Food Safety: Guidance for food safety auditors

Information for food safety auditors
on compliance assessment of food safety programs
and the Food Safety Standards

October 2001

ANZFA
Australia New Zealand **Food** Authority
TE MANA WHAKARITE KAI MO AHITEREIRIA ME AOTEAROA

Acknowledgments

The Australia New Zealand Food Authority prepared this report with assistance from the Audit System Working Group:

Ms Brigid Hardy (Chair)	Australia New Zealand Food Authority
Dr Geoffrey Annison	Australian Food and Grocery Council
Mr Basil Czerwaniw	South Western Sydney Area Health Service
Mr John Dean	Joint Accreditation System of Australia and New Zealand
Mr Michael Di Giovanni	Tasmanian Department of Community and Health Services
Mr Ian Hendersen	Australian Institute of Environmental Health
Mr Brett Hughes	representing the Australian Food and Grocery Council and the Quality Society of Australasia
Mr David Larkings	Queensland Health
Mr David Matthews	Consumer Food Network
Mr Gary Smith	Food Safety Victoria
Mr Steve Tidswell	Australian Quarantine and Inspection Service
Ms Julie Woods	Public Health Association

The Authority expresses its appreciation of the assistance of these people in preparing this document and acknowledges that the views contained in the report do not necessarily represent the views of the working group members or their organisations.

©Australia New Zealand Food Authority

ISBN 0 642 34596 1

First published October 2001

This work is copyright. Apart from any use as permitted under the Copyright Act 1968, no part may be reproduced by any process without prior permission from the Australia New Zealand Food Authority. Requests and inquiries concerning reproduction and rights should be addressed to the Information Officer, ANZFA, PO Box 7168 Canberra BC, ACT 2610.

An electronic version of this document is available on the ANZFA website. This electronic version may be downloaded, displayed, printed and reproduced in unaltered form only for your personal, non-commercial use or within your organization.

ANZFA Australia
Po Box 7186
Canberra BC ACT 2610
Australia
Tel: +61 2 6271 2613
Fax: +61 2 6271 2278
Email: info@anzfa.gov.au

ANZFA New Zealand
PO Box 10559
Wellington
New Zealand
Tel: +64 4 473 9942
Fax: +64 4 473 9855
Email: nz.reception@anzfa.gov.au

Contents

Introduction **5**

Scope of the handbook **8**

1 Types of auditors **9**

2 General requirements **9**

2.1 Confidentiality 9
2.2 Maintenance of impartiality and independence 10
2.3 Insurance 11
2.4 Certificates of authority 11
2.5 Appeals, complaints and disputes 12
2.6 Contracting with a food business 12
2.7 Priority classification 12

3 Roles and responsibilities **13**

3.1 The food business 13
3.2 The food safety auditor 13
3.3 The enforcement agency and relevant authority 14

4 Audit procedures **15**

4.1 Documentation review 15
4.2 Planning the audit 16
4.2.1 Determining the scope and objectives of the audit 16
4.2.2 Determining audit duration 16
4.2.3 Announced and unannounced audits 16
4.2.4 Establishing audit competency requirements 17
4.2.5 Audit teams 17
4.2.6 Notifying the food business of the audit 17
4.3 Preparing for the on-site audit 17
4.4 Performing the on-site audit 18
4.4.1 Opening meeting 18
4.4.2 Examination 18
4.4.3 Verification and validation 18
4.4.4 Closing meeting with the food business 18
4.5 Audit reporting 19
4.5.1 Audit outcome reporting 20
4.5.2 Non-conformance reporting 20
4.6 Audit completion 21
4.7 Corrective action follow-up 21

5 Other considerations **21**
5.1 Auditing of multi-sited food businesses 21
5.2 Audit frequency model 22
5.2.1 Scope of audit 23
5.2.2 Movement of frequency within classification 23

Glossary **28**

References **30**

Tables and figure

Table 1 Documentation of deficiencies and compliance 15
Table 2 Frequency ranges 23
Table 3 Guidance on movement within audit frequency ranges 25
Table 4 Examples of audit frequency adjustments 26
Figure 1 Guide for auditors on movement within audit frequency ranges 27

Introduction

The aim of this publication is to guide food safety auditors in the appropriate procedures for auditing food safety programs and the Food Safety Standards. State and Territory Governments have established these procedures, with the assistance of the Australia New Zealand Food Authority (ANZFA), to ensure that there is a nationally consistent approach to the way in which food businesses across Australia are assessed for compliance with food safety programs and the Food Safety Standards. These procedures and their consistent application are important to both food businesses and consumers as they help to maintain the integrity of the audit system. The integrity of the audit system is paramount in ensuring the production of a safe food supply for all Australians.

An audit system has been developed by ANZFA for the purposes of auditing food safety programs and is described in the publication *Food Safety: An audit system*, published in March 2001.

A food safety program is based on Hazard Analysis and Critical Control Point (HACCP) principles and is a documented program that systematically identifies potential hazards in food handling operations that, if not controlled, may lead to the preparation of unsafe food. ANZFA recognises that food safety programs are in line with international best practice and has recommended that food safety programs become mandatory for all food businesses in Australia.

Food safety programs are a requirement of one of four food safety standards in Chapter 3 of the *Australia New Zealand Food Standards Code*. The standards are:

Standard 3.1.1 *Interpretation and Application*

Standard 3.2.1 *Food Safety Programs*

Standard 3.2.2 *Food Safety Practices and General Requirements*

Standard 3.2.3 *Food Premises and Equipment*.

These standards do not apply in New Zealand.

The Food Safety Standards 3.1.1, 3.2.2 and 3.2.3 are currently being introduced by State and Territories, and should be in place in all jurisdictions by mid-2002.

Standard 3.2.1 *Food Safety Programs* is a ‘model’ standard. It will only apply to food businesses if a State or Territory Government chooses to introduce a mandatory requirement for food safety programs for some or all types of food businesses. If a State or Territory does introduce a requirement for food safety programs, it has agreed to use this ‘model’ standard.

