



Fonterra Food Safety and Quality Requirements for **THIRD PARTY LABORATORIES**

April 2017





Contents

Introduction	2
Scope	2
People and Systems	3
Buildings and Equipment	6
Laboratory Processes	8
Communication	14
Regulatory Compliance	15
Social Responsibility	16
Definitions	19
Summary	20



Introduction

Fonterra is committed to produce and supply safe, quality food. Quality is everyone's responsibility. Every step of the way, from our farms to the market, Fonterra is trusted by customers and consumers to supply them the best.

To earn this trust, we will ensure food safety and quality throughout the supply chain – from grass to glass. As a testing laboratory partner you are an integral part of our supply chain and we seek your assistance to meet our objectives, satisfy our customers and deliver on our promise.

These guidelines supplement the terms of any service or supply contract that you may have entered into with Fonterra, and broadly reflect the scope of any compliance audits we may undertake. In the event of an inconsistency between these guidelines and the terms of any contract, the terms of the contract will prevail to the extent of any such inconsistency.

Scope

Fonterra's Food Safety and Quality requirements apply to all third party laboratories contracted to supply routine laboratory testing services to Fonterra.

These requirements set out our core expectations of you as a third party laboratory to Fonterra. The majority of requirements have been based on globally recognised standards for food related laboratory services.



People and Systems

Laboratory Quality Management System

All laboratories conducting food safety or regulatory testing shall be accredited by a recognised body to an internationally recognised laboratory quality management standard. The preferred standard is ISO 17025. The accreditation shall include the food safety and regulatory test methods.

For all other testing the laboratory must be able to demonstrate that it has quality systems in place to ensure method validation, verification and equipment calibration occurs as necessary. The laboratory must seek to participate in an Inter Laboratory Comparison Programme (ILCP) to demonstrate proficiency.

The laboratory shall establish and maintain procedures to control all documents that form part of the laboratory quality management system, such as regulations, standards, other normative documents, test and/or calibration methods, as well as drawings, software, specifications, instructions and manuals.

Laboratory Management will regularly review the quality management system to ensure the desired outcomes are being achieved, and to identify and implement opportunities for continuous improvement.

Role Description and Accountabilities

The laboratory shall maintain current job descriptions for managerial, technical and key support personnel involved in testing and/or calibrations.

The roles and responsibilities of the laboratory management team shall be defined. Such personnel shall have the authority to carry out their duties, including:

- The implementation, maintenance and improvement of the laboratory quality management system
- Ensuring the provision of the resources needed to ensure the required quality of laboratory operations.

Personnel responsible for opinions and interpretations included in test reports must, in addition to the appropriate qualifications, training and experience, also have:

- Relevant knowledge of the technology used for the manufacturing and testing of the products, and/or the way they are used or intended to be used
- Knowledge of any regulatory requirements *and*
- An understanding of the impact of any testing result deviations found with regard to the normal use of the products concerned.



People and Systems

Training

The laboratory shall have procedures for identifying training needs and providing training of personnel. The training programme shall be relevant to the requirements of each position within the laboratory.

Personnel operating equipment, performing tests and/or calibrations, evaluating results, managing data, and signing test reports and calibration certificates shall:

- Be appropriately trained
- Have records verifying their competence
- Be regularly assessed to demonstrate continued competence.



Non-Conformance

The laboratory shall have a documented process to ensure that deviations from policies and procedures set out in the laboratory quality management system are appropriately managed. Such a process shall have components that include:

- Records shall be maintained of all non-conformances and of the investigations and corrective actions taken
- Responsibility and authority for the management and evaluation of the non conforming work are defined
- Corrective action is taken immediately, together with any decision about the acceptability of the non-conforming work
- Actions (including halting of work, withholding of test reports and calibration certificates, as necessary) are defined and implemented when non-conforming work is identified
- Where necessary, the customer is notified and work is recalled
- The responsibility for authorizing the resumption of work is defined
- Data is captured and is available in a format that enables identification of trends and supports root cause analysis.



