, “Regulatory Verification Sampling Programme;”
- report selected information concerning their own operations, to MAF Compliance; and
- manage approved individuals providing assessment services

to give MAF Food confidence that the New Zealand dairy industry regulatory system is providing the food safety and truth of labelling outcomes required by legislation.

In any situation involving disposal of non-conforming produce, a written order must be obtained from MAF Compliance to confirm disposition of non-conforming produce.

8.0 VERIFICATION

Verification of compliance with this Standard is undertaken by MAF Food and accreditation bodies during the assessment process.

MAF Food verifies, on an ongoing basis, that information is complete and is being reported in a timely manner.

8.1 Criteria

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

- The TPA operates in accordance with the requirements of ISO Standard 17020, MAF Standard D502, “Accreditation and Approval of TPAs,” and this Standard.
- The TPA complies with the accreditation criteria and conditions.
- The TPA does not misuse or abuse its accreditation status.

8.2 Decision

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

8.3 Result

8.3.1 Compliant TPAs

Compliant TPAs are approved by MAF Food to provide assessment and verification services to the New Zealand dairy industry if they also comply with the requirements MAF Standard D502, “Accreditation and Approval of TPAs.”

8.3.2 Non-compliant TPAs

- Non-compliant TPAs have approval to provide assessment and verification services to the New Zealand dairy industry withdrawn until the issue has been resolved to the satisfaction of MAF Food.
- The reports from non-compliant TPAs are not accepted by MAF Compliance.
- TPAs allegedly committing an offence under the *Dairy Industry Act 1952* or the *Dairy Industry Regulations 1990* are investigated by MAF Enforcement Unit.

9.0 VERSION CONTROL

Version	Date	Status	By	Approved
503.1	23 December 1999	Promulgated by Circular no. 54	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/) to confirm that this is the current version.

Appendix One

ACCEPTABLE CRITERIA

The following are criteria by which a TPA may be judged to satisfactorily achieve the outcomes of section 7 of this Standard. TPAs which have demonstrated that they meet each of the criteria will be approved 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 Verification of compliance with PSPs

The TPA verifies the client's PSP at the frequency assigned by MAF Food and advised by the accountable person.

The PSP/PSP component is assessed by an individual approved by MAF Food to assess PSPs/PSP components in the relevant product group. Refer to MAF Standard D501, "Technical Competency of TPA Individuals."

The PSP and its components are verified against the requirements in MAF Standard D101, "Product Safety Programmes."

Following the assessment of the PSP, including its components, the TPA recommends an assessment frequency category for the client, to MAF Food.

2.0 Verification of compliance with RVSP

On receipt of the RVSP report from its dairy factory clients, the TPA checks to confirm the following.

- The RVSP report was received within 5 days of receipt of the RVSP test results by the designated person. If not, a non-compliance is issued. The non-compliance is managed in accordance with section 3.1.
- The analysis of the test results, and comparison of the test results and conformance decisions were correct. If not, MAF Compliance is informed within 24 hours.
- The appropriate decisions and follow-up actions have been taken in response to analysis of the results. If not, a non-compliance is issued. The non-compliance is managed in accordance with section 3.1.

3.0 Management by TPAs of client non-compliances

3.1 PSP non-compliances identified during assessments

The TPA manages the resolution of non-compliances and critical non-compliances identified during assessment of client PSPs and PSP components. It:

- advises MAF Compliance of any critical non-compliances within 24 hours,
- agrees corrective actions proposed by the client, and
- agrees and sets with the client, a target date for resolution of the non-compliance/critical non-compliance by the client.

On the target date for resolution, the TPA:

- confirms with the client that resolution/corrective action has been completed,
- confirms that the PSP/PSP component has been reviewed and, where necessary, submitted to the TPA for assessment and MAF Food for re-approval,
- reports to MAF Compliance concerning resolution of critical non-compliances, and
- recommends to MAF Food increasing the frequency of assessment of the client, if required.

In the event of a critical non-compliance being identified, the TPA notifies MAF Compliance within 24 hours. Initial verbal reporting is acceptable, but is confirmed in writing within 12 hours. Where initial notification is in writing (email or fax), the TPA has a telephone conversation with MAF Compliance staff to confirm receipt. A message on an answering service is not sufficient.

Refer to Figure A1.1 for a diagram of the escalation process.

3.2 PSP critical non-compliances reported by clients

Within 24 hours of receiving notification of a critical non-compliance, the TPA:

- notifies MAF Compliance of the critical non-compliance,
- agrees with the client, appropriate corrective actions. If the critical non-compliance results in non-conforming product, the TPA ensures that the client is following the requirements specified in MAF Standard D108, “Non-conforming Dairy Produce,” and
- agrees and sets with the client, a target date for resolution of the critical non-compliance by the client.

If the critical non-compliance results in non-conforming produce, the TPA subsequently manages the non-conformance as described in MAF Standard D108, “Non-conforming Dairy Produce.”

On the target date for resolution, the TPA:

- confirms with the client that resolution/corrective action has been completed,
- confirms that the PSP has been reviewed and, where necessary, re-approved,
- reports to MAF Compliance concerning resolution of the critical non-compliance, and
- recommends to MAF Food increasing the frequency of assessment of the client, in accordance with MAF Standard D201, “Performance Measurement of Dairy Manufacturers.”

3.3 Critical situations

When the TPA becomes aware of a critical situation, whether as a result of a PSP assessment or from notification by the client or any other party, it immediately advises MAF Compliance. Initial verbal reporting is acceptable, but is confirmed in writing within 12 hours. Where initial notification is in writing (email or fax), the TPA has a telephone conversation with MAF Compliance staff to confirm receipt. A message on an answering service is not sufficient. The approved individual briefs MAF Compliance and hands over all information relevant to the critical situation. MAF Compliance is responsible for ensuring resolution of the critical situation.