Although food safety programs have been required for food businesses in some sectors of primary industry for some time, currently Victoria is the only State where food safety programs are required for food businesses in the food service sector. This is required by the Victorian Food Act, not by the adoption of the ‘model’ standard.

State and Territory Health or Human Services Departments are responsible for food regulation and enforcement under State and Territory Food (or Health) Acts. States and Territories are currently

reviewing their Food (or Health) Acts to support the introduction of nationally consistent offences, defences and other legislative arrangements for the sale of safe and suitable food. States and Territories have agreed to amend their legislation in accordance with the terms of an intergovernmental agreement to adopt provisions of a Model Food Act. The Model Food Act describes the roles and responsibilities of food safety auditors and other matters related to auditing. This publication includes the provisions of the Model Food Act in shaded boxes identified by the section number and explains these provisions in detail.

Auditors should note that States and Territories may produce handbooks or other guidance materials on the roles and responsibilities of food safety auditors assessing food businesses located within their jurisdictions. These information materials may refer to relevant sections of the State's or Territory's Food (or Health) Act. Auditors should ensure that they are aware of, and comply with, any such guidance material.

Under the Food (or Health) Acts, Health or Human Services Departments may delegate some of their responsibilities under the Acts to local government or councils. However, delegation is likely to differ between jurisdictions. The term 'enforcement agency' has been used throughout this publication to represent State and Territory Health or Human Services Departments or their delegates.

The audit procedures are based on international best practice for managing system audits: the international standard ISO 10011-1. This standard is published in Australia and New Zealand as standards AS 3911.1 and NZS 10011.1 respectively. The international standard only provides general requirements for undertaking audits, and must be interpreted to reflect the Australian food regulatory environment.

Scope of the handbook

ANZFA intends that this document act as a framework for a nationally consistent approach to auditing. Approved auditors should use the guidance in the handbook when planning audits, carrying out audits or following up audit findings, that is, at any time when the auditor is undertaking an assessment for compliance with a food safety program requirement and the Food Safety Standards.

This document does not cover every eventuality that may occur. There will be isolated incidents that fall outside the standard procedures. Where these occur, the enforcement agency can assist and provide direction.

1 Types of auditors

Auditors are usually referred to as ‘first-’, ‘second-’ or ‘third-’ party auditors.

First-party auditors are (usually) employees of a food business who carry out internal auditing of the same business. Internal audits may be useful for the business to assess whether it is meeting regulatory requirements and to review its food safety program to ensure that it is adequate. The outcomes of the audit will not be recognised by the enforcement agency as an audit to satisfy the requirements of Standard 3.2.1.

The term ‘food safety auditors’, for the purposes of the legislation, means either a second-party or third-party auditor to the food business. Second-party food safety auditors are auditors employed by the government to undertake audits of food businesses on behalf of the government. Third-party auditors are private and independent of the government and the food business. They are contracted by a food business to fulfil its legal requirements to have its food safety program audited.

All auditors—second- or third-party auditors for the purposes of the legislation—must meet auditor approval criteria and be approved by the State or Territory Health or Human Services Department in the jurisdiction in which they are auditing.

Officers of government agencies who are authorised under food (or other appropriate) legislation may also be eligible to be food safety auditors. In order to become approved as a food safety auditor, authorised officers will have to be assessed against the auditor criteria and be approved by State and Territory Health or Human Services Departments as food safety auditors. Once approved, they will have the duties and responsibilities of approved auditors as described within the Model Food Act, as well as retaining the powers of an authorised officer. ANZFA will develop, in consultation with the Australian Institute of Environmental Health (AIEH), a document to provide guidance for authorised officers who are also food safety auditors.

There is more information on approval of auditors in *Food Safety: An audit system*.

2 General requirements

2.1 Confidentiality

The following provisions within the Model Food Act restrict the disclosure of information gained through the audit process. Auditors may be asked by food businesses to sign additional confidentiality statements to protect commercial-in-confidence information.

110 Disclosure of certain confidential information

(1) A person who has, in connection with the administration or execution of this Act, obtained information relating to manufacturing secrets or commercial secrets or working processes must not disclose that information unless the disclosure is made:

(a) with the consent of the person from whom the information was obtained, or

(b) in connection with the administration or execution of this Act, or

(c) for the purposes of any legal proceedings arising out of this Act or of any report of any such proceedings, or

(d) in accordance with a requirement imposed by or under this Act or any other law, or

(e) to a person administering or enforcing a law of another jurisdiction that corresponds to this Act or any other law prescribed by the regulations, or

(f) to the Australia New Zealand Food Authority, or

(g) to a law enforcement authority, or

(h) with other lawful excuse.

Maximum penalty: $50,000.

(2) A person is not guilty of an offence under this section if the information was publicly available at the time the disclosure concerned was made.

2.2 Maintenance of impartiality and independence

An important auditing principle is that the auditor should be free from bias and influences that could affect the objectivity of the audit. All persons involved in the audit process should respect and support the independence and impartiality of the auditor, as this reflects on the auditor's integrity. The objectivity of the auditor may be compromised if the auditor has:

- provided a consultancy service to the food business for food safety program development and/or implementation; or
- provided food safety training courses that include specific advice on addressing food safety issues in a particular food business; or
- any ownership of the food business, either partial or full, or ownership by a family member; and/or
- previously been or is currently employed by the food business.

The Model Food Act includes a provision requiring food safety auditors to notify the relevant authority of any direct or indirect interest in a food business.

62 Food safety auditor to give notice of certain interests

(1) A food safety auditor must notify the relevant authority of any direct or indirect interest in any food business that the auditor has as soon as possible after becoming aware of that interest.

Maximum penalty: $5,000.

(2) Payment to an auditor for carrying out the functions of an auditor does not constitute a direct or indirect interest in a food business for the purposes of subsection (1).