People and Systems

Complaints

The laboratory shall have a documented process for the resolution of complaints received from Fonterra and/or other customers of the laboratory. Records shall be maintained of all complaints, and of any subsequent substantiation, investigation and corrective action taken by the laboratory.

Complaints and Non-conformance trends are to be reviewed regularly by the laboratory management team as part of a continuous improvement programme.

Timely escalation shall occur for repeat events and major food safety testing complaints to ensure management is informed and immediate action is taken.

Internal Audit Programme

The laboratory shall periodically, and in accordance with a predetermined schedule and procedure, as documented in its laboratory management system, conduct internal audits of all activities to verify that the laboratory continues to comply with the requirements of its quality management system.

The internal audit programme shall address all elements of the laboratory management system, including the testing and/or calibration activities, and shall be conducted at least annually. Such audits shall be carried out by trained and qualified personnel who, where possible, are independent of the activity to be audited.

The audit frequency shall be sufficient to provide a high level of confidence that the laboratory processes are operating effectively.

Change Control

The laboratory shall have a system in place to manage the change of test methods and critical equipment. The system shall include the notification to Fonterra of any test method change prior to implementation.



Buildings and Equipment

Building

Structures shall be designed and constructed to comply with applicable building codes, be built from durable, impervious materials, and shall be easy to maintain in a clean and hygienic condition.

There shall be effective separation between areas in which there are incompatible activities. Measures shall be taken to prevent cross-contamination.

Access to and use of areas that may affect the quality of the tests and/or calibrations shall be controlled. The extent of control shall be determined by the laboratory using risk assessment principles as applied to the specific situation.

Equipment and Fittings

The laboratory shall maintain all sampling, measurement and test equipment in good working order. Equipment and associated software used for testing, calibration and sampling shall be capable of achieving the accuracy required for the given application.

The laboratory shall have procedures for safe handling, transport, storage, use and planned maintenance of measuring equipment to ensure proper functioning of the equipment, and to prevent the contamination or deterioration of the equipment.

Test and calibration equipment, including both hardware and software, shall be safeguarded from unauthorised adjustments which would invalidate the test and/or calibration results.





Buildings and Equipment

Security

The laboratory shall have documented systems to protect samples and documentation from deliberate acts of tampering.

As a minimum:

- Access to sample reception, laboratories and ancillary buildings must be controlled and requirements understood by all visitors and contractors prior to entry
- Confidential Fonterra information will be stored securely.

Pest Management and Control

The laboratory must have a Pest Management plan in place to ensure that the integrity of product samples and retentions is not compromised by pest activity.

The plan must include the protection of samples, test consumables and raw materials.





Laboratory Processes

Testing Laboratory Requirements

Laboratories shall be able to verify the following practices:

- Sample receipt procedures that ensure identification and traceability of samples at all times
- Sample reception, storage and handling procedures that ensure the prevention of sample cross contamination and degradation of the sample
- Records completed in a permanent manner at the time of test, traceable to the samples and the tester, any amendments properly authorised, stored and protected from deterioration and easily retrieved
- Up to date SOPs are available and training against those SOPs is current
- There are procedures that ensure that a sample is homogenous and any testing or sub-sampling performed is representative of the sample as a whole
- There are procedures that outline actions, including communication to Fonterra, if a sample is compromised and not fit for testing
- There are procedures to ensure that media, reagents and other test consumables are fully traceable and are not compromised.

Retesting

Retesting of food safety tests exceeding the food safety limit is not permitted unless the laboratory has unequivocal evidence that the "suspect" result arises from a failure of its internal systems.

All retesting shall be authorised by personnel with appropriate technical competency after consideration of the following criteria:

- Is there doubt about sample integrity
- Is there a known technician error, failure of test controls or a failure of test equipment
- Has there been any recent contamination
- What is the current ILCP performance (where applicable) *and*
- Is the result outside established test control limits?

All decisions relating to retesting shall be documented.



Laboratory Processes

Approval of Suppliers

The laboratory shall have a procedure(s) for the selection and purchase of:

- Goods and services that affect the quality of the tests and/or calibrations
- Reagents and laboratory consumable materials relevant for the tests and calibrations *and*
- Third party laboratories.

