

Food Safety: An audit system

**An information paper outlining an audit system
developed for the purpose of auditing food safety programs**

Acknowledgments

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Executive summary

At the request of State and Territory Health Ministers, the Australia New Zealand Food Authority (ANZFA) developed a package of food safety reforms to update existing regulatory requirements and to ensure a nationally consistent approach to food safety. As part of these reforms, ANZFA proposed that food businesses should be required, over time, to implement a food safety program based on Hazard Analysis and Critical Control Points (HACCP) to control potential food safety hazards. ANZFA has developed a draft food safety program standard for this purpose. To help businesses meet such a requirement, a process for recognising the equivalence of existing food safety, quality and regulatory systems is being developed.

Jurisdictions that implement a food safety program requirement will need to develop an audit system infrastructure in order to assess compliance. ANZFA has developed an audit system for the purposes of auditing food safety programs. The audit system comprises three major elements. These are:

1. the food safety auditor approval process;
2. the audit process; and
3. the audit management system.

The roles and responsibilities of State and Territory Governments in ensuring the integrity of the audit system have been outlined throughout this paper.

Food safety auditor approval

The audit system outlines three food safety auditor levels and appropriate criteria against which applicants should be assessed. The system ensures that auditors have the appropriate competencies required to audit food safety programs.

A rigorous approval process by an approval body accredited to an internationally recognised standard has been recommended for approving food safety auditors. A process for re-assessing auditors is also recommended, to maintain confidence in the competency of food safety auditors.

Audit process

The audit process outlines the role and responsibilities of food safety auditors and describes an audit methodology based on an international standard.

Models have been developed for determining appropriate audit frequencies, for reporting nonconformances and for moving within audit frequency ranges.

Audit management

The management system is based on an international standard and involves the development of policies and procedures to ensure the integrity of the audit system. It covers areas relating to auditing personnel, conflict of interest and commercial confidentiality.

The management system includes internal audits and review of the management system and associated documentation by State and Territory Governments.

Scope and objectives

This paper describes an audit system that has been developed by the Australia New Zealand Food Authority (ANZFA) in consultation with its stakeholders. The policy relating to the audit system is clearly defined in this paper. There may, however, be implementation issues that require further consultation with State and Territory Governments. ANZFA will continue to play a role in identifying these issues and will strive for a consistent approach to implementation where appropriate. This document has outlined issues regarding implementation and the role of State and Territory Governments in the process.

1 Background to the audit system

1.1 The food safety reforms

The audit system has been developed for the purposes of auditing food safety programs. A food safety program is based on the Hazard Analysis and Critical Control Point (HACCP) principles and is a documented program that systematically identifies critical points in food handling operations that, if not controlled, may lead to 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 Australia¹. ANZFA's proposed Food Safety Standards include a food safety program requirement.

ANZFA has proposed that four new standards be adopted nationally for inclusion in the *Australia New Zealand Food Standards Code*. These 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*

Standard 3.2.1 *Food Safety Programs* is a standard that sets out the requirements of a food safety program. The standard requires businesses to document and implement a food safety program based on the HACCP principles. With the shift to requiring food businesses to document their food safety practices and record how they control food safety in their processes, there will be a move from inspection to audit to assess compliance. Through audit, regulators can look at records of what has been happening within the food business, a day-to-day history of compliance, and not just the 'snapshot in time' of current inspection methods. This method gives regulators and the community increased confidence that food safety is being maintained by food businesses on a continuing basis.

Standard 3.2.1 was put on hold by ANZFSO in October 1999 after recommending that a two-year study be undertaken by the Commonwealth Department of Health and Aged Care (DHAC) to assess the cost and feasibility of a mandatory food safety program requirement. While the Territories were generally supportive of a delay in introducing a mandatory requirement for food safety programs, some States indicated their wish to implement an earlier requirement for food safety programs in their jurisdictions. To minimise the potential for the fragmentation of food safety program requirements between jurisdictions, ANZFSO adopted Standard 3.2.1, in the form of a standard with voluntary implementation at their last next meeting in November 2000.

¹ In July 1996 an Agreement between Australia and New Zealand came into effect which established the Australia New Zealand Food Authority. ANZFA is developing joint food standards for both countries to be contained in an *Australia New Zealand Food Standards Code*. Although the Food Safety Standards will be contained within the Code, they will fall outside the scope of the Agreement and therefore will only apply in Australia.

ANZFA recommends that implementation of Standard 3.2.1 *Food Safety Programs* should be risk-based and has developed a priority classification system which can be used to classify food businesses based on their inherent food safety risk.

Standard 3.2.2 *Food Safety Practices and General Requirements* and Standard 3.2.3 *Food Premises and Equipment* will require food businesses to:

- ▶ comply with the requirements for food safety practices and food premises and equipment;
- ▶ ensure that staff have skills and knowledge in food hygiene and safety matters commensurate with their work activities;
- ▶ have in place a system for food recall; and
- ▶ notify the relevant authority about the business.

Nationally consistent implementation of the standards will overcome existing regulatory duplication and overlap between the States and Territories and achieve greater national consistency. The standards were gazetted in the Commonwealth of Australia Gazette (No. S464) on Thursday 24th August 2000 and will be legally enforceable six months from this date.

Underpinning the introduction of the Food Safety Standards is a draft Model Food Act that will allow for the consistent adoption, interpretation and enforcement of the Food Safety Standards. Aspects of the Act will be adopted uniformly by State and Territory Governments.

The Food Safety Standards will not apply in New Zealand as the treaty establishing ANZFA does not include food hygiene standards. New Zealand currently has a voluntary system that allows food businesses to implement food safety programs and have these audited, as opposed to being inspected by local authorities.

1.2 Consultative processes undertaken during the development of the audit system

1.2.1 The audit system working group

To ensure that key issues were addressed in the development of the audit system, ANZFA established a working group with membership drawn from government, industry and consumer groups. The purpose of the working group was to develop an audit system infrastructure suitable for auditing food safety programs. The recommendations of the working group were made available for public comment and consultations were also undertaken with State and Territory Health Departments.

1.2.2 Public comment

The working group developed and distributed four discussion papers for public comment.

These discussion papers were titled:

1. *Food Safety Auditor Approval Criteria* (distributed December 1998);
2. *Guidelines for the frequency and duration of food safety program audits* (distributed February 1999);
3. *Recognition of equivalence of food safety and HACCP-based audit systems* (distributed February 1999); and
4. *Infrastructure for the auditing of food safety programs and the management of the audit process* (distributed March 1999).

The discussion papers proposed recommendations on which submitters were asked to comment. A summary of submissions, which outlines the responses received and how the submissions and concerns were addressed, is at Appendix E.

1.2.3 The implementation working group

The responsibility for food regulation and enforcement is held by individual State and Territory Governments. Senior Food Officers (SFOs) from each State and Territory Health Department and an Australian Quarantine and Inspection Service (AQIS) representative have formed an implementation working group (IWG) to consider the issues surrounding implementation of the Food Safety Standards. This forum often has representation from the Australia New Zealand Food Authority Advisory Council. The IWG is chaired by ANZFA and provides the opportunity for SFOs to identify and discuss common issues and concerns and to develop strategies for progressing such matters.

The IWG has considered the proposals of the audit system working group and supports the audit system outlined in this paper. ANZFA will continue to work with the IWG to promote a consistent approach to implementing the audit system.

2 The existing food regulatory system

Although food standards for such matters as the labelling and composition of food are nationally uniform, there were no nationally uniform food hygiene regulations in Australia until ANZFSC agreed to the adoption of Standards 3.1.1, 3.2.2 and 3.2.3 in July 2000. Each State and Territory currently has its own hygiene regulations leading to national inconsistency. In some jurisdictions existing regulations are out-dated and inappropriate for modern practices. Local government councils are also able to make by-laws or ordinances to regulate food businesses, which compounds the lack of consistency between jurisdictions.

In the current regulatory environment, authorised officers inspect food businesses for compliance against the appropriate State and Territory regulations. ANZFA's proposed changes to the current regulatory environment aim to create a preventive culture to food safety. If Standard 3.2.1 *Food Safety Programs* is approved by ANZFSC as a mandatory standard after considering the outcomes of the DHAC study, businesses will be legally required to take preventive steps to control food safety hazards through the development and maintenance of a food safety program based on HACCP principles. This approach requires the business to take responsibility for the preparation of safe food, as opposed to relying on authorised officers to identify problems within the food business.

3 Cost to government and business

Those jurisdictions that implement a food safety program requirement will need to implement an audit system to assess compliance. State and Territory Governments will have to identify the role of authorised officers in the new system. For authorised officers to have a role in auditing food safety programs, appropriate training and experience will need to be provided. This may require additional resources. The Regulatory Impact Statement *Food Safety Standards Costs and Benefits* developed by ANZFA discusses the impact on government and industry of the cost of reforms.

4 Introduction to the audit system

A food safety audit focuses on gathering information about a food business to identify any areas of potential improvement in the business's food safety processes and systems. It also identifies areas of the business that have deficiencies and the appropriate action to correct any deficiencies.

The audit system comprises three inter-related elements, as represented in Figure 1. Each element is essential to the integrity of the system. These three elements are:

1. an approval criteria and assessment process for food safety auditors;
2. an audit methodology/process that allows for variations in the size and complexity of food businesses; and
3. a management system to respond to audit findings and monitor the efficacy of audits and approved food safety auditors.

The audit system provides an infrastructure within which State and Territory Health Departments can implement a food safety program. It is imperative that certain aspects of the audit system are implemented consistently between jurisdictions. Other aspects of the system are more flexible and implementation procedures and policies will need to be developed by States and Territories. It is anticipated that these policies and procedures will depend on existing operational structures and availability of resources. The role of State and Territory Governments in maintaining the integrity of the audit system has been highlighted in this paper where appropriate.

4.1 First-, second- and third-party auditors

There is scope within the audit system for auditors to be either second-party or third-party to the food business. Second-party auditors are auditors employed by the government and third-party auditors are private and independent of the government. All auditors must meet the approval criteria and be approved by a State or Territory Health Department.

First-party audits involve internal auditing of the food business by the business itself. Internal audits can be useful for the business to assess whether or not it is meeting regulatory requirements. However, there will be no requirements for first-party audits and the outcomes of the audit will not be recognised by the enforcement agency.

4.2 Responsibility for food safety and liability

Requiring food businesses to implement preventive food safety programs shares the responsibility for food safety between food businesses and government. The auditor's role is to carry out audits of food safety programs and to assess the compliance of businesses with food safety program requirements and the requirements of the Food Safety Standards, and then to report the outcomes of the audits and assessments to the enforcement agency. It is then the responsibility of the enforcement agency to implement appropriate enforcement measures when a food business's food safety program is not effective in producing safe food.

Health Departments are responsible for food regulation and enforcement under existing State and Territory Food Acts. Under these Acts, and the draft Model Food Act, Health Departments may delegate some of these responsibilities to local government. However, delegation is likely to differ between jurisdictions. Where delegation is likely to occur, the term 'enforcement agency' has been used throughout this paper to represent State and Territory Health Departments or their delegates.

There are specific requirements within the draft Model Food Act for auditors, regarding the reporting of nonconformances and audit findings. Where nonconformances indicate a risk to public health, the enforcement agency must be notified immediately. It is then the enforcement agency's responsibility to appraise the situation and take the necessary action.

Role of State or Territory Governments

The intention to legislate for a food safety program requirement must be conveyed to food businesses by State and Territory Governments. If such a requirement is implemented, any role for second- and third-party auditors must be clearly defined within each jurisdiction.