It is the responsibility of the food business, not the auditor, to identify how non-conformances should be remedied. In some circumstances it is appropriate for auditors to provide general advice to food businesses regarding food safety issues. However, the auditor should not provide a consultancy to the food business or tell them what they must do to comply with the Food Safety Standards. While there may be some instances where this cannot be avoided, it should be minimised through a general policy of not allowing auditors to develop food safety programs or have a role in their implementation if there is a possibility that they may have to audit it. This is vital to the integrity of the audit system. Where the situation cannot be avoided, the responsibility to monitor it should fall on State and Territory Health or Human Services Departments.

2.3 Insurance

There is no specific requirement, either in the legislation or the approval conditions, for auditors to have adequate insurance cover. However, because the Crown will not be vicariously liable for the negligent acts of third-party auditors, these auditors should have adequate professional indemnity insurance.

2.4 Certificates of authority

On approval, an auditor will be issued with a certificate of authority. The Model Food Act outlines the minimum information that the certificate should include.

70 Certificates of authority of food safety auditors

(1) The relevant authority is to provide each food safety auditor with a certificate of authority as a food safety auditor.

(2) The certificate of authority:

(a) must state that it is issued under this Act, and

(b) must give the name of the person to whom it is issued and bear a photograph of that person and the person's signature, and

(c) must state the date (if any) on which it expires, and

(d) must specify any conditions to which the person's approval is subject, and

(e) must bear the signature of the person by whom it is issued and state the capacity in which the person is acting in issuing the certificate.

Food safety auditors are required to carry identification on them when auditing so that food businesses can readily identify auditors and any associated approval conditions.

2.5 Appeals, complaints and disputes

Disagreements or disputes that arise during the audit process should be dealt with appropriately. If disputes cannot be resolved between parties these complaints should be taken to a third party for resolution. Complaints and disputes would generally relate to such issues as:

- interpretation of the requirements of the standards;
- level of non-conformance raised (that is, whether notifiable or non-notifiable);
- whether a follow-up audit is necessary for verifying corrective action taken by the food business;
- the level of audit frequency; and/or
- the priority classification assigned to a food business.

Where food businesses are unhappy with a decision made by an auditor or enforcement agency, they are able to appeal the decision. Each State and Territory will have processes for appeals; some may involve an appeals tribunal. The enforcement agency or State and Territory Health Department will be able to inform food businesses and auditors of the arrangements for each jurisdiction.

2.6 Contracting with a food business

The contract between the auditor and the food business is an important part of the audit process as it outlines the agreement for the provision of services. Optimally, the contract is a written contract, to protect both parties; however, it may also be verbal. Whether verbal or written, the contract should include the following as a minimum:

- the type of service to be provided, for example, the auditing of the food business to assess compliance with the Food Safety Standards;
- the cost of the service (usually in dollars per hour or day);
- the type of audit covered, for example, whether the cost quoted includes follow-up audits where required;
- the requirements covering confidentiality and conflict of interest;
- the dispute resolution process; and
- the roles and responsibilities of each party.

2.7 Priority classification

The frequency of audits is based on a priority classification system approved by the State or Territory Health Department. The enforcement agency assigns a classification to the food business that determines when the business should implement a food safety program and the audit frequency of the business. The link to audit frequency is detailed later in this document (see Section 5.2). ANZFA has developed *The Priority Classification System for Food Businesses* for this purpose. This scoring system classifies food businesses into risk classifications according to the food safety risks that the

business presents. Food businesses are assigned a score that relates to one of three priority classifications, high, medium and low. Factors taken into consideration in the classification of food businesses include:

- food type and intended customer use;
- activity of the business;
- method of processing; and
- customer base.

The ANZFA document *The Priority Classification System for Food Businesses* can be accessed from the ANZFA website at www.anzfa.gov.au.

3 Roles and responsibilities

The following sections outline the roles and responsibilities of each participant in the audit process. However, there may be some variation among States and Territories. To account for this, reference should be made to the appropriate auditor handbook for the State or Territory in which the food business is located.

3.1 The food business

The responsibilities of the food business are clearly documented in the Food Safety Standards. If the food business does not meet one or more of these requirements, they do not comply with the Food Safety Standards and therefore must rectify any deficiencies identified. Copies of the Food Safety Standards are available on the ANZFA website or from the publishers, ANSTAT Pty Ltd.

3.2 The food safety auditor

The food safety auditor will assess whether all hazards have been identified in the food safety program and whether these hazards are being adequately controlled. The responsibilities of auditors are identified in the Model Food Act and the regulations of each State or Territory, and in the terms and conditions of approval. These may vary between States and Territories. However, the national approach requires the auditor to:

- meet and maintain the requirements for approval;
- notify the enforcement agency if he or she has a direct or indirect interest in a food business seeking his or her services;
- undertake and report on audits in accordance with legislation and this handbook;
- adjust audit frequency within the priority classification only where food business performance meets specified requirements (see audit frequency model in Section 5.2);

- where there are changes to the food business that affect the priority classification of the business, notify the enforcement agency of the changes; and
- keep information regarding a food business he or she is auditing confidential, unless required by law to disclose this information.

Auditors should also keep comprehensive records of audits undertaken for review by enforcement agencies, and be able to demonstrate the process followed should they be required to do so.

The Model Food Act goes further to identify specific duties of food safety auditors.

67 Duties of food safety auditors

A food safety auditor has the following duties:

(a) to carry out audits of any food safety programs required by the regulations to be prepared in relation to food businesses having regard to the requirements of the regulations,

(b) to carry out any necessary follow-up action, including further audits, if necessary, to check to see if action has been taken to remedy any deficiencies of any such food safety program identified in an audit,

(c) to carry out assessments of food businesses to ascertain their compliance with requirements of the Food Safety Standards,

(d) to report in accordance with section 68.

Requirements for the reporting of audit outcomes are also specified in the Model Food Act. The intent of this is to ensure that reporting is consistent and is carried out in a timely manner, dependent on the level of risk to public health. These requirements are included in Section 4.5 of this document.