When a laboratory subcontracts work, this work shall be placed with a competent subcontractor that as a minimum is compliant with the Fonterra's Food Safety and Quality Requirements for Third Party Laboratories for the work being contracted.

Fonterra must be informed in writing prior to any of its testing services being sub-contracted out.

There must be formal, risk based, acceptance criteria for each batch of test consumables, kits and media used by the laboratory, e.g. sterility assessment.

Laboratory Environment

Environmental conditions shall not adversely affect testing and/or calibration outcomes.

The technical requirements for the environmental conditions that can affect the results of tests and calibrations shall be identified and documented.

Where they may influence the quality of the results (e.g. biological sterility, dust, electromagnetic disturbances, radiation, humidity, electrical supply, temperature, and sound and vibration levels), environmental conditions shall be monitored, controlled and recorded.

Testing and calibration shall be stopped when the environmental conditions exceed predetermined limits. Response plans for environmental breaches shall be pre-determined and documented.

Measures shall be taken to ensure good housekeeping in the laboratory.

Environmental Pathogen Management

Where a laboratory is performing either microbiological testing, or sub sampling for microbiological testing or retention the laboratory must document and implement an environmental pathogen management plan appropriate for the testing performed.



Laboratory Processes

Method Selection and Validation

Either internationally recognised methods or methods provided by Fonterra shall be used. The laboratory shall ensure that it uses the latest valid edition of each specific method. Any method deviation shall be documented and validated to ensure the outcome of the method is not compromised.

Test methods shall be written in a way that they can be used by the operating staff in the laboratory.

The laboratory shall maintain current knowledge of laboratory testing methodology and best practice and implement changes where appropriate.

The laboratory shall validate non-standard methods, laboratory-designed/developed methods, standard methods used outside their intended scope, and modifications of standard methods to demonstrate that the methods are fit for the intended use. The validation shall be appropriate to the needs of the given application. The laboratory shall record the results obtained, the procedure used for the validation, and a statement as to why the method is fit for the intended use.

Note: The techniques used for the determination of the performance of a method must be one of, or a combination of, the following:

- Calibration using reference standards or reference materials
- Systematic assessment of the factors influencing the result
- Assessment of the uncertainty of the results based on scientific understanding of the theoretical principles of the method and practical experience.





Laboratory Processes

The laboratory shall have quality control procedures for monitoring the validity of tests and calibrations undertaken. The resulting data shall be recorded in such a way that trends are detectable. This monitoring shall be planned and reviewed and may include, but not be limited to, the following:

- Regular use of certified reference materials and/or internal quality control using secondary reference materials
- Participation in inter laboratory comparison or proficiency testing programmes that are applicable to the product being tested and the test methods used
- Replicate tests or calibrations using the same or different methods
- Retesting or recalibration of retained items
- Correlation of results for different characteristics of an item.

Quality control data (e.g. proficiency programme results, use of replicate testing samples) shall be analysed and, where found to be outside pre-defined criteria, planned action shall be taken to correct the problem and to prevent incorrect results.





Laboratory Processes

Calibration

A calibration programme shall be implemented for all measurement devices and reference instruments that are critical for ensuring that results being provided to Fonterra are accurate.

The calibration programme shall:

- Document and maintain a list of all devices to be calibrated
- Specify the degree of accuracy that is appropriate to the application of each instrument
- Specify the schedule of calibration activities
- Identify who is responsible for carrying out the calibration.

The frequency shall:

- Comply with any applicable regulatory requirements *and*
- Reflect the acceptable level of potentially non-conforming product that would result if the device was not operating within the required level of accuracy.

All critical measuring devices and reference instruments shall have a current calibration certificate or evidence that the device is operating within prescribed limits, readily available at all times.

Critical measuring devices and reference instruments shall have the calibration status protected from adjustment by unauthorised personnel.

Calibrations shall be traceable to a recognised national or international standard. Where there is no such standard, the basis used for calibration shall be documented.

All calibration records shall be maintained in a readily accessible format and location.