5 Criteria and approval for food safety auditors

5.1 Auditor categories

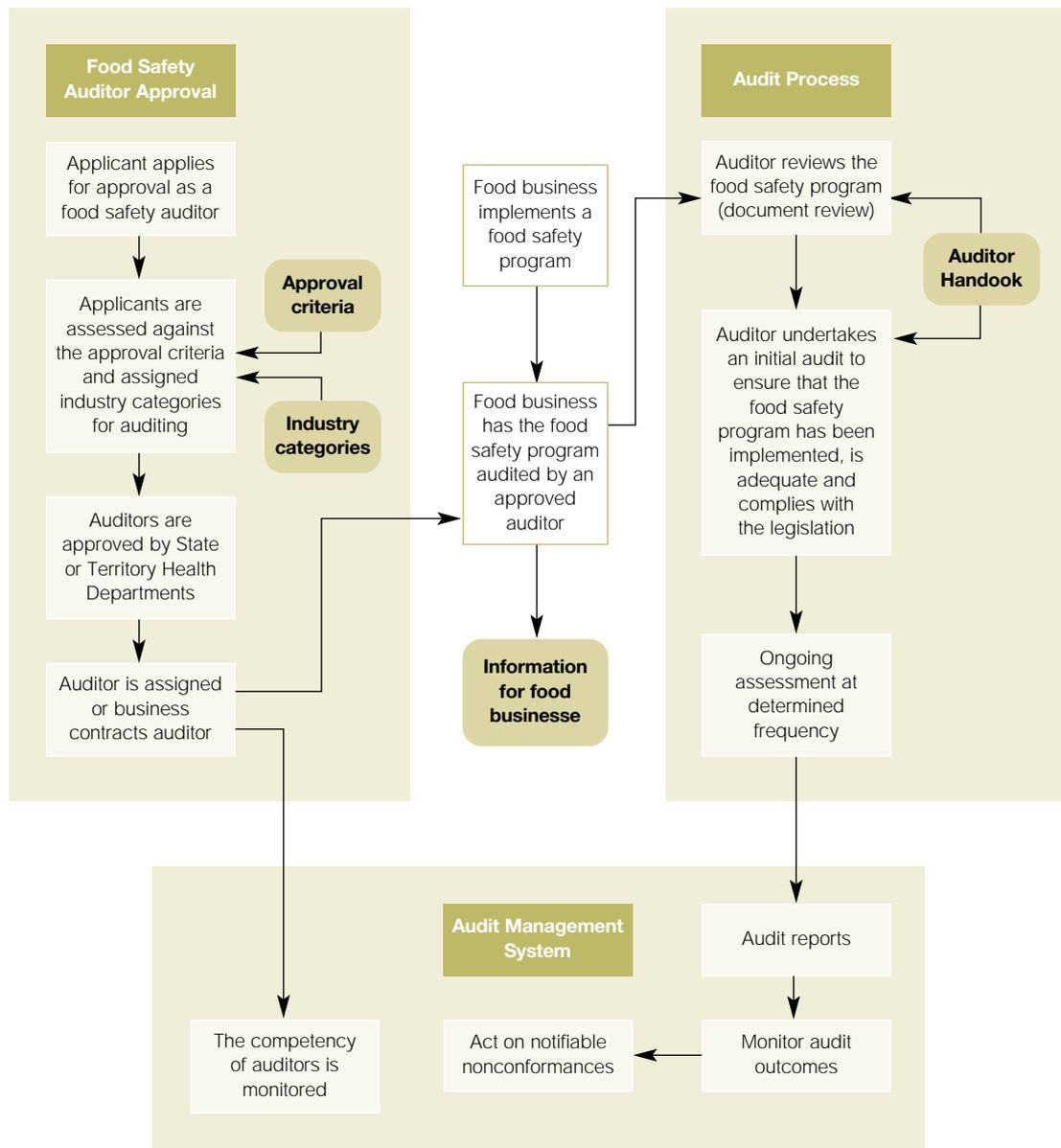
There are three levels of food safety auditors recommended in the audit system. The *Associate Food Safety Auditor*, the *Food Safety Auditor* and the *Senior Food Safety Auditor*. The basic difference between these levels is the amount of audit and industry experience required for each. All levels must be able to demonstrate appropriate competencies in auditing and food safety program development. The following paragraphs explain how auditor levels have been structured and the criteria for each level. The role of *Technical Specialists* is also outlined.

5.1.1 Associate Food Safety Auditor

The *Associate Food Safety Auditor* level gives recognition to those auditors who have the relevant training and technical knowledge but who may not have the experience required to meet the requirements of the *Food Safety Auditor* level. There is no requirement for either auditing or industry experience if the auditor has an appropriate tertiary qualification.

This auditor level will be restricted to low- and medium-priority classified businesses, within industry categories, or as part of an audit team. This allows the *Associate Food Safety Auditors* to use the training they have undertaken and gain experience to allow for progression to the *Food Safety Auditor* level.

Figure 1 The three elements of the audit system



5.1.2 Food Safety Auditor

A *Food Safety Auditor* is an experienced auditor who can work unassisted or in a team. There is no restriction on the priority classification of food businesses that the auditor is allowed to assess. The only restriction is that these be within the industry categories in which the auditor is recognised as competent.

The *Food Safety Auditor* must have completed a minimum of two year's full-time work experience with food/hygiene and food safety programs. They must also have conducted a minimum of four audits within a two-year period.

5.1.3 Senior Food Safety Auditor

A *Senior Food Safety Auditor* is recognised as having audit team management experience and competence. These competencies may be necessary for audit teams for large complex food businesses. This third level gives the auditor some recognition for these additional competencies.

The *Senior Food Safety Auditor* must have completed a minimum of two year's full-time work experience with food/hygiene and food safety programs. They must also have conducted a minimum of five audits as team leader within a two-year period.

5.1.4 Technical Specialist

The term *Technical Specialist* is used for a person who is a specialist in a given field or technology and who assists in the audit process. They do not necessarily need to have any audit experience or food safety program knowledge. Auditors and audit teams may seek assistance from a technical specialist where they do not have the necessary specific technical knowledge.

It is not necessary for technical specialists to undergo a formal approval process. However, their 'technical specialist' status must be able to be justified by the responsible auditor.

5.2 The use of audit teams and competency requirements of teams

There will be times where the size and complexity of a food business is such that a team of auditors is required, rather than a lone auditor. Where an audit team is required to assess a food business it is recognised that not all of the auditors need to have all of the necessary competencies to carry out the audit. Members of the team may have specific competencies required for different parts of the audit.

Auditors must be able to justify the competencies of audit teams if requested to do so through the monitoring process. Monitoring of the audit system by the State and Territory Health Department is discussed in Section 7 of this paper.

Audit team competencies

A factory manufactures canned fish products. It employs 100 staff on the factory floor. It will require an audit team of two auditors for approximately one day to audit the food business.

In order to carry out an effective audit the audit team must have the following competencies:

- ▶ audit skills etc., requirements to be an approved auditor;
- ▶ experience in the seafood processing industry; and
- ▶ experience in canning/retort operations.

There is no requirement that both persons on the audit team have all of these competencies. However, the audit team collectively must have these competencies, and then the audit must be managed in such a way as to ensure that the auditors have the competencies for the parts of the systems that they are assessing. For instance, in the example given, it would be inappropriate for an auditor without the knowledge of canning/retort operations to be auditing that part of the system.

5.3 The approval criteria for food safety auditors

The approval criteria cover five areas of competency. These are:

1. technical/scientific knowledge;
2. food safety program knowledge;
3. auditing skills;
4. processing knowledge; and
5. professional conduct.

The criteria are considered the minimum competencies required by auditors who assess food safety programs. They are based on the requirements of the international standard ISO 1001-2 — *Qualification Criteria for Auditors*² and the areas of competency are consistent with the food safety auditor criteria utilised by the Quality Society of Australasia³. A detailed outline of the food safety auditor approval criteria is attached at Appendix A.

5.3.1 Technical/scientific knowledge

It is considered that each level of auditor must have a basic level of appropriate technical background and knowledge to be able to make judgments regarding the food safety program that has been implemented by the food business.

2 ISO 10011-2 — *Qualification Criteria for Auditors*. This is the internationally recognised standard for the qualification criteria for quality system auditors. There are two other standards in the series, these being ISO 10011-1, *Auditing — Guidelines for Auditing Quality Systems* and ISO 10011-3, *Management of Audit Programmes*. All three standards are currently being revised and merged into one document to cover the auditing of all types of management systems, including environmental management systems for which there are currently separate requirements.

3 The Quality Society of Australasia (QSA International) is a not-for-profit company, accredited by the JAZ-ANZ for personal certification

An appropriate technical background should include grounding in food hygiene and safety matters, including food microbiology and food production and/or handling. Certain tertiary (or equivalent) qualifications would provide such grounding. Alternatively, a number of years working in industry could also provide sufficient knowledge.

It is also important that food safety auditors have a well-developed ability to locate, interpret and apply legislation. During the audit, the auditor must determine whether the business is complying with the food safety program and whether the program meets the requirements of the Food Safety Standards. Therefore, detailed knowledge of these requirements is necessary to allow for effective assessment.

5.3.2 Food Safety Program knowledge

Food safety programs are based on the principles of HACCP, therefore all food safety auditors will be required to have knowledge of food safety programs based on HACCP principles. Food safety auditors must be able to apply these principles in order to be able to effectively audit food safety programs.

Successful completion of accredited training would be recognised as meeting the requirements for a food safety auditor.

5.3.3 Auditing skills

For an audit to be undertaken effectively, the auditor/audit team must have appropriate knowledge of the audit process and have the appropriate skills and experience as an auditor.

The assessment of a food safety auditor's competence will need to take into account the training and experience of the auditor. Therefore, successful completion of accredited training would be recognised as meeting the requirements.

To meet the relevant audit experience requirements, auditors will need to provide evidence of audits undertaken. This may include a log of audits, verified by food businesses, of audits undertaken.

5.3.4 Processing knowledge

It is well recognised that food safety auditors must have knowledge of the specific hazards in an industry sector or process and the applicable control measures in order to effectively audit a food business's food safety program. Without appropriate knowledge it is not possible to competently assess the effectiveness of the food safety program. The industry categories for assessment of food safety auditors are attached at Appendix B.

Experience may be gained through industry experience, training, formal university study, inspection experience and auditing experience (with industry experts). There is also recognition that persons that have qualifications and training to become auditors, but not the specific processing knowledge experience, could be utilised under expert supervision during auditing, in order to gain the experience required.

The assessment of experience takes into consideration the knowledge that the applicant has attained during such experience, particularly with respect to specific processes and technical knowledge relating to potential problems. Where inspection and auditing experience is taken into account towards food industry experience, there will need to be some indication by applicants of the percentage of their workload that is food-based inspection.

It is recognised that many processes are not specific to individual industry sectors. For example, spray drying may be applied to dairy and non-dairy products and many different products may be pasteurised, including milk, liquid egg, fruit juice, alcoholic beverages, etc.

5.3.5 Professional conduct

The purpose of a code of conduct or ethics is to ensure that an auditor acts in an ethical and professional manner, and does not compromise the integrity of the audit process. It also forms a basis by which approval of the auditor can be withdrawn. The draft Model Food Act will give State and Territory Health Departments the responsibility for approving food safety auditors, and the power to remove that approval. Professional requirements of the auditor in the draft Model Food Act include requirements to disclose conflict of interest and to maintain commercial confidentiality. The enforcement agency will also monitor these requirements through on-site assessment of auditors and complaints received.

5.4 The use of competency standards in the approval criteria

There has been a suite of benchmark competency standards developed by the Australian National Training Authority in response to the development of the Food Safety Standards. These standards are not industry-specific, but will be recognised as guideline competency standards; that is, they indicate the minimum elements or requirements that must be addressed in food safety competency standards developed by industry training advisory boards.

Two of these guideline competency standards have been incorporated into the auditor approval criteria to ensure that auditors have the appropriate competencies. The standards that are particularly relevant to the approval process are:

1. *Develop food safety programs*; and
2. *Conduct food safety audits*.

The *Develop food safety programs* standard outlines the competencies required relating to food safety programs based on the HACCP principles. The *Conduct food safety audits* standard identifies the minimum or baseline competencies required by auditors undertaking audits of food safety programs. These guideline competency standards are attached at Appendixes C and D.

The competency standards will give direction to trainers on the competencies that training must deliver. The auditor approval process will recognise successful completion of accredited training courses (that are based on these guideline competency standards) as meeting approval criteria for food safety program knowledge and audit skills.

Where an applicant is unable to give assessors objective evidence of training, assessment against the competency standard could be used as an alternative assessment method for approval. For example, an applicant (that has not completed accredited training) may be able demonstrate experience or knowledge against all of the competencies outlined in the standard through work or experience. Competency-based assessment could also be used to demonstrate compliance with the processing knowledge.

Once auditors are approved, the State and Territory Health Departments will be responsible for monitoring the performance of the auditor in the workplace. The competency standard can be used for this purpose. State and Territory Health Departments will need to outline this process in their audit management system, which is discussed in Section 7 of this paper.

Role of State or Territory Governments

State and Territory Governments should consistently adopt the auditor approval criteria outlined in this paper.