3.3 The enforcement agency and relevant authority

The enforcement agency will in the majority of cases be the local government or council, and the relevant authority will be the State or Territory Department with food safety responsibilities. These bodies have a number of roles within the audit system that are identified within the Model Food Act and regulations. While not documented in legislation, the following responsibilities lie with the enforcement agencies and the State or Territory Health Department:

- development and maintenance of an audit management system that ensures the ongoing integrity of the audit system;
- approval of food safety auditors;
- monitoring of audits undertaken and auditors through both report reviews and on-site assessments;
- enforcement, where regulatory action is required, including prosecution;
- investigation of complaints made against auditors and food businesses; and
- definition of what constitutes a direct or indirect interest in a food business.

4 Audit procedures

The following audit procedures have been established to guide food safety auditors in the performance of the audit. These are general procedures that will apply in the majority of cases. Where a situation falls outside these procedures the enforcement agency will need to be notified to provide further direction.

4.1 Documentation review

Before undertaking an on-site audit of a food business, a food safety auditor will need to review the food business's documentation to ensure that the business has adequately documented a food safety program and that the program meets the requirements of the Food Safety Standards. If the food safety program is not adequate or is incomplete, there is nothing to be gained by completing the on-site assessment, as deficiencies will almost certainly have been identified in the documentation review.

Documentation reviews should clearly identify deficiencies or compliance against each of the requirements of the food safety program requirement and the Food Safety Standards. All reports should be clear and unambiguous to ensure that the food business is aware of where deficiencies lie. Table 1 provides an example of how these should be documented.

Table 1 Documentation of deficiencies and compliance

The examples relate to deficiencies and compliance identified in a fictional hot chicken food service outlet.

CLAUSE NO.3	REQUIREMENT	COMMENT	COMPLIES/ DEFICIENCY
5 (a)	systematically identify the potential hazards that may be reasonably expected to occur in all food handling operations of the food business.	The food safety program has identified all hazards associated with the food handling processes, to be verified at on-site audit.	Complies
5 (b)	identify where, in a food handling operation, each hazard identified under paragraph (a) can be controlled and the means of control.	The food safety program does not identify how hazards related to the cooling of chickens, to be sold as cold chickens, are controlled. Needs to be documented.	Deficiency

3 This example refers to Food Safety Standard 3.2.1 *Food Safety Programs*.

4.2 Planning the audit

Before carrying out the audit, the auditor should be well prepared, to ensure that the audit meets its objectives. Part of this planning includes:

4.2.1 *Determining the scope and objectives of the audit*

Auditors must know what the basis for the audit is and why they are going to carry out the audit. The scope of the audit will depend on a number of factors, including:

- the type of audit, that is, initial or follow-up;
- the size and complexity of the food business; and
- the nature of the business, for example, whether seasonal or all-year.

It is the responsibility of the food business to ensure that the food safety program is audited, in its entirety, at the minimum frequencies established by the enforcement agency. Partial audits are an acceptable method of assessment, that is, for only a part of the food safety program to be assessed at each audit. When partial audits are undertaken, collectively they must achieve the minimum frequency levels. For example, an auditor may undertake two partial audits to collectively cover the entire food safety program within the minimum yearly frequency. The auditor should discuss the advantages and disadvantages of such an approach with the food business and the enforcement agency.

4.2.2 *Determining audit duration*

A number of factors affect the duration of an audit. These include, but are not restricted to:

- the scope of the audit to be undertaken;
- the size of the food business;
- the complexity of the food business;
- the complexity of and the level of documentation included in the food safety program;
- the degree of cooperation of the food business in providing information and promptly remedying deficiencies when reported;
- the number and type of changes in the food business since the last audit; and
- the number of non-conformances found during the audit.

The auditor is responsible for determining audit duration, as he or she will have access to the appropriate information about the business. It is likely that the duration of the initial audit will be longer than subsequent audits, as the auditor will need to become familiar with the food business's operations and food safety program. The auditor will be required to justify audit duration if required to do so by the enforcement agency. The auditor should also clearly outline charging arrangements if overall costs are likely to increase due to one or more of the above factors.

4.2.3 *Announced and unannounced audits*

The majority of audits will be announced to the food business before the audit date. However, unannounced audits are permitted if the auditor believes that it will achieve a more satisfactory outcome or a more accurate indication of the business's operations. Any arrangements in relation to

unannounced audits should be discussed with the enforcement agency before conducting such an audit. Under normal circumstances, the auditor should notify the food business of the audit date.

4.2.4 *Establishing audit competency requirements*

Before conducting audits, auditors must ensure that they have the appropriate competencies required to carry out the audit. The auditor must not conduct an audit within an industry category, classification or high-risk process in which the auditor has not received prior approval to audit. Other factors such as language requirements and/or experience with certain processing techniques should also be considered. If the auditor is not competent in the required areas, the auditor should ensure that a technical specialist, interpreter or another auditor is available for the audit.

For information on the approval of auditors, see *Food safety: An audit system*.

4.2.5 *Audit teams*

There may be instances where, due to the size and/or complexity of the food business, an audit team, rather than an individual auditor, may be needed to carry out an audit. For instance, a dairy manufacturer with a number of different production lines and production technologies may require a team of two or more auditors for a number of days. The competencies identified for the assessment may be held by the team. Not all members would need to have all the competencies required. The assignment of tasks within the team should be based on the competencies of audit team members.

4.2.6 *Notifying the food business of the audit*

Unless the audit is to be unannounced, it is the auditor's responsibility to ensure that the food business is aware of the arrangements for the audit and negotiate with the food business on the audit arrangements.

4.3 Preparing for the on-site audit

This section refers to the preparation of on-site auditing activities. This could include such activities as preparing an audit plan. If the food business is large and complex, and an audit team is required, an audit plan will be helpful to ensure that the audit team members are organised. An audit plan can also give the food business an idea of timings for the audit.