Where a measuring device requires re-alignment (due to being outside critical limits) at calibration, results shall be deemed non-conforming, and a risk analysis carried out to ensure that results since the previous effective calibration meets quality requirements. Where appropriate, the product/material shall be deemed non-conforming and managed appropriately with Fonterra informed immediately.

Records and Reporting

All records shall be legible, controlled and securely stored in a manner that protects their integrity and provides ready accessibility. Retention times of records shall be defined, and at a minimum must meet the relevant local regulation.



Laboratory Processes

All testing and calibration activities shall be traceable forwards and backwards, from receipt of samples to despatch of results, including personnel responsible for each activity.

There shall be a controlled process for the release of results from the laboratory. Responsibilities and authorities for test results release and calibration acceptance activities must be clearly defined and delegated in accordance with an appropriate level of competence and understanding of technical risk.

Calculations and data transfers shall be subject to appropriate checks in a systematic manner.

When computers or automated equipment are used for the purchasing, recording, reporting, storage or retrieval of test or calibration data, the laboratory shall ensure that:

- Procedures are established and implemented for protecting the data. Such procedures shall include, but not be limited to, integrity and confidentiality of data entry or collection, data storage and back up, data transmission and data processing
- Computers and automated equipment are maintained to ensure proper functioning and are provided with the environmental and operating conditions necessary to maintain the integrity of test and calibration data.





Communication

The laboratory must have a documented agreement with Fonterra outlining the reporting format and the time of reporting following reception of sample(s) for routine testing.

Exception Reporting

Notification must be provided to Fonterra as soon as practicable if the laboratory becomes aware of any Fonterra product that poses a food safety risk.

In addition, written notification of the following must be provided to Fonterra within 24 hours of the event where:

- Any third party certification breaches which impact the laboratory's certification status
- An event has caused significant disruption to testing
- Critical non-conformances arising from an external audit that affect or put Fonterra test results at risk
- Any matter which calls the laboratory to public question or public enquiry, either through a government or consumer organisation. Legal action/takeover from any party must also be reported

- There is reason to believe that test results supplied to Fonterra are incorrect
- Notification of any significant test method, management or certification changes.

All events requiring exception reporting must initially be notified verbally to Fonterra. Verbal notification must be confirmed by written confirmation within 24 hours. Reporting requirements may be defined as part of the contractual agreement.

Regular Reporting

Regular reporting must be determined on a case by case basis and documented as part of contractual agreements and may include:

- Achievement against quality and agreed performance KPI's.
Examples of typical KPI's are:
 - Test turnaround time
 - ILCP or Proficiency programme performance
 - Quality Reporting.



Communication

Audits

The laboratory shall at any time, upon reasonable notice, allow Fonterra representatives and/or agents access to all facilities and relevant records for the purpose of an operational and/or technical audit to ensure compliance with Fonterra's contractual requirements. Should a laboratory refuse access to Fonterra auditors, the business relationship between the laboratory and Fonterra will be reviewed.

Information Requests

The laboratory shall provide any relevant information and documentation (including quality control, assurance records and applicable internal audit reports) requested by Fonterra to support it with any customer or regulatory queries regarding testing activities.

Regulatory Compliance

The supplier shall operate in full compliance with international, national, local laws and regulations applicable to their business operations, and obtain all necessary permits.





Social Responsibility

To Fonterra, acting in a socially responsible manner means taking responsibility for the impacts of its decisions and activities on society and the environment. It is about respecting the perspectives of our stakeholders, behaving transparently and ethically, and thinking for the long term. To achieve this it is important that both, Fonterra and the suppliers that we work with, seek to operate in a socially responsible manner.

Alongside ensuring consumers' health and safety, there are other aspects where Fonterra have expectations of its suppliers and partners, as follows below:

Health and Safety at Work

The supplier shall use a proactive approach in establishing and maintaining standards of health, safety, environmental and occupational health management. This includes regular monitoring and verification of progress towards health and safety objectives or targets.





Social Responsibility

Labour and Conditions of Work

The supplier shall not make use of forced or bonded labour. Labour must be freely given and employees must be free to leave in accordance with established rules.

The supplier shall not employ children in violation of conventions 138 and 182 of the International Labour Organization.