5.5 Approval of food safety auditors

Responsibility for approval of food safety auditors for regulatory purposes will sit with the State and Territory Health Departments; however, the assessment process can be delegated to another body. There are several provisions within the draft Model Food Act for the approval of auditors, including approval conditions and provision for appeals against approval decisions.

ANZFA has been working closely with State and Territory Governments to develop a consistent approach to approval of existing authorised officers during the implementation period of the audit system. ANZFA has proposed that 'grandfathering' be used initially to utilise the expertise that already exists within local government.

5.5.1 The assessment process

The importance of the assessment of food safety auditors must be recognised in ensuring the integrity of the audit system. To ensure that the auditor competency criteria are applied consistently and effectively across State and Territory boundaries it is important to have a national set of criteria for assessing and approving auditors, and to have a process and method of assessment that is rigorous and consistent.

The best means of achieving a rigorous and consistent approach to approval is for State and Territory Health Departments to delegate the assessment of food safety auditors to an appropriately accredited personnel certification body. The approval body should be accredited against the requirements of EN 45013 — *General criteria for certification bodies operating certification of personnel*.⁴

5.5.2 The advantages of using an international standard

The use of the internationally recognised standard EN 45013 as the assessment body standard provides the following advantages:

1. being based on internationally accepted practice it is defensible to government, the public and the media in terms of rigour and effectiveness;

⁴ The use of this standard allows for any body that meets the standard to offer certification of auditors. There are currently two bodies accredited to the standard EN 45013 by JAS-ANZ. However, the Quality Society of Australasia is the only body currently assessing the competence of auditors.

2. certified auditors have a qualification that is 'transportable', i.e. it will have credibility outside their current field of employment;
3. there is transparency of process;
4. there is scope for the assessment body to be government or non-government;
5. there is scope for different bodies to have different processes for the assessment of applicants, provided they can demonstrate effectiveness and equivalent outcomes;
6. there is scope for contestability, i.e. applicants can choose their certification body on the grounds of, for example, geography, fee structure or process; and
7. auditor certification under the auspices of accreditation by the Joint Accreditation System of Australia and New Zealand (JAS-ANZ)⁵ has the potential to lead to international recognition and improved employment prospects.

EN 45013 includes requirements for the assessment body to ensure that there is impartiality and integrity in the assessment process. This is achieved through the involvement of all interested stakeholders in the management of the certification body, usually through membership of the governing board or a technical advisory committee. Figure 2 shows the steps involved in the approval process.

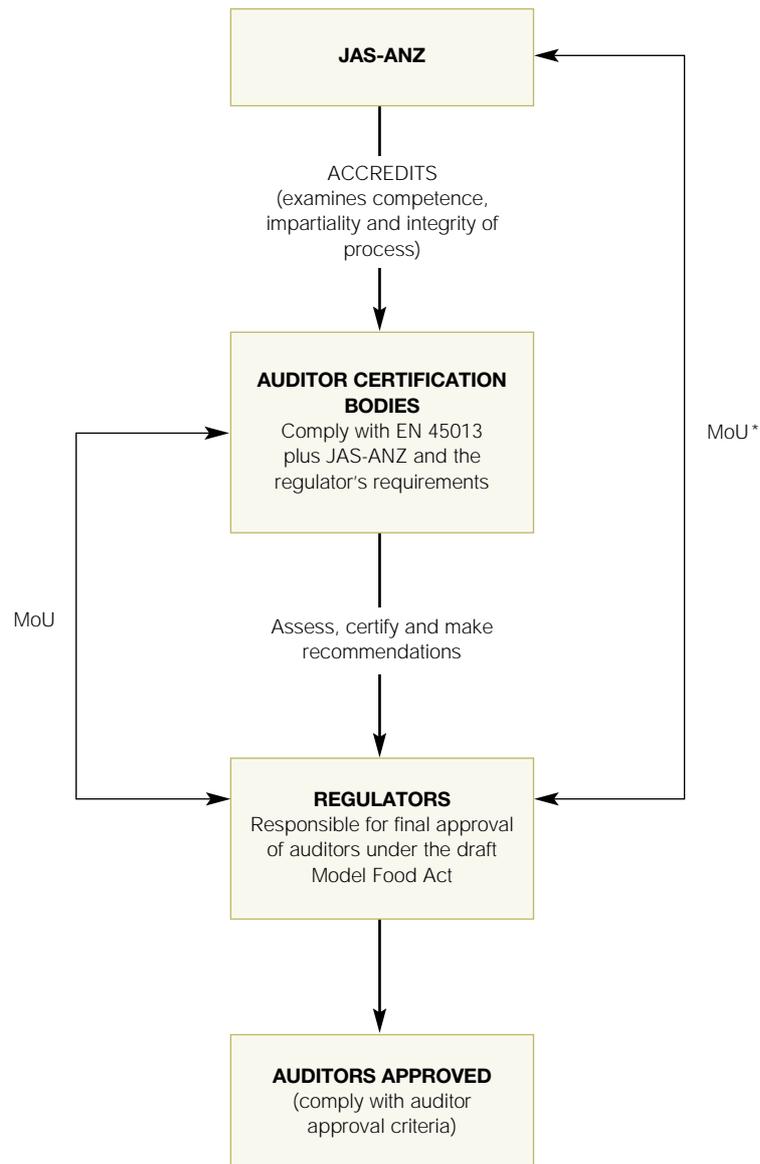
5.5.3 Re-approval of auditors

A process for the ongoing re-assessment of auditors, based on the maintenance of competence, should be implemented by State and Territory authorities. It is recommended that re-approval is required once every two years.

Role of State or Territory Governments

State and Territory Governments should establish a rigorous, consistent and defensible auditor approval process. To achieve this, it is recommended that responsibility for the assessment process of food safety auditors be delegated to an appropriately accredited personnel certification body. The assessment process should be against the nationally consistent approval criteria adopted by all jurisdictions. A process for re-assessing auditors should also be implemented.

5 The Joint Accreditation System of Australia and New Zealand was established in 1991 by a Treaty between the Governments of Australia and New Zealand, to be the accreditation body, in both countries, for certifiers of management systems, personnel and products. It is a not-for-profit organisation that is funded from the fees that it charges for its services.

Figure 2 The approval process

* MoU stands for memorandum of Understanding or agreement between the bodies (in some circumstances a contract may be more appropriate)

6 Audit process

The majority of regulatory and industry audit systems employ the international standard ISO 10011-1 *Guidelines for auditing quality systems Part 1: Auditing* as the audit methodology. This standard is referenced in ISO/IEC Guide 61 and 62, the standards to be met by accreditation and certification bodies respectively, and a prerequisite for acceptance by the International Accreditation Forum (IAF)⁶ for its multilateral recognition agreement. Internationally all accredited quality system certification internationally is undertaken in accordance with ISO 10011-1 and the standard is equally appropriate for food safety auditing.

ISO/IEC Guide 62⁷ also requires that internal audits of certification bodies be undertaken in compliance with ISO 10011-1.

6.1 What and how auditors will assess

Auditors will assess whether businesses are complying with their documented food safety program and the Food Safety Standards. Auditors must be familiar with the requirements of the standards, as they will be required to assess whether the food business complies with each of the standards. Aspects of the audit process are outlined in Figure 3.

Auditors will be required to keep all commercial-in-confidence material confidential. This includes process and product formulation information, food safety program information and audit outcomes. This requirement is discussed further in the section regarding the audit management system.

Auditors will audit in accordance with ISO 10011-1, as interpreted within the Auditor Handbook⁸. This audit methodology is flexible enough to allow the same methodology to be employed for large, medium and small food businesses. The Auditor Handbook will be available from State and Territory Health Departments.

6.1.1 Powers and duties of auditors and authorised officers

Auditors are not assigned any powers in the draft Model Food Act to direct the food business to carry out specific remedial action. They are, however, assigned duties in the Act and these are:

- ▶ to carry out initial audits of food safety programs at the frequency determined by the enforcement agency;
- ▶ to determine subsequent audit frequencies within the range appropriate for the priority classification of the business;

6 The International Accreditation Forum (IAF) was established so that accreditation bodies could meet to discuss issues of mutual interest and to reach a consensus view on important issues that need a common interpretation. The aim of the IAF is to promote mutual recognition between accreditation bodies, and to be a forum for the exchange of information and ideas of common interest.

7 *ISO/IEC Guide 62 — General requirements for bodies operating quality management system certification systems.* This guide has been recognised by Standards Australia and Standards New Zealand as a joint standard SAA/SNZ HB18.65:1998 and AS 3843:1998. This standard forms the basis for quality management certification system accreditation criteria.

8 ANZFA has developed an Auditor Handbook to ensure a consistent approach to the auditing of food safety programs.

- ▶ to assess food businesses for compliance with the Food Safety Standards;
- ▶ to carry out follow-up action to ensure that nonconformances have been rectified; and
- ▶ to report the outcomes of the audit.

Where nonconformances are raised that do not indicate a risk to public health (guidelines are provided in section 6.3.3 of this paper), the auditor can require a food business to provide information on how the nonconformance will be addressed and to assess whether this is adequate. This may or may not require the auditor to carry out a follow-up audit to assess compliance. In some circumstances, follow-up could be a simple process of the business demonstrating to the auditor that corrective action has been taken through provision of invoices or records of services provided to the business.

Directing a food business to carry out any specific action to rectify a nonconformance is the responsibility of the enforcement agency and authorised officers. The powers of the authorised officers have been clearly specified within the draft Model Food Act. The Act gives authorised officers the power to:

- ▶ enter and inspect food premises;
- ▶ examine food, equipment, packages, records and documents;
- ▶ sample food and the equipment;
- ▶ require persons to provide information or answer questions;
- ▶ investigate possible offences under the Act; and
- ▶ seize food, records and/or equipment.

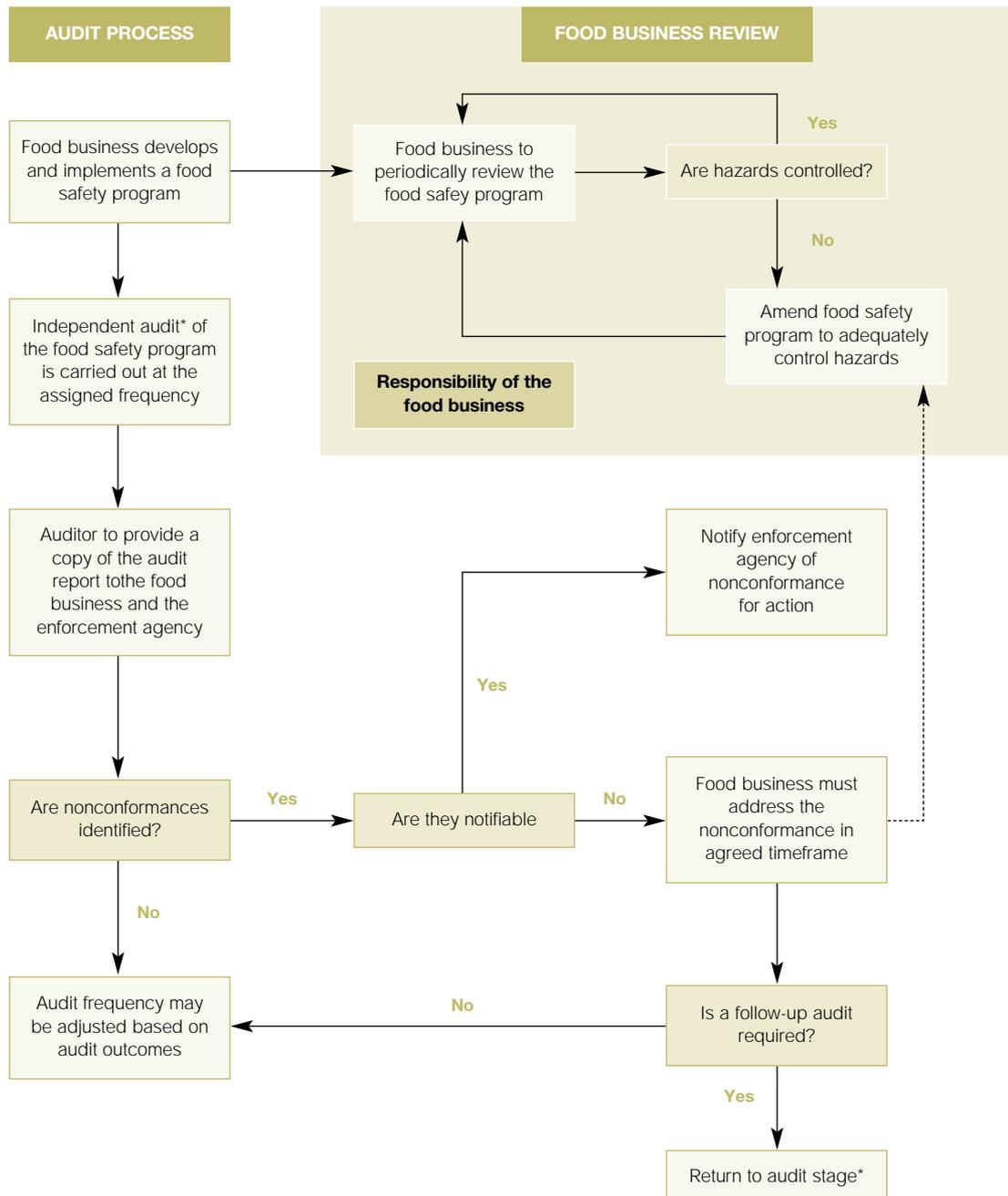
Although the draft Model Food Act delineates the roles and responsibilities of an authorised officer and an auditor, authorised officers can also become auditors. In order to become approved as a food safety auditor, authorised officers will have to be assessed against the auditor criteria and be approved by State and Territory Health Departments as food safety auditors. Once approved, they will have the duties and responsibilities of approved auditors as described within the draft Model Food Act, as well as retaining the powers of an authorised officer.

