

National Regulatory Food Safety Auditor Guideline

Developed by the Implementation Sub-Committee of the Food Regulation Standing Committee.

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Dr Anne Astin Chair Implementation Sub-Committee

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Executive summary

The *National Regulatory Food Safety Auditor Guideline* (the Guideline) has been developed to provide guidance to food regulators¹ in how to implement the *National Food Safety Audit Policy* (the Policy).

The Policy was endorsed by the Australia New Zealand Food Regulation Ministerial Council in October 2006, with food regulators given five years to implement it. The Policy may be downloaded from the <u>Food Regulation Secretariat website</u>. All food regulators will be required to establish processes and procedures to meet the requirements of the Policy by 25 October 2011.

The Guideline aligns elements of the Policy with the industry National Food Safety Auditor (NFSA) Scheme. It does not reflect the Policy in its entirety.

The Guideline is a 'living document' because it outlines the recommended minimum elements of a regulatory audit system to demonstrate compliance with the Policy. Food regulators are advised that the Guideline will be periodically updated as new information comes to light. Regulators using this guideline to inform their regulatory audit systems are urged to ensure they are referring to the latest version.

Food regulators may choose to implement arrangements beyond those outlined in the Guideline or vary methodologies to better suit their existing audit management systems. However, regulators are recommended to not go below the outcomes outlined in this Guideline.

The Guideline is divided into three chapters as follows.

Chapter 1 Criteria and approval processes for regulatory food safety auditors

This chapter outlines recommended criteria and approval processes for assessing persons who wish to become regulatory food safety auditors. It covers:

- the National Regulatory Food Safety Auditor Framework
- the National Regulatory Food Safety Auditor Code of Conduct (refer Appendix A)
- the application of pre-approval additional provisions to those applying to become regulatory food
- safety auditors
- assessment of auditor competency
- maintenance of an auditor register
- impact of mutual recognition legislation on approved regulatory food safety auditors.
- processes that food regulators will follow when approving regulatory food safety auditor
- applications.

An example application form² is included in Appendix B.

N.B. Persons intending to conduct regulatory food safety audits must be assessed as competent to audit against the specific legislation of a food regulator before they may conduct regulatory audits on behalf of that regulator.

¹ Food regulator means those bodies of the Commonwealth of Australia, the Government of New Zealand, or Australian states and territories that are responsible for food safety legislation. These bodies may belong to government departments or may be semi-independent of government and, while some may be enforcement agencies, some may delegate enforcement to other bodies such as local governments. Note that local legislation may need to be consulted to accurately define powers and responsibilities.

² Note this is an example application form only. There is no impost upon food regulators to use this form.

Further, a person may only be appointed as a regulatory food safety auditor by a food regulator. A food regulator's legislation will be specific, and an approval under one regulator's legislation to audit does not constitute an approval under another regulator's legislation (even within the same Australian State).

Chapter 2 Managing the audit process

This chapter provides guidance on how to manage the regulatory audit process, covering topics such as audit activities, the duties of regulatory food safety auditors, the audit process, reporting requirements for a regulatory auditor and assigning audit frequencies.

Chapter 3 Managing approved regulatory food safety auditors

This chapter outlines recommended practices for managing regulatory food safety auditors, covering topics such as managing potential conflicts of interest, maintenance of auditor impartiality and independence, check audits, and on-going mechanisms for the review of regulatory food safety auditor's performance by food regulators.

This chapter also covers suggested procedures for maintaining auditor competency and disciplinary procedures against regulatory auditors should they be required.

Glossary

Refer to Appendix C for key terms used in the Guideline.

Scope and objectives

The Guideline applies to the regulatory food safety audit system and to the regulatory food safety auditor who audit businesses under that system.

The Guideline, by providing advice that may be adopted or incorporated into the audit management systems of food regulators, should assist in harmonising arrangements for the regulatory food safety auditing system across Australia, thereby meeting one of the principal objectives of the Policy.

Introduction to the regulatory food safety audit system

The regulatory food safety audit system provides an infrastructure for food regulators to monitor the compliance of individual businesses with legislative food safety requirements, through routine audit of a business's food safety arrangement.

The role of the regulatory food safety auditor in that system is to conduct regulatory audits of a business's food safety management system to determine whether it complies with the appropriate legislative requirements. The appropriate food regulator may be required to approve the business's system before it is subject to routine regulatory audit, or it may require the business to adopt a recognised system. The food regulator may determine the approval of a business's system through conditions of legislative administration tools such as licensing, accreditation or registration.