Some businesses operate from more than one location. For example, a caterer may prepare food at a central kitchen and then transport it to serve at another location. The auditor will need to be satisfied that the food safety program covers all stages of the business's operations and plan to conduct parts of the audit at each of the separate locations. Involvement of the business in planning the audit will be particularly important to ensure that separate locations are visited at appropriate times.

Auditors should ensure that they have the appropriate working documents, forms, and standards against which the assessment is being made. Good audit planning is important in minimising audit duration and disruption to the food business, and ensuring that audit objectives are met.

4.4 Performing the on-site audit

4.4.1 Opening meeting

In a large, complex food business the opening meeting is a chance for an audit team to be introduced to management, for the audit plan to be discussed and for logistical arrangements, such as guides and work areas, to be confirmed. In a small food business it may be no more than making staff aware of the auditor's presence and confirming that the arrangements made prior to the audit do not need to be altered. The opening meeting is an opportunity to let the food business know why the auditor is there and the arrangements for the audit.

4.4.2 Examination

This is the body of the audit, and covers the collection of objective evidence and documentation of audit observations. Evidence can be collected through interviews, examination of documentation and/or observation of activities. Where there are deficiencies or non-conformances detected, these need to be documented clearly and concisely against specific requirements of the Food Safety Standards. The food business should also be made aware of deficiencies when they are found during the audit.

During the audit, the auditor will be verifying that the food business is complying not only with the documented food safety program, but also with the Food Safety Standards. Auditors should review their findings before the closing meeting, to ensure that all audit objectives have been met.

4.4.3 Verification and validation

A food safety program is based on the HACCP principles and is a documented program that systematically identifies potential hazards that may be reasonably expected to occur in food handling operations and, if not controlled, may lead to the preparation of unsafe food. The food business is responsible for ensuring that any processes put into place to control hazards are effective. The auditor's responsibility is to verify that the food business has appropriate controls in place. The auditor must also verify that the food safety program complies with the Food Safety Standards and that the food business is complying with the food safety program.

4.4.4 Closing meeting with the food business

It is important that the auditor reports the findings of the audit to the food business at the completion of the audit so that the food business has an opportunity to discuss the findings and provide further information to the auditor if appropriate. The number of people involved and the time taken for a closing meeting will depend on the size and complexity of the food business and the number and extent of the audit findings. The main objective is to ensure that all personnel in the audit have a clear understanding of all findings, including positive ones. The food business's representative should acknowledge any non-conformances raised by the auditor. The preferred form of acknowledgment would be for the audit report to be signed by the relevant personnel.

4.5 Audit reporting

The auditor is required to report on the outcomes of the audit to both the enforcement agency and the food business. The following is the provision that has been included in the Model Food Act for the reporting of the outcomes of food safety program audits.

68 Reporting requirements

(1) A food safety auditor must report in writing to the appropriate enforcement agency the results of any audit or assessment carried out by the food safety auditor for the purposes of this Act.

(2) A report under subsection (1) must:

(a) be in the prescribed form,

(b) be submitted to the appropriate enforcement agency within 21 days after the completion of the audit or assessment, and

(c) take account of any action taken before the submission of the report to remedy any deficiency identified by the food safety auditor.

(3) A food safety auditor must indicate in a report of an audit under subsection (1):

(a) whether or not the food safety auditor is of the opinion that the food business is being carried on in compliance with the requirements of the regulations relating to food safety programs, and

(b) any such requirements that the food safety auditor is of the opinion are being contravened in relation to the food business and the manner in which they are being contravened.

(4) A food safety auditor must indicate in a report of an assessment under subsection (1):

(a) whether or not the food safety auditor is of the opinion that the food business is being carried on in compliance with the provisions of the Food Safety Standards, and

(b) any such provisions that the food safety auditor is of the opinion are being contravened in relation to the food business and the manner in which they are being contravened.

(5) A food safety auditor must report any contravention of this Act, the regulations relating to food safety programs, or the Food Safety Standards that comes to the food safety auditor's attention in the course of carrying out an audit or assessment for the purposes of this Act:

(a) that is an imminent and serious risk to the safety of food intended for sale, or

(b) that will cause significant unsuitability of food intended for sale,

as soon as possible but in any event within 24 hours after the contravention comes to the food safety auditor's attention.

(6) A food safety auditor must report in writing to the appropriate enforcement agency, giving reasons, if the food safety auditor considers that the priority classification of a food business that has been audited by the food safety auditor should be changed.

(7) A copy of a report provided to the appropriate enforcement agency in relation to an audit or assessment must be given to the proprietor of the food business concerned.

4.5.1 Audit outcome reporting

The food safety auditor is required to report the outcomes of the audit to the enforcement agency and the food business within 21 days of carrying out the audit. The enforcement agency and the relevant authority will establish the content requirements of the report and a form will be prescribed for this purpose. The report should, however, include the following minimum requirements:

- the date(s) of the audit;
- the name(s) of the auditor or audit team, and signatures of those responsible for the report;
- the names and addresses of the food business or food business units audited;
- the scope and objectives of the audit, including the type of audit, that is, whether a scheduled or follow-up audit;
- information regarding non-conformances raised during the audit (this could be copies of the non-conformances themselves if requested by the enforcement agency);
- copies of records relating to non-conformances, if applicable;
- information regarding any change in the food business's food handling operations that would affect the priority classification of the food business; and
- a statement of compliance on which to base audit frequency variation. If a variation is proposed, there should be sufficient information within the report to substantiate the variation.

Enforcement agencies should inform auditors of the requirements for reporting and the method of reporting, such as facsimile or e-mail.

The auditor should retain audit documents for review by the enforcement agency. The review of such documents will be included in the monitoring of the auditor's performance.

4.5.2 Non-conformance reporting

Notifiable non-conformances must be reported to the enforcement agency, as soon as possible after the audit and within 24 hours. The actual audit may be abandoned to allow a report to the enforcement agency if an imminent risk to public health exists. As the approved auditor does not have any powers under the Model Food Act, an authorised officer must be called to take action on notifiable non-conformances.