6.1.2 The role of the auditor in regulation of food businesses

Where a food safety program requirement has been implemented and food businesses are being audited by approved auditors, the powers of the authorised officer are not diminished. It is only the responsibility for compliance assessment against the food safety program that is transferred to the auditors. Auditors should, however, be kept aware of enforcement activity related to a food business to which they are auditing, such as improvement notices issued or prosecutions. A process for this should be developed within the audit management system.

Inspection and audit are only two forms of compliance assessment. Both assess compliance to a standard. Authorised officers currently inspect and enforce. They also have an educational role in many jurisdictions. Changing to audit as the method of assessment need not change the assessment/enforcement/educational roles that authorised officers currently have. It is only the method of assessment that needs to change, due to the new standards being outcomes-based.

Figure 3 Food safety audit and review process



Inspection and audit

Inspection is used to assess compliance where the standard is fairly prescriptive and where no documentation or records are required to be kept by the business. The recognised international definition for inspection is:

'Evaluation for conformity by measuring, observing, testing or gauging the relevant characteristics.'

Audit, on the other hand is used to assess systems. Where a standard requires a business to have a management system to control either processes or the quality of product, then audit is used to assess whether the system has been implemented and is effective in meeting that standard. Audit is used where there is a documented system and records to review. The recognised international definition for audit is:

'A systematic and independent examination to determine whether quality/safety activities and related results comply with planned arrangements and whether these arrangements are implemented effectively and are suitable to achieve objectives.'

6.2 Issues relating to the auditing of food safety programs

6.2.1 Contracting with a food safety auditor

Food safety programs will require auditing at an appropriate frequency that will be determined by the enforcement agency. The *Priority Classification System*⁹ has been developed by ANZFA for this purpose. When third-party auditors are involved, the food business must contract with an auditor to carry out audits. Where second-party audits are involved the enforcement agency will provide auditors for the food business and a contract may not be required.

In instances where a third-party audit is being undertaken, it is the responsibility of the food business to ensure that the third-party auditor is approved for the type of business that requires auditing before entering into the contract. When government is the audit body a review process needs to be implemented to ensure that the auditor assigned to a business is appropriately qualified. There should also be a defined process for determining audit team composition where more than one auditor is required to undertake an audit.

6.2.2 Approval of the food safety program

The audit system does not include a requirement for a food business to apply for recognition or approval of their food safety program. An approval process is not recommended because it has significant resource implications for State and Territory Health Departments and shifts liability from the food business to the approving body. It is also unnecessary, as each audit will reassess the food safety program. Also, any approval loses significance as a business changes with time.

⁹ The Priority Classification System classifies food businesses into risk categories based on the type of food, activity of the business, method of processing and customer base. Food businesses are assigned a score that relates to one of three priority classifications, high, medium and low. The classification system can be used by State and Territory Governments to determine a food safety program implementation timetable and the initial audit frequency for food businesses.

6.3 Preparing and planning for audits

6.3.1 Frequency of audits

The following audit frequency proposal is based on the *Priority Classification System*. Three priority classifications have been proposed. The selection of minimum audit frequencies for each priority classification has been based on a maximum of six-monthly audits (which can be reduced to three-monthly on poor performance) and a minimum of one every twenty four months. A minimum of twelve monthly audits is the average frequency for many audit systems, and the other frequencies have been gauged around these figures.

Follow-up audits and inspections are not included in this audit frequency model. There may be a need to follow-up nonconformances raised at audit, or for the enforcement agency to follow-up on complaints made or incidents reported. These will be in addition to the audit frequencies stated in this model.

Table 1 Frequency ranges

CLASSIFICATION	AUDIT FREQUENCIES (every x months)		
	<i>Starting point</i>	<i>Maximum</i>	<i>Minimum</i>
Low	18	12	24
Medium	12	6	18
High	6	3	12

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

6.3.2 Scope of audit

The frequencies have been established as minimums for assessing 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, 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.

6.3.3 Movement of frequency within a classification

In order to be able to reward good performers, that is, where there is a high level of confidence in the food safety program and the food business, and penalise poor performers, that is, where there is a risk to public health and safety, there must be a process for varying audit frequencies. Table 2 offers a means for variation.

6.3.4 Nonconformance categories and recording

Nonconformances will fall into one of two categories: notifiable or non-notifiable. These have been defined as:

Notifiable: 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 nonconformance being identified.

Non-notifiable: Where there is a nonconformance 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 nonconformance has been rectified. Non-notifiable nonconformances are reported to the enforcement agency by means of the audit report.

The Auditor Handbook will have a key role in standardising reporting of nonconformances and examples are given in the handbook to guide auditors. Nonconformances will need to be formally recorded using appropriate forms. These will be developed and included in the Auditor Handbook. The enforcement agency will have to develop processes for the notification of notifiable nonconformances, and for actioning these.

Table 2 Guidance on movement of food businesses within audit frequency ranges

LEVEL OF CONFIDENCE	AUDIT FREQUENCY	NOTES
Notifiable nonconformance	To be determined by authorised officer, relative to the breach.	The food business's food safety program is not effective in producing safe food. The auditor raises a notifiable nonconformance and the enforcement agency is notified. It is then the responsibility of the enforcement agency to take action to address the identified problems. Assessment of the food business, on identification of a notifiable nonconformance, may include inspection as well as audit, whatever is determined to be appropriate by the enforcement agency.
Marginal food safety program	Audit frequency increases to the maximum level. (i.e. if the food business has a high-priority classification on six-monthly audits the frequency would move to three-monthly).	The food safety program has been implemented but does not always follow the documented process i.e. there may be a nonconformance identified that has not placed public health at risk, and therefore does not constitute a notifiable nonconformance. A nonconformance against specific controls within the food safety program would automatically make the program marginal, whereas it may take a number of nonconformances against prerequisite or support programs ¹⁰ to make the program marginal. The food business may move to 'satisfactory' only on reporting of a satisfactory audit. The food business is not able to move to 'confidence in the food safety program' level directly from 'marginal' level.

¹⁰ The term prerequisite or support program has been used to differentiate between general and specific hazards to the food business. Prerequisite program is a general term used to identify those programs that are implemented by a food business to control general hazards such as personal hygiene and pest control. Specific hazards require specific controls and will be documented within the food safety program.

LEVEL OF CONFIDENCE	AUDIT FREQUENCY	NOTES
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 nonconformances raised against prerequisite or support programs.
Confidence in the food safety program	Frequency reduces to the minimum level (i.e. if the food business has high-priority classification and the frequency is currently six-monthly, 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 there is compliance history available to the auditor, or if the food business has had no nonconformances identified in two previous audits.

Allocation of audit frequency based on audit outcomes

A café has been allocated a medium-risk priority classification and assigned an initial audit frequency of once every 12 months. The business has identified that the refrigeration of ready-to-eat foods is a control point in ensuring food safety. The business's food safety program requires ready-to-eat food to be stored at a temperature of 5°C or below. The initial audit is conducted and the auditor identifies that the temperature of food in the storage area is 10°C.

The business is assigned a nonconformance because it is not following the documented process outlined in the food safety program. The outcome of the audit is that the business is found to have a marginal food safety program. The audit frequency of the food business is increased to the maximum level for a medium-risk business, which is once every six months.

6.3.5 Audit duration

It would not be practical, given the number of variables that effect the duration of any audit, to provide set audit durations. Therefore the Auditor Handbook will include guidelines on the types of variables that auditors must take into consideration when determining 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;
- how cooperative the food business is 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 nonconformances found during the audit.

Auditors will be responsible for determining audit duration, as they will have access to the appropriate information about the businesses. However, it is likely that the duration of the initial audit will be longer than subsequent audits as the auditors will need to familiarise themselves with the food businesses' operations and food safety programs. The auditors will be required to justify audit duration when required by the enforcement agency as part of the auditor monitoring process outlined in Section 7.4 of this paper.

6.3.6 Auditing multi-sited food businesses

There are many food businesses across Australia that are franchised or have a number of business sites. Some businesses have a quality or food safety system that includes or is the same for all sites; others have individual systems or programs for each site.

The audit of a selection of sites would not be effective in ensuring the safety of food produced as hazards to food-handling processes are often site-specific, and therefore each site must be individually assessed.

6.3.7 Unannounced audits

The majority of audits, particularly those that are scheduled, will be announced audits. The benefits of announced audits are that they:

- ▶ encourage a compliance relationship with the food business, where the food business and auditor work together to ensure that the food safety program is compliant;
- ▶ ensure that relevant personnel are available on the day of the audit and that the timing of the audit minimises disruption to the food business; and
- ▶ ensure that the food business is actually operational on the day of the audit.

It is noted that there is a perceived disadvantage to announced audits: the food business would have time to correct deficiencies before the audit, and therefore would not be 'caught' doing the wrong thing. However, should a food business 'correct' deficiencies before an audit, the auditor should be able to establish this through interviews with relevant staff and review of records.

There is scope, however, for auditors and the enforcement agency to conduct unannounced audits if it is considered that the desired outcomes can not be achieved through announced audits. This could be the case if complaints received indicate that the food business is not remaining in compliance between audits, or that it is suspected that fraudulent activities are being undertaken by the food business.

6.4 Conducting the audit

The audit process comprises five separate stages. These are:

1. audit preparation;
2. the opening meeting;
3. examination of the business;
4. the closing meeting; and
5. reporting audit findings.

6.4.1 Preparing for the audit

The auditor should plan and prepare for on-site auditing activities. These may include preparing an audit plan or undertaking a review of the food business's documented food safety program to ensure that it complies with the requirements of the standard against which it will be assessed. If the food business is large and complex, and an audit team is required, an audit plan would 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.

Before an on-site assessment it is necessary for the auditor to undertake a review of the food business's documented food safety program to ensure that it complies with the requirements of the standard against which it will be assessed. This will indicate to the auditor whether it is appropriate to go ahead with an on-site assessment. This activity can be carried out on- or offsite, depending on logistical constraints and the complexity of the food safety program. Where deficiencies are identified they are best resolved before an on-site audit is scheduled.

6.4.2 Opening meeting with the food business

The opening meeting is an opportunity to let the food business know why the auditor is there, meet with key personnel and outline the arrangements for the audit. In a large, complex food business the opening meeting is an opportunity for an audit team to be introduced to management, the audit plan to be discussed and logistical arrangements, such as guides and work areas, to be confirmed. In a small food business the meeting would normally be brief.

6.4.3 Examination

This is the body of the audit, and covers the collection of objective evidence and documenting audit observations. Evidence can be collected through interviews, examination of documentation and observation of activities. Where there are deficiencies or nonconformances detected they should be documented clearly and concisely and should outline the legal requirements that are being contravened.

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.

6.4.4 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 involved in the audit have a clear understanding of the findings.