As part of the regulatory food safety audit process, regulatory food safety auditors are required to identify areas in a business's food safety management system where, in the auditor's opinion, the business is unable to display sufficient evidence that it is compliant with the appropriate legislation (i.e. identify non-conformances). The identification of a non-conformance should prompt the business to instigate corrective action with the auditor or the food regulator (depending on the severity of the breach) to address the non-conformance.

Responsibility for food safety and liability

Responsibility for the regulatory food safety audit system is shared between food regulators, regulatory food safety auditors and food businesses.

Food regulators (including primary production and processing agencies, health departments and local government) are responsible for food regulation under existing state and territory food acts and other legislative instruments. The Australian Quarantine and Inspection Service (AQIS) is responsible for monitoring the compliance of imported food with the requirements of the *Australia New Zealand Food Standards Code* (the Code).

Under state and territory food acts, food regulators may choose to delegate some of these responsibilities to local government. The extent of delegation may differ between food regulators (even within the same Australian state). However, where delegation occurs, the term 'food regulator³' only applies to the delegated body if it is a government or semi-government entity. It does not apply to a non-government entity, individual or body (e.g. third party food safety auditor).

The specific duties of a regulatory food safety auditor will be described in the appropriate food regulator's legislation.

Annex B, Section 67 of the Model Food Provisions sets out example duties for a regulatory food safety auditor that may be adopted or incorporated into state and territory food legislation. The duties of a food safety auditor as outlined in Section 67 of the Model Food Provisions are to:

- conduct audits of any food safety programs required to be in place by the regulations
- conduct any necessary follow up action, including further audits, as necessary, to determine if action has been taken to remedy any deficiencies in a food safety program as identified during an audit

³ Regulators using this document to inform their audit management systems are urged to consult their local legislation for further information on powers and responsibilities.

- conduct assessments of food businesses to ascertain their compliance with requirements of the Food Safety Standards
- submit audit reports (including non-conformances) to the food regulator and the food business, in accordance with the stipulated requirements.

Where non-conformances are identified during a regulatory audit, it is likely that the relevant legislation will require the auditor to outline in the audit report the nature and extent of the non-conformance. Should an auditor consider any matter encountered during a regulatory audit to pose an imminent and serious risk to the safety or suitability of food intended for sale, the legislation is likely to require that auditor to notify the appropriate food regulator within 24 hours.

1.0 Criteria and approval processes for regulatory food safety auditors

The criteria and approval processes described in this section are the recommended minimum that regulators should implement when approving people as regulatory food safety auditors.

1.1 National Regulatory Food Safety Auditor Framework

The National Regulatory Food Safety Auditor Framework, as approved by the Food Regulation Standing Committee (FRSC), describes the following:

- auditor competencies (national units of competency).
- technical and educational qualifications
- specialised auditing competencies
- witness audits
- legislative assessment
- regulatory food safety auditor code of conduct
- application of pre-approval additional provisions.

Table 1 outlines the national regulatory food safety auditor framework.

High risk activities and complex processes requiring individual endorsements	Audit competency	Education and technical qualifications	Other requirements
Food service, whereby potentially hazardous food is served to vulnerable populations Catering operations serving food to the general public	Auditor competency: • FDFFSCOMA • FDFFSCFSAA • FDFFSCHZA	Certificate IV or higher in food science or related field (including 40 hours of food microbiology).	 Competency examination to be completed during on-site audit (High risk business). Knowledge of jurisdictional legislation and regulator's system. Applicant to sign regulatory food safety auditor code of conduct. Applicant to complete signed declaration. Suitability checks conducted by the food regulator if required.
Cook chill processes	Auditor competency as above <i>plus</i> specialised competency FDFFSCC4A.	As above	As above
Heat treatment processes	 Auditor competency as above plus specialised competency: FDFFSHT4A. 	As above	As above
Producing manufactured (RTE) and uncooked comminuted fermented meat (UCFM) products	Auditor competency as above <i>plus</i> specialised competency: FDFFSME4A	As above	As above
Raw ready-to-eat seafood. Raw oysters and bivalves production and processing.	Auditor competency as above <i>plus</i> specialised competency: FDFFSBM4A.	As above	As above

Medium risk

High risk activities and complex processes requiring individual endorsements	Audit competency	Education and technical qualifications	Other requirements
	Auditor competency: • FDFFSCOMA • FDFFSCFSAA • FDFFSCHZA	Certificate IV or higher in food science or related field (including 40 hours of food microbiology).	 Competency examination to be completed during on-site audit (Medium risk business). Knowledge of jurisdictional legislation and regulator's system. Applicant to sign regulatory food safety auditor code of conduct. Applicant to complete signed declaration. Suitability checks conducted by the food regulator if required.