Non-conformances should be documented on a prescribed form that contains the following information:

- name and address of food business being audited (and site if applicable);
- the date on which the non-conformance was issued;
- a non-conformance number;
- the requirement against which the non-conformance is being raised;
- the details of the non-conformance, including copies of records if required (that is, for non-conformances);
- signatures of the auditor and the person in the business with whom the non-conformance was discussed;

- proposed corrective action (as indicated by the food business); and
- details of verification of corrective action.

In this way, all relevant information regarding a non-conformance is contained on one form. Non-conformance reports should be included with audit reports, including notifiable non-conformances that have already been notified to the enforcement agency.

4.6 Audit completion

The food safety audit is completed when all planned audit activities have been concluded and the audit report has been provided to the enforcement agency and the food business.

4.7 Corrective action follow-up

It is the responsibility of the food business to determine the corrective action needed to rectify non-notifiable non-conformances (see Section 2.2). Once the food business has decided on the most appropriate corrective action, the business notifies the auditor. The auditor will then have to decide whether a follow-up audit is required to verify the corrective action taken. A follow-up audit is only required if verification cannot be carried out through the review of documentation provided by the food business. This includes situations where activities have to be observed in order to ensure that the corrective action is effective.

The timing of the follow-up audit will be the auditor's decision, in liaison with the enforcing agency, based on the severity, scale or importance of the non-conformance and the amount of time needed to effect corrective action. For minor non-conformances, the auditor may agree to leave follow-up activities to the next scheduled audit.

5 Other considerations

5.1 Auditing of multi-sited food businesses

There are a number of food businesses across Australia that are franchised or operate on a number of business sites. These businesses may have a food safety program that is used by the operators of each of the sites or they may have individual systems or programs for each site.

Whatever the policy of the business regarding development, application and implementation of a food safety program, the auditor must ensure that the food safety program used in relation to a particular business on a particular site is appropriate for the food handling operation at the site of the audit. It is not sufficient to judge the adequacy or implementation of a food safety program on the basis that it conformed when used by another business on another site, even if the businesses have the same parent company or appear to be the same type.

5.2 Audit frequency model

The following audit frequency model is based on the ANZFA-developed *Priority Classification System for Food Businesses*. Three priority classifications have been proposed: low, medium and high. The selection of minimum audit frequencies for each priority classification has been based on a maximum of one every six months (which can be reduced to one every three months on poor performance) and a minimum of one every twenty-four months. A minimum of one every twelve months is the average frequency for many audit systems, and the advised frequencies have been gauged around these figures. The requirement linking audit frequency to priority classification is contained in the Model Food Act.

66 Priority classification system and frequency of auditing

(1) The appropriate enforcement agency must determine:

(a) the priority classification of individual food businesses for the purposes of the application of the food safety requirements of the Food Safety Standards to food businesses, and

(b) the frequency of auditing of any food safety programs required to be prepared by the regulations in relation to the food businesses.

(2) The determination must be made having regard to a priority classification system for types of food businesses approved by the relevant authority.

(3) The appropriate enforcement agency must provide written notification to the proprietor of a food business of:

(a) the priority classification it has determined for the food business, and

(b) the frequency of auditing of any food safety programs required by the regulations in relation to the food business, and

(c) the date by which the food business must have implemented any food safety program required to be prepared by the regulations in relation to the food business.

(4) The appropriate enforcement agency may change the priority classification of an individual food business if the appropriate enforcement agency believes that the classification is inappropriate for any reason, including as a result of changes made to the conduct of the food business.

(5) The appropriate enforcement agency must provide written notification to the proprietor of a food business of any change in priority classification of the food business under subsection (4).

There may be a need for an auditor to follow up non-conformances raised at audit, or for enforcement agencies to follow-up on complaints made or incidents reported. Regulatory and follow-up audits are not included in this audit frequency model and will be in addition to the frequencies stated. Table 2 outlines the audit frequencies for each classification.

Table 2 Frequency ranges

CLASSIFICATION	AUDIT FREQUENCIES (AUDIT OCCURS EVERY *X* MONTHS)		
	INITIAL	MAXIMUM	MINIMUM
Low	18	12	24
Medium	12	6	18
High	6	3	12

If there is a compliance history available to the auditor or enforcement agency as a result of the inspection process, this may be taken into consideration after the initial audit, and the frequency of audit may be adjusted accordingly. Otherwise, the outcomes of two audits will be required to establish a compliance history that can allow the adjustment of audit frequency.

5.2.1 Scope of audit

The frequencies have been established as minimums for assessment of the entire food safety program. That is, if the auditor undertakes audits at the set frequency, for instance once a year, then the entire food safety program should be assessed at each audit. However, there is scope for partial audits (see Section 4.2.1).

5.2.2 Movement of frequency within classification

In order to be able to reward good performers and penalise poor performers, there is a process for variation of audit frequencies. Under the provisions of the Model Food Act, the food safety auditor can change the frequency of audits for a specific business. In determining the change, the auditor must consider the compliance history of the business in regard to the Food Safety Standards and any regulations for food safety programs, and also the compliance history of the business in relation to previous food hygiene legislation. If the business is newly established, there may only be compliance history with the current legislation. A change of frequency should not be based on the outcome of only one audit if there is no previous history to refer to.

69 Re-determination of frequency of auditing

(1) A food safety auditor may determine that the audit frequency of a food safety program required by the regulations to be prepared for a food business that has been audited by a food safety auditor be changed from the initial audit frequency applicable to a food business within the relevant priority classification to another audit frequency within the range of audit frequencies appropriate for food businesses within that priority classification, as set out in the priority classification system referred to in section 66.

(2) A food safety auditor must have regard to the following matters in making such a determination:

(a) the compliance history of the food business concerned in relation to any requirements of the regulations regarding food safety programs and the requirements of the Food Safety Standards,

(b) the audit compliance history (if any) established before the commencement of the Food Safety Standards.