6.4.5 Reporting audit findings

The food safety auditor must report the outcomes of the audit to the enforcement agency within 21 days of the audit being completed. This includes information obtained from follow-up audits. The report must also be provided to the food business. The enforcement agency should provide prescribed forms to the

auditors to ensure that they are aware of the requirements for reporting and that the information being gathered is consistent and adequate. The report will need to include the following minimum requirements:

- the date(s) of the audit;
- the name(s) of the person(s) responsible for the report;
- the names and addresses of the food business or food business units audited;
- the scope and objectives of the audit;
- information regarding nonconformances raised during the audit that have not been corrected within the 21-day period;
- copies of records relating to nonconformances, if applicable; and
- a statement of level of confidence (guidelines are provided in Table 2) on which to base audit frequency variation. If a variation is recommended, there must be sufficient information within the report to justify the variation.

The enforcement agency will need to determine the method or process for auditors to submit audit reports, that is, whether there are facilities for faxing or e-mailing audit reports. Auditors may also be required to retain audit documents for review. The review of such documents may be used for monitoring the auditor's performance.

6.4.6 Review of audit reports

Audit reports provided to the enforcement agency should be reviewed for outcomes and discrepancies by the enforcement agency. Whether this is carried out on a sampling basis or for each report is the decision of the enforcement agency. State and Territory Governments should further explore reporting requirements in the development and implementation of their audit infrastructures.

Role of State or Territory Governments

State and Territory Governments should adopt the audit methodology outlined in this paper. A food business's food safety program should be audited at a frequency sufficient to ensure ongoing compliance with the food safety program requirement and the Food Safety Standards, and should be determined using the audit frequency model. Guidance on reporting requirements and the movement of food businesses within frequency ranges, as outlined in this paper, should be provided to auditors and food businesses.

7 Audit management system

One of the most important aspects of the audit system is the overarching management system that ensures all parts are documented and implemented, and are effective in ensuring both the integrity of the assessed food safety programs and conformance with the Food Safety Standards. This system includes monitoring and reviewing performance against specified performance indicators and objectives. It is anticipated that this will be conducted by the enforcement agency.

The management system is based on internationally recognised ISO/IEC Guide 62, which forms the basis of accreditation criteria for bodies certifying management systems. A number of the elements of this standard have been modified to fit the operating environment. The following explains the minimum requirements to establish and maintain the integrity of the management system.

7.1 Preventing conflict of interest

An important aspect of the integrity of the audit process is to ensure that the auditor does not have a conflict of interest or an interest in the outcome of an audit. The draft Model Food Act requires the auditor to notify the enforcement agency where a conflict of interest may exist.

7.2 Maintaining impartiality

If a third-party or regulatory auditor has developed a food safety program and then has responsibility for auditing the program, this would be seen as a conflict of interest, as the auditor could not remain objective and impartial. There are also similar problems if the auditor is involved with the business in another capacity, say as an employee, business partner, part-owner or shareholder.

During an audit the auditor will raise nonconformances where deficiencies are identified. It will be the responsibility of the food business, not the auditor, to identify how these nonconformances are addressed. The auditor is able to provide advice as to how a nonconformance may be addressed but specific advice on how the food business should address a nonconformance would be considered to be a conflict of interest.

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. 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 it should be the State and Territory Health Departments' responsibility to monitor.

Conflict of interest

In remote areas the authorised officer is often the only educational resource for food businesses. In these areas, the authorised officer may also be the auditor responsible for auditing food businesses to which they are an educational resource. A conflict of interest is likely to occur in

this situation. If, however, they only assist in developing the food safety program, a conflict of interest may not occur. Assistance can include providing advice to the food business through examples of how hazards may be controlled. However, it does not include giving specific direction to the food business on how specific hazards will be controlled by that business.

There has been some concern that a conflict of interest could occur if a food business is required to contract directly with an auditor. However, it should be noted that the draft Model Food Act specifically identifies this as not being a conflict of interest. The argument is that the 'contract' would indicate an employer — employee relationship, and the auditor may then be biased to protect that relationship. This is not the case where regulators are auditors, as the contract is with the government. The same might be said of audit organisations where the auditor is employed by the organisation and not directly by the food business. It is considered that the code of ethics that an auditor is required to observe as part of approval, and the assessment of the auditor by the enforcing agency through on-site monitoring will ensure that the auditor remains impartial.

7.3 How the system will ensure confidentiality

Within the draft Model Food Act there are requirements for keeping information confidential. These requirements apply to anyone carrying out work under the Act, whether they are authorised officers or approved food safety auditors.

7.4 Identifying changes in the food business or its food-handling operations and the implications for auditing

Any changes to a food business or its food-handling operations may affect the priority classification of the food business. This may affect the business's audit frequency and can also impact on the type of auditor that is required. It is important that the third-party auditor has a process for gathering all relevant information pertaining to the food business. ANZFA proposes that specified food business information be provided to the enforcement agency through a process of notification. Standard 3.2.2 *Food Safety Practices and General Requirements* requires businesses to notify the enforcement agency about themselves and provide information about the nature of the business. This will then enable the enforcement agency to allocate an appropriate priority classification and subsequent audit frequency to the business.

Food businesses should be aware of their responsibility to report these changes to the enforcement agency. They should also be aware of the audit process and the conditions that may trigger auditing or action. For example, it may be appropriate, where there has been a change of ownership of a business or where changes in the food-handling operations are substantial, for a re-audit to be conducted outside scheduled audits.

7.5 Auditing personnel

This management system requires that all personnel involved in auditing or managing the audit process are appropriately qualified for the functions they perform. Food safety auditors must be approved as meeting the requirements of the *Food safety auditor approval criteria*. There must be clearly defined

processes for approval and for the removal of approval. There must also be a clearly defined process for the extension, downgrading (in areas of competency) or placing of conditions on an auditor's approval. State and Territory Governments are also required, under the draft Model Food Act, to keep a current register of approved food safety auditors and to make it available to food businesses.

The competence of food safety auditors should be monitored by State and Territory Governments. However, the task may be delegated to an appropriate body with expertise in this area. Monitoring should include a review of audit reports and on-site assessment to ensure that the food safety auditor is able to competently audit food safety programs. On-site assessment of auditors allows the enforcement agency to monitor the auditor's skills in interviewing personnel and reviewing records to achieve audit objectives.

Monitoring should also ensure that the auditor is auditing food businesses within his or her area(s) of technical competence, and in accordance with any conflict of interest requirements. The auditor's area(s) of technical competence will be established and documented during the approval process. The auditor should only assess in these areas, unless assisted by an appropriately qualified technical specialist. Breaching these requirements would be cause for withdrawing the auditor's approval.

7.6 Procedures for auditors

Information relating to audit procedures (see Section 6) should be made available to auditors, and the information should be updated when any changes occur. This includes any changes to reporting requirements, logistics and the manner in which the audit is carried out. Easy access to this information will ensure that all approved auditors are using the same procedures and undertaking food safety program audits in a consistent manner.

7.7 Dealing with appeals, complaints and disputes

There will be occasions when the food business does not agree with the findings and/or decisions made by an auditor or enforcement agency. When this occurs the food business should have the opportunity to complain or appeal against decisions. There may also be occasions when the auditor lodges complaints against the food business, for instance where the food business is not being cooperative during an audit.

Many regulators already have provisions in current legislation for dealing with appeals and complaints. However, where a third-party auditor is used in the auditing infrastructure, whether it is an individual auditor or an auditing body, there must be clear procedures for dealing with appeals, complaints and disputes. Such procedures should include:

- the requirement for food businesses and auditors to notify the enforcement agency where complaints are made, including the nature of the complaint;
- how complaints and appeals will be investigated;
- the appropriate process for hearing appeals; and
- what action will be taken should an appeal be successful.

Information relating to appeals, complaints and disputes and how to progress when these do occur should be available to local government, auditors and food businesses. It is anticipated that this would be managed by the State and Territory Health Departments.

7.8 Regular reviews of the management system

Internal audits and reviews of the enforcement agency's management system will ensure that the system is effective and will allow for appropriate adjustments to be made. It will also allow for the detection of deficiencies and inconsistencies that may impinge on the integrity of the audit system. Any review should incorporate the requirements outlined in the internationally recognised ISO/IEC Guide 62.

7.9 Documentation

It is imperative that procedures and policies critical to the efficacy of the audit system are documented and that these documents are controlled. The enforcement agency should ensure that appropriate documentation relating to existing procedures and policies is available to auditors, food businesses and relevant government officers. Appropriate updates should be provided when any changes occur. Examples of controlled documents may be the Food Safety Standards, audit procedures or standards and policy documents produced by State and Territory Governments.

7.10 Records

Appropriate record keeping by the enforcement agency is necessary to facilitate internal audit and management review of the audit system. Records are also necessary for legal purposes, to prove that due process has been observed in the auditing of food businesses. These records should be sufficient to demonstrate that the audit procedures have been effectively fulfilled. There should also be a process for handling and storing records to maintain the confidentiality of commercial-in-confidence material and to ensure that they are kept for the appropriate lengths of time, as required by law.

7.11 Changes to legislative requirements

Auditors, food businesses and relevant government officers should be informed of any changes to the legislative requirements against which they assess. This would include the Food Safety Standards and any changes in powers or roles and responsibilities under the draft Model Food Act.

Role of State and Territory Governments

State and Territory Governments need to implement an audit management system that will ensure the integrity of the audit system. Appropriate policies and procedures should be developed and provided to auditors, food businesses and appropriate personnel as outlined in this paper. Reviews of the management system should be conducted at a frequency determined by State and Territory Health Departments.

8 Implementation issues

8.1 Recognition of equivalence

A number of auditing systems have been implemented to address existing regulatory requirements or to assess a supplier's ability to produce food to customers' specifications. Many of these are HACCP-based systems that may meet the requirements of a food safety program. Current estimates suggest that there are over 90 regulatory and industry systems. Some sections of the food industry therefore already experience a number of audits assessing compliance with customers' and regulatory requirements.

A recommendation in the *Food Regulation Review (Blair) report, Food: a growth industry* was that there should be a 'formal recognition system for existing and future quality assurance programs which deliver food safety outcomes that are substantially equivalent to any regulatory requirements'. This was in response to information gathered in the review process indicating that many food businesses were being audited a number of times by different customers and regulators, at great cost and inconvenience to the food business.

ANZFA recognises the importance of minimising the cost of compliance for food businesses. Therefore, there needs to be a process for recognising the equivalence of other food safety or HACCP-based audit systems where they meet the food safety objectives of the food safety program requirement and the Food Safety Standards. The objectives of such a process are to:

- ▶ ensure that food safety is not compromised through the process of recognising equivalence;
- ▶ minimise the costs to food businesses of compliance assessment through reducing the number of audits, and related inconvenience, for those food businesses being assessed by a number of agencies;
- ▶ develop a system that is not resource-intensive and costly to food businesses and food industry sectors;
- ▶ allow for optimum use of limited appropriately qualified audit resources available; and
- ▶ maintain nationally consistent food safety program auditing standards.

8.1.1 Scope of recognition of equivalence

The outcome of recognition of equivalence of food safety or HACCP-based audit systems will be that food businesses being audited by systems deemed equivalent, and being found to comply with requirements, will not need any additional auditing to assess compliance with the Food Safety Standards or the food safety program requirement. In this way the inconvenience and costs of assessment may be reduced for food businesses. Recognition of equivalent audit systems will not diminish the powers or responsibilities of the enforcement agency. State and Territory Health Departments will still be responsible for monitoring auditor performance, and may wish to carry out joint audits to monitor performance of any recognised system. State and Territory Health Departments will determine monitoring activities as part of their food safety audit management system.

8.1.2 Recognition of equivalence process

Any process for recognising equivalence will need to consider:

1. Does the standard against which food businesses are assessed meet the objectives of the food safety program requirement and the Food Safety Standards? For example, does it require that food businesses have:
 - ▶ a procedure to handle food recalls, as required by Standard 3.2.2 *Food Safety Practices and General Requirements*; and
 - ▶ a requirement that personnel handling food have the appropriate skills and knowledge commensurate with their work activities, as required by Standard 3.2.2 *Food Safety Practices and General Requirements*.
2. Are the auditors undertaking the assessments competent and approved? It would be expected that auditors of equivalent systems would be required to meet the same approval criteria, and therefore be approved by the State and Territory Health Departments. Auditors would also need to meet independence and impartiality requirements, and declare interests in food businesses as required by the draft Model Food Act.
3. Is the audit methodology consistent with ISO 10011–1 (AS 3911.1)?
4. Are the frequency and duration of the audits consistent with those established in this paper?