Low risk

High risk activities and complex processes requiring individual endorsements	Audit competency	Education and technical qualifications	Other requirements
	 Auditor competency: FDFFSACA4⁴ FDFFSCOMA FDFFSCFSAA, FDFFSCHZA 	Not applicable	 Competency examination to be completed during on-site audit. Knowledge of jurisdictional legislation and regulator's system. Applicant to sign regulatory

⁴ This competency may be superseded by a person who has already obtained competency FDFFSCFSAA

High risk activities and complex processes requiring individual endorsements	Audit competency	Education and technical qualifications	Other requirements
			food safety auditor code of conduct.
			 Applicant to complete signed declaration.
			 Suitability checks conducted by the food regulator if required.

Explanatory notes

- i) Low risk is mainly for the purposes of training.
- ii) All activities to be audited that do not fall with the identified high risk areas will be placed in the medium risk level until such time as an assessment is made to determine which level they ought to fit.

a) Low risk

The following are the recommended minimum requirements to be applied when a food regulator assesses a regulatory food safety auditor application at the entry level (low risk).

- *Auditor competency (low risk)* auditor competency units required as listed in Table 1, auditors competent to undertake systems and compliance audits.
 - a. Statement of attainment or RPL assessment against the following competencies:
 - i) FDFFSACA⁵ Assess compliance with food safety programs
 - ii) FDFFSCOMA Communicate and negotiate to conduct food safety audits
 - iii) FDFFSCFSAA Conduct food safety audits
 - iv) FDFFSCHZA Identify, evaluate and control food safety hazards.
- Regulator's system requirements knowledge of jurisdictional legislation and regulator's system.
- *Pre-approval additional provisions* The applicant has signed a code of conduct, completed and signed a declaration (to verify the accuracy and integrity of information provided) and has been subject to further suitability checks if required.
- Legislative assessment, inclusive of 'witness audit' This audit should only be conducted by a regulatory food safety auditor (approved by the appropriate regulator) who at the very least is competent at the low risk level.

FDFFSACA - Assess compliance with food safety program

This unit covers the following elements:

- audit planning (includes defining audit scope)
- review and assessment of food safety programs (includes pre-requisite programs)

⁵ This competency may be superseded by a person who holds competency FDFFSCFSAA.

- review and assessment of the implementation of food safety programs (gathering evidence to verify that the food safety program and pre-requisite programs are under control)
- management of the audit process (comparing the audit process against the audit plan)
- consolidation of audit outcomes (gathering audit evidence to identify any potential areas of nonconformance, preparing audit reports)
- confirmation and closing-out of corrective actions (review implementation of corrective actions against food safety program).

A practical assessment will be performed as part of this unit and will assess the auditor's ability to:

Confirm appropriate food safety program and/or template

Applicants are required to confirm that the business's food safety program and/or template is appropriate for the activities of the business under audit.

Review food safety program records

Applicants are required to review food safety program records to review the compliance of programs with their validated template and/or previous approval by the appropriate food regulator.

• Collect and verify information

Applicants are assessed on their ability to:

- collect information relevant to the audit scope and objectives
- only use verifiable information as audit evidence
- when required, confirm appropriateness of corrective actions for previous nonconformances
- appropriately record audit evidence
- analyse information to confirm that the program is consistently and effectively implemented
- gather evidence from sources that include, but are not limited to:
 - o interviews with employees and other persons
 - observation of activities
 - o documents, records and data summaries
 - o auditee's sampling procedures
 - o customer feedback
- Identify variations of food safety program and/or template

Applicants are assessed on their ability to identify circumstances where variation or customisation of the template or program under audit requires further validation.

• Prepare audit conclusions

Applicants are assessed on their ability to:

- review audit findings against audit objectives
- ensure audit conclusions are supported by objective evidence
- note the extent of conformity of the food safety management system under audit with the audit criteria
- note the effectiveness of the business's food safety management system with the appropriate legislation
- Determine the effectiveness of the business's internal management review process that monitors the on-going effectiveness of its food safety management system.