Table 3 offers guidance for variation of audit frequencies. Businesses at the top of the table are operating satisfactorily and therefore the auditor determines that the business should be audited at the minimum frequency. Businesses lower down the table are not operating totally satisfactorily and the auditor may decide to keep the frequency the same or increase it. Businesses at the bottom of the table are monitored by the enforcement agency because enforcement action may be necessary.

Figure 1 reflects this guidance in a flow chart that can be utilised by auditors. Table 4 provides some examples of audit frequency adjustments.

Table 3 Guidance on movement within audit frequency ranges

THE AUDITOR'S LEVEL OF CONFIDENCE IN THE BUSINESS'S OPERATIONS AS A RESULT OF AN AUDIT AND CHECK OF COMPLIANCE HISTORY	AUDIT FREQUENCY DETERMINED BY THE AUDITOR	NOTES
Confidence in the food safety program	**Minimum frequency** Frequency reduces to the minimum level (i.e. if the food business has a high-priority classification and the frequency is currently 6-monthly, then this moves out to 12-monthly). The maximum adjustment is one level.	High level of confidence in the food safety program and the food business. Confidence can be measured in one of two ways: continuing compliance with the food safety program, or the food business has an effective internal food safety audit and management review process. Food businesses cannot be moved to this audit frequency unless the compliance history is available to the auditor, or if the food business has had no non-conformances identified in two previous audits.
Satisfactory food safety program	Frequency remains the same.	Confident that the system has been implemented and is effective. There may still be a small number of non-conformances raised against prerequisite or support programs.[4]
Marginal food safety program	**Maximum frequency** Audit frequency increases to the maximum level (i.e. if the food business has a high-priority classification on 6-monthly audits, the frequency would move to 3-monthly).	The food safety program has been implemented but does not always follow the documented process, i.e. there may be a non-conformance identified that has not placed public health at risk, and therefore does not constitute a notifiable non-conformance. A non-conformance against specific controls within the food safety program would automatically make the program marginal, whereas it may take a number of non-conformances against prerequisite or support programs to make the program marginal.
There are notifiable non-conformances	The frequency of monitoring this business is determined by the authorised officer.	The food business's food safety program is not effective in producing safe food. The auditor raises a notifiable non-conformance and the enforcement agency is notified. It is then the responsibility of the enforcement agency to ensure that the business remedies the identified problems.

4 Prerequisite or support programs are general terms used to identify programs that are implemented by a food business to control general hazards such as personal hygiene and pest control.

Table 4 Examples of audit frequency adjustments

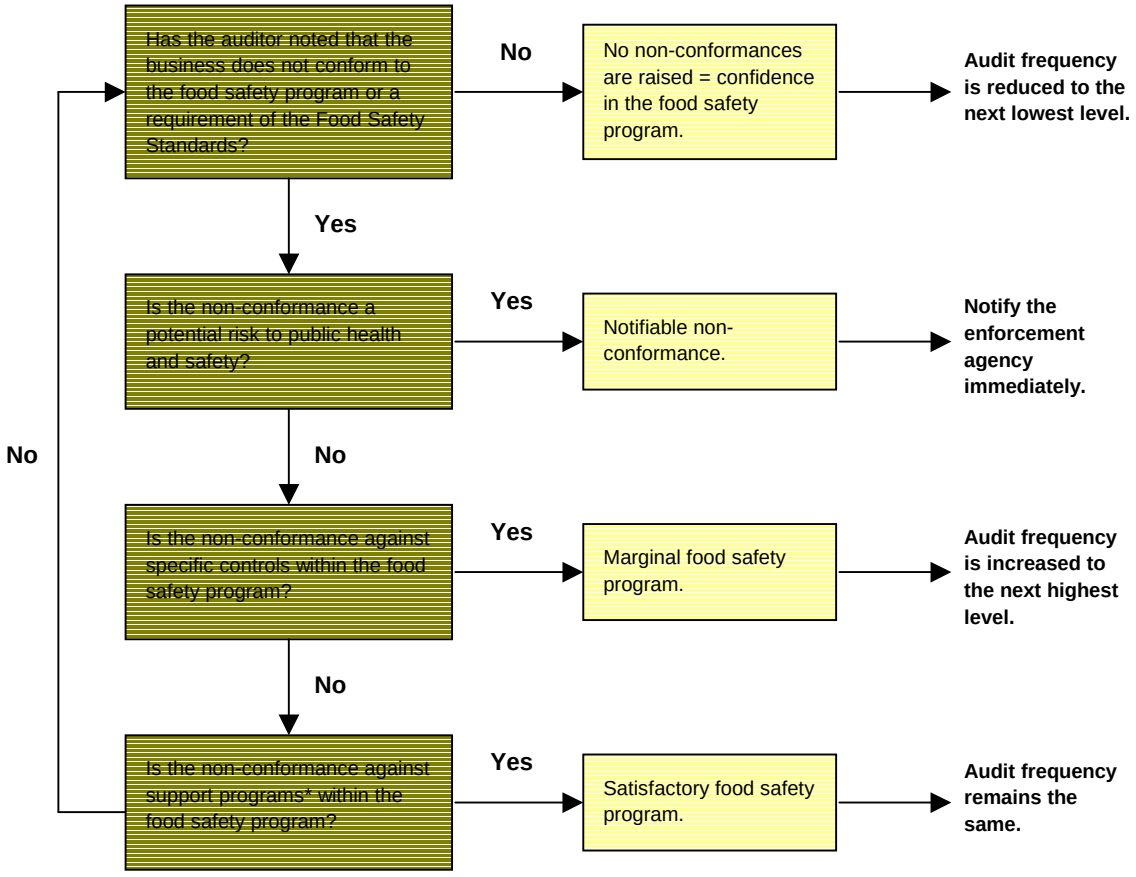
The examples below relate to a single fictional business and show how the audit frequency should be adjusted based on specific non-conformances noted. The business is a retail poultry shop that sells both raw and cooked chicken. The audit frequency for the business at the time of audit is once every 12 months.