A working group, chaired by the Department of Agriculture, Fisheries and Forestry, Australia and comprising industry and regulatory representatives, has been established to address the recognition of equivalence of existing systems. The working group has undertaken case studies of food businesses to identify the major issues relating to multiple audits. The outcome of the case studies will be used to develop an appropriate recognition of equivalence trial for existing quality, safety and regulatory systems. ANZFA is represented on the working group and will monitor the outcomes of the trial to address the issue of recognition of equivalence of food safety programs.

9 Supporting documentation

ANZFA has developed documentation relevant to the audit system for use by State and Territory Governments. These are an Auditor Handbook and *The Audit System-Advice for Food Businesses* information document regarding the audit process and what to expect when an auditor comes to audit.

9.1 Auditor Handbook

It is considered vital to national consistency that auditors work to a common set of rules and procedures. The handbook identifies the essential stages of the audit and what the auditor must do at each of these stages. It interprets the requirements of the international standard ISO 10011–1 and emphasises how this methodology can be interpreted to accommodate micro, small, medium and larger food businesses.

9.2 The Audit System-Advice for Food Businesses

The *Audit System — Advice for Food Businesses* information document outlines the audit process and the responsibility of the business in this process. The document summarises the major elements of the audit system and discusses the impact of the system on food businesses.

The document outlines:

- ▶ what the audit process is;
- ▶ the roles and responsibilities of governments and auditors;
- ▶ what is expected of food businesses within the process, such as when nonconformances are raised at audit or what changes to a food business have to be notified to the enforcement agency; and
- ▶ the rights and duties of food businesses within the audit system, including the right to complain and/or appeal against decisions.

10 Conclusion

The audit system outlined in this paper is based on an international best practice approach to auditing. It provides a flexible approach to implementation for State and Territory Governments while maintaining the integrity and rigour of the audit system.

The system has been developed in consultation with industry, professional and government representation and is appropriate for auditing small business establishments as well as larger businesses with existing food safety management systems.

COMPETENCY REQUIREMENT	LEVEL OF AUDITOR	JUDGMENT CRITERIA
	Food Safety Auditor (FSA) and Senior Food Safety Auditor (SFSA)	<p>Where the applicant has completed the required tertiary qualification, a minimum of two years' full-time work experience with food hygiene/safety and food safety programs or HACCP systems applicable to the industry sector in a technical, professional or supervisory position, plus ability to demonstrate competence in specific technical processes used within the industry sector (where applicable); or</p> <p>Where the applicant does not possess the required tertiary qualification but can demonstrate significant experience and practical knowledge, then a minimum of four years' full-time work experience in a technical, professional or supervisory position, with a minimum of two years' operational experience with food hygiene/safety and food safety programs or HACCP systems within the industry sector, plus ability to demonstrate competence in specific technical processes used within the industry sector (where applicable).</p>
4. Auditing Skill	All levels	<p>Successful completion of an auditor training course or possession of a qualification that satisfies the requirements of a nationally endorsed competency standard that incorporates the requirements of ISO 10011</p> <p>Auditees will be required to verify the auditor's effectiveness.</p>
	Associate Food Safety auditor (AFSA)	<p>Participated as an observer in at least two food safety program audits, in which limited participation may take place under direct supervision; and</p> <p>Minimum of two food safety audits under direct supervision of a FSA or SFSA within 12 months before applying for approval.</p>
	Food Safety Auditor (FSA)	<p>Minimum of four audits within a two-year period with a total minimum duration of 20 auditor days.</p> <p>To prove ongoing competence in auditing, FSAs shall be required to perform at least four audits with a total minimum duration of at least 10 auditor-days at the end of every two-year registration period.</p>
	Senior Food Safety Auditor (SFSA)	<p>Previous approval as a FSA.</p> <p>Minimum of five audits as team leader within a two-year period with a total minimum duration of 10 auditor-days.</p> <p>To prove ongoing competence in auditing, SFSAs shall be required to perform at least four audits with a total minimum duration of at least 10 auditor days at the end of every two-year registration period. At least two of these audits shall be as team leader.</p>
5. Professional	All levels	<p>Signed commitment to a professional code of ethics.</p> <p>Verified by personal interview or by interview with auditees.</p> <p>Mechanism for any complaints to be recorded, investigated as appropriate and considered for continuation of approval.</p>

Appendix B Industry categories

There are two areas that need to be considered when assigning an industry category to a food safety auditor. The first is the major industry group and the second is whether or not the auditor is competent to audit any high risk processes that are likely to be found within the category.

Auditors that don't have the expertise with a process linked to a category may still be approved within the category, however a caveat will be placed on their approval indicating that a technical specialist must be included in the audit team when auditing businesses with these processes.

1. Major Industry Groups

FOOD RETAIL, FOOD SERVICE, AND FOOD TRANSPORT AND WAREHOUSING OPERATIONS		
Major group	Descriptions	Typical businesses
Low risk ¹ . Retail of stable or pre-processed and packaged foods and/or food intended for further processing by the customer.	Retailing of pre-packaged food or food that undergoes no or minimal processing (e.g. slicing, portioning) but may require appropriate storage or handling (e.g. refrigeration). The food may also require further processing by the customer.	Dry groceries, newsagents, liquor stores, dairy retail, milk vendor, confectionery store and some greengrocers, bakeries and butchers.
Medium risk ¹ . Retail of food that is ready-to-eat and/or businesses with a large customer base.	This covers businesses that process foods so they are ready-to-eat and do not require further processing by the customer.	Cake shops, school canteens, takeaways, cafes, restaurants, hotels, bed and breakfasts, hot dog vendors and some greengrocers, bakeries, butchers and supermarkets.
High risk ¹ . Retail of food that is ready-to-eat and/or businesses that directly target vulnerable groups.	This covers businesses that sell ready-to-eat foods and directly target vulnerable groups. It also covers businesses that manufacture very high-risk foods, have a very large customer base or prepare food in one location but serve it at another location.	Caterers, nursing homes, home delivery operations, hospitals and child care centres.
Food transport ² and warehousing operations ³	Covers all food transport operations for both dry goods and perishables. Covers all warehousing operations for both dry goods and perishables.	

1 The risk levels relate to the classifications outlined in the *Priority Classification System*.

2,3 Where a specific industry cannot be identified for these operations, the applicant must demonstrate that they have knowledge of the general principles of food hygiene relating to food transport and warehousing operations.

MANUFACTURING/PROCESSING		
Major group	Descriptions	Examples of specific technical processes
Meat products Red meat ► uncooked ► cooked Poultry abattoirs and processors ► uncooked ► cooked	All animal species and game animals and extends to all cuts of meat including minced meat, slaughtering and some processing operations. Also includes cooked and canned meats	Smoking, salting, brining, crumbing, curing, drying
Manufactured meats Raw Heat treated Fermented	Involves blending meat and other foods. Includes frankfurts, devon, salami and meat paste.	Fermentation
Seafood products Uncooked Cooked	Marine and freshwater species and includes ready-to-eat uncooked products and all processing operations. Includes live seafood that does not fall into primary industry category.	Smoking, drying, freezing, purification
Dairy products Milk/cream processing Butter manufacture Cheese manufacture Yoghurt manufacture Ice cream manufacture (wholesale productions) Dried products	Covers milk collection and is extended to all processing operations. Milk substitutes such as soya would be included where the technology is the same e.g. soymilk, tofu. Also includes infant formula manufacture.	Pasteurisation, UHT, evaporation/concentration drying, spray drying, fermentation, freezing, ultrafiltration
Fats, oils and margarine manufacture	Manufacture of all vegetable/animal oils and margarine.	Clarification, refining
Cereal and nut products Cereal food processing Nut processing	Includes all processing operations for cereals and nuts.	Milling, extrusion/drying, roasting
Bakery operations (wholesale productions)	Includes all baked items.	Baking
Fruit and vegetable processing Unprocessed fresh fruit and vegetables Processed fruit and vegetables	Includes basic operations through to all processing operations. Also includes prepared salad manufacturers. NOTE: Fruit juice manufacture falls under drink and beverage manufacture.	Controlled atmosphere, sanitising washes, freezing, drying, canning, pickling
Confectionery manufacture	Includes all confectionery processing operations.	Refining, conching, starch moulding, compression, extrusion, vacuum cooking
Drink and beverage manufacture (non-dairy) Fruit juice/cordial manufacture Carbonated drinks/water/mineral water/ice Alcoholic Beverage manufacture	Includes all processing operations including powdered drinks derived from liquids in the manufacturing process.	Fermentation, concentration, pasteurisation/UHT, aseptic packaging or drying

MANUFACTURING/PROCESSING		
Major group	Descriptions	Examples of specific technical processes
Prepared meals manufacture	Includes prepared mixed foods that require cooking or heating before serving e.g. chilled meals, fresh pasta, frozen meals etc.	Cook-chill, un-cook chill, sous-vide and cook-freeze manufacture
Food ingredient manufacture	Blending and re-packing operations, additives, preservatives, flavourings, colourings, soup mixes, sauces, dehydrated culinary, sugars, salt, yeast, spices, dry blended instant drinks etc.	Dry mixing/blending, drying
Preserved food and sauces & sterilised products Pasteurisation Canning	Includes dressings, mayonnaise, sauces, marinades, jams, fillings etc. and any other food product not covered in other categories. Would be the general category for retort sterilisation where not covered above e.g. infant foods.	Pasteurisation, canning, sterilisation (retorting) UHT or other high-temperature processing.
Miscellaneous Egg product manufacture	Includes all processing operations for egg products.	Pasteurisation
PRIMARY INDUSTRIES ⁴		
Major group	Descriptions	Specific technical processes
Live animal and animal feeds	Feed-lotting, intensive husbandry (e.g. piggeries and chicken raising), game animals, as well as the feed source industries (e.g. hay, compounded feeds and medicated feeds).	
Intensive horticulture operations (does not include fruit and vegetable processing)	Fresh and pre-packed fruit and vegetables, hydroponics production and silviculture/nursery operations.	
Extensive broadacre operations Seafood operations (does not include seafood processing)	Free-range operations, cereal and other grain cropping and processing, grain storage. Including fishing, aquaculture and fish farming.	
Miscellaneous	Apiculture	

4 The requirements of the Food Safety Standards will not apply to food businesses within the primary industry sector unless State and Territory Governments include this sector, or parts of this sector, by regulation.

2. High Risk Processes

The following processes, and the industry groups they relate to, have been identified as high risk processes that are critical to public health and safety and require significant technical knowledge to audit effectively.

- | | |
|--------------------------|---|
| Pasteurisation | <ul style="list-style-type: none">▶ egg manufacture▶ dairy products |
| Aseptic packaging | <ul style="list-style-type: none">▶ dairy products▶ drink and beverage manufacture▶ prepared meals manufacture |
| Retorting | <ul style="list-style-type: none">▶ meat products▶ manufactured meats▶ seafood products▶ dairy products▶ cereal and nut products▶ fruit and vegetable processing▶ drink and beverage manufacture▶ prepared meals manufacture▶ preserved food and sauces and sterilised products |

Notes

All applicants will be expected to demonstrate that they have knowledge of the general principles of food hygiene relating to the industry group that they are applying for, and not just process experience or expertise.

Process experience or expertise will be required to qualify for approval of a high risk process that is critical to public health and safety and require significant technical knowledge to audit effectively.

Categories are generally broad-based. Assessment may, where appropriate, restrict approval of individuals to specific segments or technologies based on experience and knowledge.

There are specific requirements for charitable organisations. Some food services, such as cake stalls and sausage sizzles, fall outside of the requirements of the standards and therefore are not included in any of the above categories.

Where businesses fall across the industry categories identified the auditor will have to be experienced in both fields or be accompanied by another auditor or technical expert.