FDFFSCOMA - Communicate and negotiate to conduct food safety audits

This unit covers the following elements:

• development of communication plans to support audit processes

- selection and use of appropriate communication methods for conducting audits (communications must respect anti-discrimination, anti-harassment and privacy legislation)
- negotiation skills to achieve agreed audit outcomes (including issue resolution strategies)
- confidentiality needs and expectations of food businesses
- communication methods relevant to different groups and audiences.

A practical assessment will be performed as part of this unit and will assess the auditor's ability to:

• Maintain communication during the audit

Applicants are assessed on their ability to maintain periodic communication with auditees and on their ability to report matters of significant food safety risk without delay.

Conduct interviews.

Applicants must demonstrate an ability to conduct an interview appropriately and with relevance to the audit scope. Applicants are further assessed on their ability to:

- apply appropriate interview techniques so as to avoid unnecessary conflicts
- explain to interviewees the reasons for conducting interviews and why notes are taken
- during interviews
- avoid leading questions during interviews, except where confirmation from interviewees is required
- summarise the results of interviews with interviewees
- express thanks to interviewees for their assistance.
- Prevent and resolve conflicts

Applicants are assessed on their ability to use appropriate skills to prevent conflicts from arising during audits. Applicants are further assessed on their ability to use appropriate conflict resolution skills to manage conflicts when they do arise. It is at the food regulator's discretion as to whether a conflict resolution scenario is presented to an applicant during assessment.

FDFFSCFSAA - Conduct food safety audits

This unit provides knowledge and develops skills in the following areas:

- auditor roles and responsibilities (includes audit planning and defining audit scope)
- food safety management systems
- food safety legislation
- food safety audit process including:
 - planning the audit (includes reviewing and assessing the business's food safety management system and its implementation in the business)
 - conducting the audit (includes gathering evidence to verify that the business's food safety management system and pre-requisite programs are under control)
 - managing the audit process (comparing the audit process against the audit plan)
 - consolidating audit outcomes (gathering audit evidence to identify any potential areas of non-conformance and preparing audit reports)
 - confirming and closing out corrective actions (review implementation of corrective actions against food safety management system).

A skills assessment will be performed as part of this unit and will assess the auditor's ability to:

Implement the audit plan

Regulatory food safety applicants are assessed on their ability to:

- discuss audit plans with auditees, gain agreement from auditees on audit plans and ensure that auditees clearly understand the audit scope and objectives
- agree on the language to be used during audits and have interpreters ready as required

- ensure appropriate documentation for audits is used
- gain consent from auditees if there are any proposed changes to an agreed audit plan.

Collect and verify information

Applicants are assessed on their ability to:

- collect relevant information to the audit scope and objectives
- only use verifiable information as audit evidence
- when required, confirm appropriateness of corrective actions for previous non conformances
- appropriately record audit evidence
- analyse information to confirm that the program is consistently and effectively implemented
- gather evidence from sources that include, but are not limited to:
 - o interviews with employees and other persons
 - o observation of activities
 - o documents, records and data summaries
 - o auditee's sampling procedures
 - customer feedback.
- Assess food safety and implementation of food safety programs

Applicants must demonstrate an ability to assess the effectiveness of food safety plans and/or programs, particularly critical control points (CCP's). Applicants must further be able to assess programs to determine compliance with legislative requirements.

Conduct interviews

Applicants must demonstrate ability to appropriately interview people relevant to the audit scope. Applicants must further demonstrate ability to:

- apply appropriate interview technique so as to avoid unnecessary conflicts
- explain to interviewees the reasons for conducting interviews and why notes are taken during interviews
- avoid leading questions during interviews, except where confirmation from interviewees is required
- summarise the results of interviews with interviewees
- express thanks to interviewees for their assistance.
- Generate audit findings

Applicants are required to demonstrate the ability to:

- generate audit findings through review of audit evidence against audit criteria
- determine the conformity or non-conformity of audit findings with respect to audit criteria
- use objective evidence to support audit findings
- discuss potential non-conformances with auditees to ensure evidence in support of claimed non-conformances is accurate and clearly understood by auditees
- record any unresolved differences of opinion concerning audit evidence and/or audit findings.

• Prepare audit conclusions

Applicants are assessed on their ability to:

- review audit findings against audit objectives
- ensure audit conclusions are supported by objective evidence
- note the extent of conformity of the food safety management system under audit with the audit criteria
- note the effectiveness of the business's food safety management system with the appropriate legislation
- determine the effectiveness of the business's internal management review process that monitors the on-going effectiveness of its food safety management system.