4.0 Reporting

4.1 General requirements

The TPA reports information accurately and in a timely manner.

The TPA obtains written authority from its clients to report relevant information about them to MAF Compliance.

All reports are sent directly to MAF Compliance. Faxed and emailed transmission of data is acceptable, provided it is signed/sent by an authorised signatory.

4.2 PSP reports

4.2.1 Exception reporting

Within 24 hours of receipt of an exception report from a client, the TPA notifies MAF Compliance. The exception report contains all the information specified in MAF Standard D102, “PSP Reporting Requirements.” If the report received from the client is incomplete, the TPA obtains the missing information. The completed exception report is forwarded to MAF Compliance.

Initial verbal reporting is acceptable, but is confirmed in writing within 12 hours. Where initial notification is in writing (email or fax) the TPA has a telephone conversation with a MAF Compliance staff member to confirm receipt. A message on an answering service is not sufficient.

4.2.2 Regular reporting

The TPA reports to MAF Compliance, within 14 days of month end, a summary of the monthly reports from organisations operating under PSPs. Regular reports are done every month.

Reports are brief, concise and unambiguous, and include the following.

- The total number of critical non-compliances reported in each category from all contracted parties, and the status of resolution of these critical non-compliances.
- The total quantities of mislabelled and unsafe produce that were disposed of during the month.
- The results of the trend analysis (refer to MAF Standard D102, “Product Safety Programme Reporting Requirements”).
- For each non-compliant party:
 - name of the party,
 - the number of critical non-compliances reported in each category,
 - status of resolution of the critical non-compliances,
 - if a site visit was required and why,
 - date of next assessment by the TPA, and
 - recommendation concerning assessment frequency of the party.
- For each party who fully complied with the standards, the name of the party.
- For each party whose PSP was verified during the past month:
 - name of the party,
 - a summary of the non-compliances and critical non-compliances and outstanding corrective actions, and
 - a recommendation concerning assessment frequency of the party.

- For each party a component of whose PSP was evaluated during the past month (e.g. pasteuriser, pest/pathogen management programme):
 - name of the party, and
 - a summary of the non-compliances and critical non-compliances and outstanding corrective actions.
- For each party required to participate in RVSP:
 - name of the party;
 - a list of the product groups sampled, so that MAF can check all product groups being sampled;
 - if there were any significantly different results, a list of the products and tests involved, so that MAF can monitor trends; and
 - if there were any discrepant decisions concerning conformance, a list of the products and lots involved, so that MAF can check that they were advised;
- Any other information that would give MAF Food a more complete picture of food safety issues in the dairy industry.

4.2.3 Reporting on demand

The TPA supplies, on demand, any additional information concerning the PSP or product, requested by MAF Food, to enable it to investigate product safety problems or potential risks, or to support statements contained in export certificates.

4.3 TPA reports

4.3.1 Exception reporting

A Critical non-compliances within the TPA's quality system

The TPA reports to MAF Compliance, within 24 hours, any critical non-compliances which have a potential impact on the effectiveness of the assessment services provided, which are detected within its own quality system. Critical non-compliances may arise from customer complaints, internal assessment findings, identification of non-compliant assessors and internal management review findings.

B Non-compliant individuals

The TPA reports to MAF Compliance, within 24 hours, the details of any non-compliant approved individuals, and the corrective actions to be taken.

C Disputes with clients

The TPA reports to MAF Compliance, within 24 hours, any disputes with clients concerning regulatory non-compliance.

4.3.2 Regular reporting

The TPA reports to MAF Compliance, within 14 days of month end, a summary of its own performance. The frequency of regular reporting depends on the performance assessment category to which the TPA is allocated. Refer to Standard D504, “Performance Measurement of TPAs and Approved Individuals.”

Reports are brief, concise and unambiguous, and include the following:

- A schedule of assessments planned for the coming 3 months.
- Positive verification of the TPA’s performance, including:
 - number of performance assessments of approved individuals,
 - occurrence of internal or external reviews of the quality system,
 - any proposed changes to the TPA’s staff or operations relevant to dairy industry assessment services,
 - number of complaints received from dairy industry clients and resolution status, and
 - any other information that would give MAF a more complete picture of the TPA’s performance in managing its dairy industry clients.

5.0 Management of approved individuals

Full assessment of approved individuals follows the assessment of the TPA by the accreditation body.

Initially individuals have a full assessment on an annual basis. Re-assessment frequency will be reviewed in accordance with MAF Standard D504, “Performance Measurement of TPAs and Approved Individuals.”

The TPA reviews the performance and competency of each approved individual, at least annually, by management review and internal peer review. Where internal peer review is not possible, peer review is by an accreditation body or an approved individual working for another approved TPA.

The consistency of assessment work done by approved individuals within the TPA is assessed at least annually. If their performance is not consistent, corrective action is taken.

TPAs ensure that only approved individuals provide evaluation and verification services.

The TPA ensures that when the performance of any individual is deemed to be non-compliant, appropriate corrective action is taken.

The TPA ensures that approved individuals do not become so familiar with client systems and processes that their ability to effectively assess is impaired.

The TPA manages potential conflicts of interest when undertaking consultancy and evaluation/verification contracts for the same client.

TPAs participate in industry standardisation sessions (organised by MAF Food) to ensure uniformity when Standards are issued or reviewed.

The TPA maintains full records of all training and experience of all approved individuals providing assessment services on behalf of the TPA.

6.0 Internal review

The TPA conducts an internal management review of its own quality system at least annually.

Figure A1.1: Diagram of the escalation process