Appendix C Develop a food safety program guideline competency standard

GFSDFSPA	DEVELOP FOOD SAFETY PROGRAMS
<p>Descriptor</p>	<p>This unit is a minimum competency standard for a person responsible for developing food safety programs. The person responsible for development of a food safety program may be internal or external to the food business.</p> <p>This unit supports the implementation of national and state food safety legislation and regulations.</p>
<p>Element</p>	<p>Performance criteria</p>
<p>Prepare to develop a food safety program</p>	<p>The scope of the food safety program is agreed with the food business. Personnel and resources to be involved in the development of the food safety program are identified and negotiated with the food business. A plan for the development of a food safety program is agreed with the food business.</p>
<p>Identify food safety hazards</p>	<p>Processes to be covered by the food safety program are identified and steps within each process are described. Food safety hazards that are reasonably expected to occur are identified for each process. Handling methods, processing techniques and existing support programs used in the food business are identified.</p>
<p>Establish methods to control food safety hazards</p>	<p>Acceptable methods of control are established for each food safety hazard that is reasonably expected to occur. Control methods are validated. Procedures for taking preventive action are established.</p>
<p>Establish methods to monitor that controls are implemented</p>	<p>Appropriate methods for monitoring that processes remain within control are established. Monitoring requirements and responsibilities are appropriate to the food business and communicated to food business personnel.</p>
<p>Establish appropriate corrective action</p>	<p>Required corrective action to respond to situations where hazards are not effectively controlled is established. Corrective action requirements and responsibilities are communicated to food business personnel.</p>
<p>Establish a recording system to document food safety performance</p>	<p>Records required to document, implement and maintain the food safety program are established. Record keeping requirements and responsibilities are communicated to food business personnel.</p>
<p>Establish a system to regularly review the food safety program</p>	<p>A verification schedule is developed to review the food safety program to ensure adequacy. Verification requirements and responsibilities are communicated to food business personnel. The food safety program is revised to take account of verification outcomes.</p>

Range of variables

This range of variables provides further advice to interpret the scope and context of this guideline competency standard. It assumes:

- ▶ A food safety program systematically identifies the food safety hazards that may be reasonably expected to occur in all food handling operations of the food business. It identifies where and how each hazard can be controlled, describes how these controls are to be monitored, the corrective action required if control conditions are not met and information to be recorded. The food safety program must comply with relevant national, state and industry legislation/regulations.
- ▶ Methods used to control hazards include both support programs and specific hazard control limits or requirements. Typical examples of support programs include product recall, cleaning schedules, pest control programs, personal hygiene practices, calibration procedures and related operating procedures.
- ▶ Food handling refers to:
 - receiving, storing, preparing, processing, displaying, packaging, serving and transporting food
 - handling recalled or contaminated food prior to disposal
 - handling of packaging, food containers and equipment.
- ▶ A food safety program may be developed as a stand-alone program or may be integrated with the quality program in a workplace. It may be based on industry guidelines or templates, customised to the requirements of the business.
- ▶ A food safety hazard includes microbiological, chemical and physical hazards.
- ▶ A process covered by a food safety program refers to processing stage such as cooking, cook and chill, cook and hold, thaw and reheat. Each process may have a number of steps.
- ▶ Validation refers to the use of objective evidence in order to prove that materials, processes, procedures or equipment used are capable of delivering the intended result.
- ▶ Verification refers to reviewing all aspects of the food safety program and related records to determine compliance with and adequacy of the food safety program. It includes audit arrangements.
- ▶ Appropriate communication skills and techniques must take account of English language, literacy and technical skill base of food business personnel.

Evidence guide

This guide describes the evidence of skills and knowledge to be collected by the assessment process.

Demonstrated ability to:

- ▶ Determine the most appropriate approach to developing a food safety program to suit the food business.
- ▶ Plan the stages involved in developing a food safety program, establish timelines and determine the allocation of responsibilities
- ▶ Agree on the processes to be covered by the food safety program to meet the requirements of the food business and legislation/regulations

- ▶ Identify food-handling practices, processing techniques and support programs in use
- ▶ Identify hazards that are reasonably expected to occur and establish appropriate methods of control. This includes validating existing control methods and where there is no adequate control method in place, establishing an appropriate method.
- ▶ Refer to objective data, industry guidelines and codes of practice to validate existing methods of control
- ▶ Establish procedures for implementing preventive action. Typically this involves revision of materials, processes and/or food handling procedures. It may require revision of workplace practices and documentation such as specifications, operating procedures and approved supplier programs
- ▶ Describe the monitoring requirements for each food safety hazard. This includes a description of the method or procedure to be followed, the frequency and timing, the person responsible and the information to be recorded. Procedures to be followed would typically be specified in the form of a standard operating procedure or work instruction
- ▶ Describe corrective action requirements in the event that acceptable limits or requirements of support programs are not met. At a minimum corrective action requirements must cover the procedure to be followed, when corrective action must be implemented, the person responsible for taking corrective action and the information to be recorded
- ▶ Develop required documentation relating to the design and maintenance of the food safety program. This depends on the nature of the food business. It may include process flow diagrams, hazard analysis charts and tables, support program requirements, data analysis reports, corrective action reports and verification reports
- ▶ Establish record keeping requirements and system. This depends on the nature of the food business. It involves specification of information to be recorded and may include procedures for managing document control including storage, retention, retrieval and revision
- ▶ Develop a plan for the regular review of the food safety program. At a minimum the review plan must meet food safety legislation/regulations to confirm that the food safety program is current and adequate. Any change that could affect food safety should trigger a review and validation prior to change being introduced. The plan must also provide for review by an approved food safety auditor at the determined frequency
- ▶ Establish action required if the outcomes of verification indicate that the program requirements have not been met or that the original program was inadequate
- ▶ Use appropriate communication skills and techniques to consult with, negotiate and communicate roles and responsibilities to people in the food business

Underpinning knowledge:

Legal requirements

- ▶ HACCP-based concepts that support the design of a food safety program to meet legal and food business requirements
- ▶ Understanding of the purpose and intent of food safety legislation
- ▶ Legal requirements to establish support programs relevant to the industry sector and nature of the food business

- ▶ Purpose of maintaining records, minimum recording requirements and minimum period for which records must be retained. This is determined by legislation and may vary according to product
- ▶ Roles and responsibilities of internal and external auditors and of authorized officers

HACCP-based concepts, procedures and processes

- ▶ Techniques for applying HACCP-based principles in a food business. This includes techniques for identifying hazards, assessing the likelihood of occurrence, determining acceptable methods of control, monitoring and recording requirements for each control point, identifying corrective action if controls are not met and developing system review procedures
- ▶ Industry terminology, food characteristics and food handling methods as they affect food safety, relating to the food business/industry sector
- ▶ The role of consultation in the development, implementation and ongoing maintenance of the food safety program
- ▶ Techniques used to map operations for the purposes of a food safety program, appropriate to the food business
- ▶ Documentation and recording requirements of support programs used as a method of control
- ▶ Validation processes and techniques
- ▶ Verification scope and procedures

Technical food safety knowledge

- ▶ Main types of food safety hazards/contamination that may be found in food handled by the food business/industry sector and handling practices and processes used to reduce these hazards
- ▶ Conditions required for bacterial growth to occur relevant to the food handling function. These may include a_w , pH, composition, time and temperature.
- ▶ Typical support programs such as cleaning schedules, pest control, stock rotation, product recall and personal hygiene etc, and how they can be used as part of a food safety program

Specialist industry knowledge

- ▶ Relevant technical knowledge to apply HACCP-based concepts to the development of a food safety program. This requires current knowledge of relevant sections of the *Food Standards Code*, relevant food acts, industry legislation/regulations, guidelines, codes of practice, templates, protocols and other sources of current technical advice relevant to industry sector and food business processes
- ▶ Industry terminology, raw materials/ingredient composition and characteristics and food handling practices and processing techniques relevant to the food business/industry sector, as they affect food safety
- ▶ Issues to consider relating to intended use of food products
- ▶ Acceptable control methods for the hazards identified and required corrective action when control requirements are not met
- ▶ Where no industry standards exist, technical knowledge to determine appropriate controls
- ▶ Information required and collection methods to support validation of the food safety program

Food business liaison

- ▶ Options to fulfill the requirements of the food safety program to suit the capacity and culture of the food business
- ▶ Documentation procedures to meet food safety program requirements appropriate to the food business
- ▶ Effective communication skills required to consult, negotiate and communicate with people in the food business
- ▶ Resources required to implement and maintain the food safety program
- ▶ Level of competence and current systems used by food business personnel to support food safety

Assessment guide

This guide describes basic assessment principles which need to be observed when conducting assessment.

- ▶ The competencies described in this standard need to be assessed over time and events under normal industry conditions.
- ▶ The assessment process must support the key assessment principles of validity, reliability, fairness and flexibility.
- ▶ Assessment must provide opportunities for the assessee to address all components of the Evidence guide.
- ▶ The assessor must be competent in this unit of competence.

Assessment context

Assessment of this unit of competence is conducted within the context of one or more nominated industry categories.

Assessment must occur in the context of real food businesses within the nominated industry sector where normal food safety hazards and control requirements exist. Such an environment must provide an opportunity for the assessee to demonstrate the development of a food safety program consistent with food safety legislation and appropriate to the needs of the food business.

Key competencies

Key competencies will be determined according to the packaging of this unit with other industry units to achieve a qualification outcome.

Appendix D Audit a food safety program guideline competency standard

GFSCFSAA	CONDUCT FOOD SAFETY AUDITS
Descriptor	<p>This unit is a minimum competency standard for any person involved in auditing against the Food Safety Standards. At this level, an auditor would typically work under supervision.</p> <p>The unit <i>Develop a food safety program</i> is a co-requisite for this unit of competence.</p> <p>This unit supports the implementation of national and state food safety legislation and regulations.</p>
Element	Performance criteria
Plan a food safety audit	<p>Information and resources required to conduct the audit are identified and located.</p> <p>An audit plan is developed and negotiated with the food business to meet audit scope.</p>
Conduct a food safety audit	<p>Information is collected that is adequate, representative and meets audit requirements.</p> <p>Information is analysed to assess adequacy of the food safety program.</p> <p>Records are reviewed to assess compliance with the food safety program.</p> <p>Compliance with the food safety program is assessed in the food business.</p> <p>Premises and transport vehicles are inspected as required to confirm that they meet the design and construction requirements set out by food safety legislation.</p> <p>Areas requiring corrective action are identified.</p>
Report and follow-up audit outcomes	<p>Situations presenting an imminent and serious risk to the safety of food are reported in accordance with legislative requirements.</p> <p>Audit reports are prepared to address audit scope requirements.</p> <p>The results of the audit are communicated to the food business and to enforcement agencies as required by legislation.</p> <p>Areas requiring corrective action are acknowledged by the food business.</p> <p>A corrective action plan is developed.</p> <p>Implementation of corrective action as set out in the corrective action plan is confirmed.</p>

Range of variables

This range of variables provides further advice to interpret the scope and context of this guideline competency standard. It assumes:

- A food safety audit is conducted against relevant food safety legislation.
- A food safety program systematically identifies the food safety hazards that may be reasonably expected to occur in all food handling operations of the food business. It identifies where and how each hazard can be controlled, describes how these controls are to be monitored, the corrective action required if control conditions are not met and information to be recorded. The food safety program must comply with relevant national, state and industry legislation/regulations.
- Audit scope is established by the contract between the auditor and the food business and by legislation.
- Audits may be undertaken for advisory or regulatory purposes and may be conducted by internal or external auditors. Internal audits do not meet regulatory requirements.

- ▶ Information collection methods include interviews, observance, review of workplace records and accessing relevant technical information.
- ▶ A corrective action plan identifies non-conformance, corrective actions, date by which action must be taken and any other follow up requirements. Depending on the nature and scope of an audit, the business is typically responsible for identifying appropriate corrective action. However the auditor must be able to determine whether an appropriate corrective action plan has been developed and must therefore have the technical knowledge to do so.
- ▶ Appropriate communication skills and techniques must take account of English language, literacy and technical skill base of food business personnel.
- ▶ Design and construction requirements of food safety premises, fixtures, fittings, equipment and transport vehicles are set out in Food Safety Standard 3.2.3 and or relevant state legislation/regulations.
- ▶ The relevant state audit management system may specify additional requirements of auditors such as meeting appropriate ISO standards. This may vary on a state-by-state basis.

Evidence guide

This guide describes the evidence of skills and knowledge to be collected by the assessment process.