LEVEL OF CONFIDENCE	AUDIT FREQUENCY	TYPE OF NON-CONFORMANCE	EXAMPLES
Confidence in the food safety program	Moves from 12-monthly to 18-monthly	Non-notifiable non-conformance	No non-conformances noted. The business complies with their food safety program and the Food Safety Standards.
Satisfactory food safety program	Stays at 12-monthly	Non-notifiable non-conformance	*Example 1:* The auditor notes that although the premises appear clean, there is no cleaning schedule and no records to indicate that the premises have been maintained clean. **The business is deficient in meeting the requirement of Standard 3.2.1 clause 5(f) to provide for appropriate records to be made and kept by the food business demonstrating action in relation to, or in compliance with, the food safety program.** *Example 2:* The auditor notes that the business has missed a quarterly pest control inspection as is specified in the food safety program. **The business is deficient in meeting the requirement of Standard 3.2.1 clause 3(d) to comply with the food safety program.**
Marginal food safety program	Moves from 12-monthly to 6-monthly	Non- notifiable non-conformance	*Example 1:* The auditor notes that the delivery temperature of raw product was accepted by the business at a temperature higher than that specified in the food safety program. **The business is deficient in meeting the requirement of Standard 3.2.1 clause 3(d) to comply with the food safety program.** *Example 2:* The auditor notes that copies of previous audit reports are not available on request. **The business is deficient in meeting the requirement of Standard 3.2.1 clause 4(b) to make the written document that sets out the food safety program, and the appropriate records referred to in paragraph 5(f), available to any food safety auditor who has been requested to conduct an audit of the food safety program.**
Notifiable non-conformance	Frequency must be determined by the enforcement agency.	Notifiable non-conformance	*Example 1:* The auditor notes that cooked ready-to-eat chicken is being contaminated by raw chicken because the same trays are used for raw and cooked chicken and are not adequately cleaned and sanitised between uses. This hazard is not addressed in the food safety program. **The business is deficient in meeting the requirement of Standard 3.2.1 clause 5(a) to systematically identify the potential hazards that may be reasonably expected to occur in all food handling operations of the food business.**

Continued

LEVEL OF CONFIDENCE	AUDIT FREQUENCY	TYPE OF NON-CONFORMANCE	EXAMPLES
			Example 2: The auditor notes that the cooking temperature of chickens is not high enough to destroy pathogens that may be present. This hazard is not addressed in the food safety program. **The business is deficient in meeting the requirement of Standard 3.2.1 clause 5(a) to systematically identify the potential hazards that may be reasonably expected to occur in all food handling operations of the food business.**

Figure 1 Guide for auditors on movement within audit frequency ranges



* A number of non-conformances against prerequisite or support programs may make the program marginal.

Glossary

Source: MFA: Model Food Act

Enforcement Agency means the relevant authority, or any person or body, or a person or body within a class of persons or bodies, prescribed by regulations for the purposes of this definition. (MFA)

Note: In many cases, the enforcement agency is the local government or council, as enforcement responsibilities are often delegated to these bodies.

Food business means an enterprise or activity (other than a business, enterprise or activity that is primary food production) that involves:

a) the handling of food intended for sale, or

b) the sale of food

regardless of whether the business, enterprise or activity concerned is of a commercial, charitable or community nature or whether it involves the handling or sale of food on one occasion only. (MFA)

Food Safety Auditor means a person approved by the relevant authority as described under the Model Food Act. (MFA)

Model Food Act

In order to assist in the development of nationally uniform Food Acts for each State and Territory, ANZFA developed a model Food Act, in consultation with State and Territory Governments. Jurisdictions were invited to enact this model in a uniform manner. State and Territory Governments have reviewed, or are currently reviewing, their food legislation to incorporate the provisions of the model. The version referred to in this document is that forming part of the intergovernmental agreement signed by the Commonwealth, State and Territories in November 2000 agreeing to a cooperative national system of food regulation.

Non-conformance: Where food handling practice(s) are found not to comply with specified requirements. Specified requirements include requirements documented in the food business's food safety program or the requirements of the Food Safety Standards.

Notifiable non-conformance: Where a serious or imminent risk to public health is identified, that is, if the food, practice or situation has compromised consumers' health, or if allowed to continue will compromise consumers' health. The enforcement agency must be notified immediately or at least within 24 hours of such a non-conformance being identified.

Non-notifiable non-conformance: Where there is a non-conformance against the food safety program or Food Safety Standards that is not considered to be a serious or imminent risk to public health. It is the responsibility of the auditor to set an appropriate timeframe for rectification, and to follow up as to how the non-conformance has been rectified. Non-notifiable non-conformances are reported to the enforcement agency by means of the audit report.

Objective evidence: Information that can be proved true, based on facts obtained through observation, measurement, test or other means.

Relevant authority: The relevant authority is the authority in each State and Territory with regulatory responsibility for food safety (usually the State and Territory Health Department). In some States and Territories this responsibility may be shared.

References

AS 3911.1-1992, NZS 10011.1:1992, ISO 10011-1:1990 *Guidelines for auditing quality systems. Part 1: Auditing*.

Australia New Zealand Food Standards Code Chapter 3

Standard 3.1.1 *Interpretation and Application*

Standard 3.2.1 *Food Safety Programs*

Standard 3.2.2 *Food Safety Practices and General Requirements*

Standard 3.2.3 *Food Premises and Equipment.*

Australia New Zealand Food Authority, 2000. Available from ANSTAT Pty Ltd.

Food Safety: An audit system, Australia New Zealand Food Authority, 2001. Available from the Information Officer, ANZFA.

The Australia New Zealand Food Standards Code and other ANZFA publications are available on the ANZFA website www.anzfa.gov.au or www.anzfa.govt.nz. For copies of the Code and User guides to the Code contact ANSTAT, PO Box 447, South Melbourne, Vic. 3205 or telephone 03 9278 1144.