The supplier shall not discriminate in any manner on the basis of race, ethnic background, age, religion, gender, sexual orientation or disability.

The supplier shall ensure that working hours and remuneration are in compliance with all applicable laws.

Anti-Corruption and Political Activities

The supplier will demonstrate high standards of business conduct and responsible political behaviour. This includes avoiding involvement in disreputable business measures such as bribes, corrupt payments or kickbacks. Any lobbying activities must comply with all legislative and regulatory requirements.





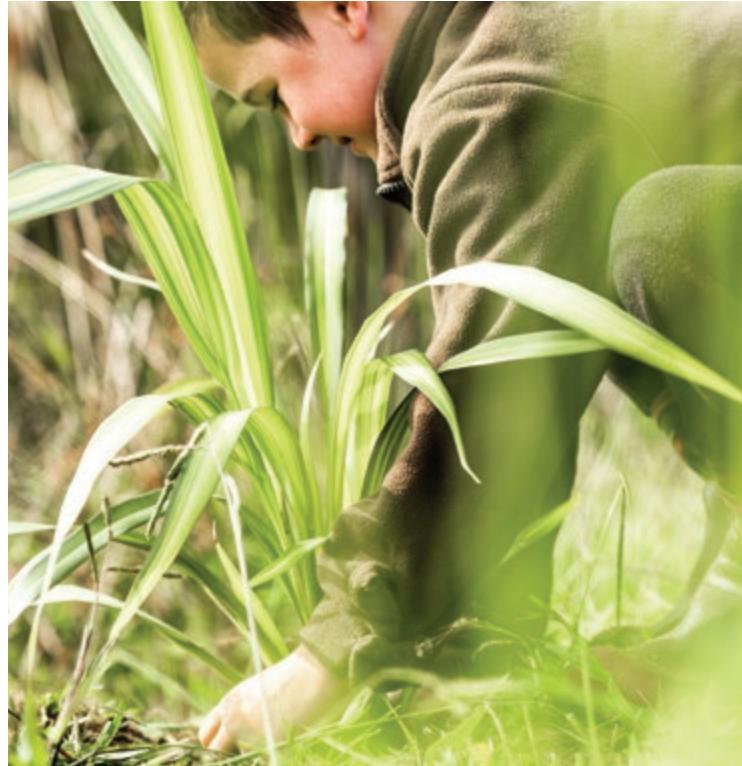
Social Responsibility

Environment

The supplier must be committed to protecting the environment through the use of sound environmental practices. This must include an environmental risk management plan to actively identify, manage and report environmental risks; and environmental management systems to regularly monitor and verify progress toward environmental objectives or targets.

The supplier should include, but not be limited to the following:

- Water – seeking to use water responsibly and prevent water pollution
- Climate and energy – establishing programmes to reduce energy usage and greenhouse gas emissions
- Efficiency and waste – reducing all forms of waste and other emissions (e.g. dust, noise); and ensure that hazardous substances are managed responsibly and safely.





Definitions

Calibration is the process of checking and aligning the accuracy of a measuring device to a known standard.

Critical means absolutely necessary for success (in achieving food safety and/or product identity characteristics of the product being processed).

Food safety testing is the testing of parameters deemed critical to food safety such as pathogen, some chemical contamination and foreign matter.

ILCP is an Inter Laboratory Comparison Programme or Proficiency Testing Programme

Processed includes material transported, manufactured, tested or stored.

Reference instrument is an instrument used to verify the calibration of on-site devices.

Sampling is a defined procedure whereby a part of a substance, material or product is taken to provide for testing or calibration of a representative sample of the whole.

SOPs are Standard Operating Procedures.

Validation is the process by which a process or equipment item is assessed to determine whether it will be effective in meeting the required outcomes and any regulatory requirements, and when implemented will be able to consistently achieve the intended and required outcomes. Validation = before time = Will it work?





Summary

By having a collaborative relationship between Fonterra and our laboratory services, we can:



1. Ensure that the quality and integrity of our product is maintained throughout the supply chain.



2. Fulfil our promise of consistent delivery of safe product to customers.