Demonstrated ability to:

- ▶ Refer to the contract with the food business and legislative requirements to identify the scope of the audit
- ▶ Establish the audit sequence, activities and timelines
- ▶ Identify and locate information required to conduct the audit
- ▶ Review food business documentation to confirm that required information is available
- ▶ Prepare tools to collect information. These typically include checklists and interview schedules
- ▶ Communicate the audit plan to the food business and agree on audit timetable
- ▶ Review records, conduct interviews, observe workplace practice and collect other relevant information as required to assess compliance with the food safety legislation
- ▶ Verify that the food business is implementing the food safety program. This includes identification of all food safety hazards that may be reasonably expected to occur, determining adequate methods to control hazards, monitoring and record keeping procedures, validating and corrective action requirements
- ▶ Confirm that food premises, fixtures, fittings, equipment and transport vehicles meet the minimum requirements of food safety legislation
- ▶ Take immediate action to report non-conformities that present an imminent and serious risk to the safety of food
- ▶ Identify any changes that have occurred in the food business since the commencement of the food safety program or since the last audit that could affect food safety
- ▶ Assess the adequacy of the food safety program. This involves verifying information used by the food business to establish methods of controlling food safety hazards

- ▶ Identify, investigate and record evidence of non-conformance and judge significance
- ▶ Form conclusions on audit outcomes that can be duplicated, given the evidence collected
- ▶ Apply appropriate questioning, observation and related communication skills to support information collection, appropriate to the food business
- ▶ Report the findings of the audit in appropriate format to meet legal and food business requirements
- ▶ Report imminent and serious risks as required by legislation/regulations
- ▶ Where findings indicate either a failure to comply with the food safety program or inadequacy of the food safety program, document areas of non-conformance
- ▶ Confirm that the food business has implemented appropriate corrective action within the timeframe established by the corrective action plan
- ▶ Communicate the audit findings including any relevant follow up actions to the food business as required by legislation

Underpinning knowledge:

Legal requirements

- ▶ The purpose and intent of food safety legislation
- ▶ Other relevant legislation that could impact on the application of food safety legislation in the business and/or industry
- ▶ Understanding of food safety auditor roles, responsibilities and legal liability as established by relevant legislation. This includes an understanding of the responsibilities of different types of auditors and of authorized officers
- ▶ Legal requirements of food businesses relating to food safety
- ▶ Legal responsibilities for reporting findings of the audit, conflict of interest, confidentiality, rights of appeal and giving evidence in court
- ▶ Legal responsibilities for reporting to enforcement agencies any non-conformities that present an imminent and serious risk to the safety of food
- ▶ Food business classification systems and the implications of these for determining the frequency and scope of audit
- ▶ Relevant legislation determining scope of audit where relevant for the industry sector

Audit roles and responsibilities

- ▶ Appropriate ethical conduct of auditors as set out in codes of ethics of auditors and additional requirements as determined by employment arrangements
- ▶ Requirements and procedures for certification/registration of auditors and authorized officers
- ▶ Any requirements for prescribed fees and charges that may be levied on a food business and the process by which this occurs

Audit procedures and techniques

- ▶ The purpose and stages involved in a food safety audit
- ▶ Business systems and related reference documents and appropriate application of these in an audit

- ▶ Techniques for collecting information, including choice of appropriate methods to ensure data is adequate and representative
- ▶ Data analysis methods relevant to the audit process
- ▶ Communication skills and techniques appropriate to the food business
- ▶ Appropriate recording and reporting formats

Specialist food safety and industry knowledge

- ▶ Techniques for applying HACCP concepts in a food business. These include techniques for identifying hazards that may be reasonably expected to occur, determining appropriate control method, monitoring and record keeping, validating and corrective action requirements
- ▶ Industry terminology, food characteristics and food handling practices and processing techniques relevant to the industry sector, as they affect food safety
- ▶ Relevant technical and industry knowledge required to verify compliance and assess compliance with food safety legislation/regulations. This requires current knowledge of relevant sections of the *Food Standards Code*, relevant food acts, industry guidelines, codes of practice, templates, protocols and other sources of current technical advice relevant to industry sector and food business processes
- ▶ Where food business control methods or limits vary from industry standards or where there are no industry standards, technical knowledge required to assess data used by the business to validate acceptable limits
- ▶ Minimum standards of design and construction required of food premises, fixtures, fittings, equipment and transport vehicles as required by food safety legislation. This includes relevant Australian Standards.
- ▶ Competency standards and related assessment and training options for people working with food to develop relevant food safety skills and knowledge
- ▶ Situations which could present a serious risk to food safety and related reporting responsibilities under food safety legislation

Assessment guide

This guide describes basic assessment principles which need to be observed when conducting assessment.

The competencies described in this standard need to be assessed over time and events under normal industry conditions.

- ▶ The assessment process must support the key assessment principles of validity, reliability, fairness and flexibility.
- ▶ Assessment must provide opportunities for the assessee to address all components of the Evidence guide.
- ▶ The person assessing this unit of competency must be a competent food safety auditor. This requires that they are an approved auditor as defined by food safety legislation. The use of this competency standard as part of a wider process to approve auditors will be determined by the audit management system in each state and territory.

Assessment context

Assessment of this unit of competence is conducted within the context of one or more nominated industry categories.

Assessment must occur in the context of real food businesses within the nominated industry sector where food safety hazards are identified and controlled by a food safety program. Such an environment must provide opportunities for the assessee to demonstrate their ability to conduct food safety audits to meet the audit scope, legal and food business requirements.

Key competencies

Key competencies will be determined according to the packaging of this unit with other industry units to achieve a qualification outcome.

Appendix E Summary of submissions

Food Safety Auditor Approval Criteria

Feedback was sought on the following questions and proposals:

Recommendation 1 The body responsible for the assessment of food safety auditors be required to meet the internationally accepted standard EN 45013. If approval of food safety auditors, by the relevant authority under the relevant Act, is based solely on the assessment outcome then the relevant authority will not have to meet a specific standard.

Recommendation 2 The competency requirements for food safety auditors documented at Appendix 4 be considered for acceptance as the auditor approval criteria.

Recommendation 3 The three levels of auditors identified in Auditor Categories and Appendix 4 be incorporated into the food safety auditor approval process. This will allow for the auditing experience of the auditor to determine the role an auditor can play in an audit.

Recommendation 4 The industry categories documented at Appendix 5 be considered for acceptance for the identification of specific food industry experience of food safety auditors. In this way an auditor with the appropriate industry sector experience can be selected by a food business.

Recommendation 5 The development of a food safety auditor competency standard be initiated by ANZFA and incorporated into the approval criteria for food safety auditors. The competency standard will form the basis for training program requirements within the approval criteria.

RECOMMENDATION	AGREE	DISAGREE	NOT SPECIFIC
Question	107 (87.7%)	3 (2.5%)	12 (9.8%)
Recommendation 1	74 (60.7%)	10 (8.2%)	38 (31.1%)
Recommendation 2	69 (56.6%)	16 (13.1%)	37 (30.3%)
Recommendation 3	81 (66.4%)	9 (7.4%)	32 (26.2%)
Recommendation 4	80 (65.6%)	12 (9.8%)	30 (24.6%)
Recommendation 5	97 (79.5%)	4 (3.3%)	21 (17.2%)

57 of 122 submissions (46.7%) included 'other comments'.

Guidelines for the frequency and duration of food safety program audits

Feedback was sought on the following issues and recommendations:

Comment is sought as to the appropriateness of Option 1 or Option 2 as the model on which frequency of audit will be determined. Option 1 initially bases audit frequency on the priority categories within the *Priority Classification System*, and Option 2 incorporates a base-line approach for initial audit frequency. Each option then allows for frequency adjustment on the basis of performance of the food safety program assessed through audit. Stakeholders are asked to consider each option and indicate their preferred option in their submissions to the Authority.

Recommendation 1 That a strategy be developed for assessing and liaising with multi-sited food businesses that may extend over local and state boundaries. The objectives of such could be based on the UK *Home Authority Principle*. Comment is sought on the applicability of, and conditions that may allow sampling of sites.

Recommendation 2 That prior to the implementation of the Food Safety Standards a study be carried out to determine if there will be a sufficient number of appropriately qualified auditors to service food businesses, given the minimum audit frequencies proposed.

Recommendation 3 That guidelines be developed in order to educate food businesses as to appropriate audit durations and also to provide performance indicators for regulators to monitor the audit process.

Table of submission break-up, by recommendation.

RECOMMENDATION	AGREE	DISAGREE (OR OPTION 2)	NOT SPECIFIC (OR NEITHER)
Question	88 (88.9%)	0 (0.0%)	11 (11.1%)
Option	46 (46.5%)	35 (35.4%)	18 (18.2%)
Recommendation 1	37 (44.0%)	22 (26.2%)	25 (29.8%)
Recommendation 2	61 (72.6%)	3 (3.6%)	20 (23.8%)
Recommendation 3	61 (72.6%)	4 (4.8%)	18 (21.4%)

Recognition of equivalence of food safety and HACCP based audit systems

Feedback was sought on the following issues and recommendations:

Recommendation 1 It is recommended that the outline of assessment criteria for the recognition of equivalent audit systems be accepted for further development.

Recommendation 2 That the recognition of equivalence be coordinated by a central body, with the recognition decision made by a panel of experts drawn from a majority of stakeholders.

Prior to implementation further discussion and consultation will take place to determine the most appropriate agency for overseeing the assessment and recognition process.

Recommendation 3 The process for assessment of equivalence outlined in the paper be accepted and further developed.

Recommendation 4 ANZFA work closely with other agencies, particularly Agriculture Forestry and Fisheries Australia (AFFA) and the Quality and Safety Working Group, in the further development of equivalence recognition frameworks.

Table of submission break-up, by recommendation.

RECOMMENDATION	AGREE	DISAGREE	NOT SPECIFIC
Question	76 (85.4%)	8 (9.0%)	5 (5.6%)
Recommendation 1	66 (74.2%)	2 (2.2%)	21 (23.6%)
Recommendation 2	66 (74.2%)	2 (2.2%)	21 (23.6%)
Recommendation 3	69 (77.5%)	3 (3.4%)	17 (19.1%)
Recommendation 4	64 (71.9%)	3 (3.4%)	22 (24.7%)

Infrastructure for the auditing of food safety programs and the management of the audit process

Feedback was sought on the following issues and recommendations:

Recommendation 1 The working group recommends that the international standard ISO 10011–1 (also published as AS 3911.1 and NZS 10011.1) be adopted as the basis for the audit methodology for undertaking food safety program audits under the *Food Safety Standards*. This standard sets out general audit objectives, general roles and responsibilities of auditors, a general process for auditing on-site and ways in which information may be collected during the audit and reported.

Recommendation 2 An auditors' handbook be developed to give guidance regarding interpretation of the requirements of ISO 10011–1, and that this form a template for relevant authorities to customise with contact details and/or specific instructions.

Recommendation 3 That the national audit system not include formal 'approval' of a food safety program, rather the documented food safety program be submitted and reviewed to ensure that the food business has adequately documented the program and is therefore ready for an initial on-site assessment.

Recommendation 4 The working group recommends that all scheduled food safety program audits be announced, that is that the food business is aware of where and when the audits will be undertaken. Further, it is recommended that there be provision for unannounced audits, outside of the scheduled audits, but only on approval of the enforcing agency.

Recommendation 5 That the terms 'notifiable' and 'non-notifiable' be adopted for use by auditors to describe and record nonconformances found during audit. The type of nonconformity will then determine the actions taken by the auditor, in accordance with the draft draft food bill.

Recommendation 6 That the relevant authorities establish audit management systems incorporating the elements discussed within the *Management System Elements* section of Part 2 of this paper. This can then facilitate the monitoring of national consistency and implementation of the *Food Safety Standards*.

Comment is sought from stakeholders as to whether the act of a food business contracting with an auditor constitutes a conflict of interest. Current drafting of the draft food bill indicates that the contract between the food business and the auditor, for provision of auditing services, does not constitute a conflict of interest.

The following table indicates the number of submissions that either agreed with the proposals presented, disagreed or were not specific in their response. Also indicated is the % that these responses represented of total responses. No further statistical analysis was undertaken.

Table of submission break-up, by recommendation.

RECOMMENDATION	AGREE	DISAGREE	NOT SPECIFIC
Recommendation 1	61 (83.6%)	5 (6.8%)	7 (9.6%)
Recommendation 2	64 (87.7%)	1 (1.4%)	8 (10.9%)
Recommendation 3	52 (71.2%)	8 (10.9%)	13 (17.8%)
Recommendation 4	52 (71.2%)	11 (15.0%)	10 (13.7%)
Recommendation 5	59 (80.8%)	3 (4.1%)	11 (15.0%)
Recommendation 6	53 (72.6%)	1 (1.4%)	19 (26.0%)
Conflict of interest	24 (32.9) (does not)	14 (19.2) (does)	35 (47.9%)

21 of 73 submissions (28.8%) included 'other comments'.