Conduct exit meeting

Applicants are required to demonstrate the ability to:

- appropriately chair and maintain appropriate records of exit meetings
- present audit findings and conclusions to auditees in a manner that is readily understood by auditees
- discuss with auditees any situation encountered during an audit, where the reliability of evidence gathered to support audit results and conclusions may not be completely conclusive.

FDFFSCHZA - Identify, evaluate and control food safety hazards

This unit provides knowledge and develops skills in the following areas:

- interpretation and application of relevant legislation, codes of practice and technical standards
- identification of biological, chemical and physical food safety hazards
- determination of CCP's and critical limits for identified hazards
- establishment of required procedures, systems and records to monitor CCP's in order to demonstrate that CCP's are under control
- specification of required corrective actions and corrections to be taken when critical limits are not achieved.

A skills assessment will be performed as part of this unit and will assess the auditor's ability to:

Identify food safety hazards

Applicants must demonstrate an ability to identify food safety hazards relevant to the business/process under audit.

Identify methods to control food safety hazards

Applicants are required to demonstrate knowledge of appropriate methods to control food safety hazards relevant to the business under audit.

b) Medium risk

The following are the recommended minimum requirements to be applied when a food regulator assesses a regulatory food safety auditor application at the medium risk level.

• Auditor competency (medium risk) – auditor competency units and technical and educational qualifications required as listed in Table 1, auditors competent to undertake systems and compliance audits.

Statement of attainment or RPL assessment against the following:

- i) FDFFSCOMA Communicate and negotiate to conduct food safety audits
 - ii) FDFFSCFSAA Conduct food safety audits
 - iii) FDFFSCHZA Identify, evaluate and control food safety hazards.
- b) Certificate IV or higher in food science or related field (including 40 hrs of food microbiology).
- *Regulator's system requirements* knowledge of jurisdictional legislation and regulator's system.
- *Pre-approval additional provisions* The applicant has signed a code of conduct, completed and signed a declaration (to verify the accuracy and integrity of information provided) and has been subject to further suitability checks if required.
- Legislative assessment, inclusive of 'witness audit' This audit should only be conducted by a regulatory food safety auditor (approved by the appropriate regulator) who at the very least is competent at the medium risk level.

The audit knowledge competencies and educational and technical qualifications for the medium risk level are explained below:

- FDFFSCOMA Communicate and negotiate to conduct food safety audits (as per low risk level)
- FDFFSCFSAA Conduct food safety audits (as per low risk level)
- FDFFSCHZA Identify, evaluate and control food safety hazards (as per low risk level)
- Certificate IV or higher in food science or related field (including 40 hrs of food microbiology). This provides underpinning, non-specific knowledge of food science and related matters.

c) High risk

a)

The following are the recommended minimum requirements to be applied when a food regulator assesses a regulatory food safety auditor application at the high risk level.

 Auditor competency (high risk) – auditor competency units and technical and educational qualifications required as listed in Table 1, auditors competent to undertake systems and compliance audits.

Statement of attainment or RPL assessment against the following:

- a) i) FDFFSCOMA Communicate and negotiate to conduct food safety audits
 ii) FDFFSCFSAA Conduct food safety audits
 - iii) FDFFSCHZA Identify, evaluate and control food safety hazards.
- b) Certificate IV or higher in food science or related field (including 40 hrs of food microbiology).
- *Regulator's system requirements* knowledge of jurisdictional legislation and regulator's system.
- *Pre-approval additional provisions* The applicant has signed a code of conduct, completed and signed a declaration (to verify the accuracy and integrity of information provided) and has been subject to further suitability checks if required.

• Legislative assessment, inclusive of 'witness audit' – This audit should only be conducted by a regulatory food safety auditor (approved by the appropriate regulator) who at the very least is competent at the high risk level in the activity or complex process that is the subject of the witness audit.

Regulatory auditing in the industry sectors of food service, whereby potentially hazardous food is served to vulnerable populations and catering operations serving food to the general public may not always require an auditor to possess a specialised auditor competency. Some businesses that may be audited in these sectors (e.g. a childcare centre) may not require such competencies. However, FRSC has agreed that the minimum requirement for the regulatory auditing of all businesses in these sectors is a high risk auditor who possesses all three auditing competency units and a Certificate IV or higher in food science or related field (including 40 hours of microbiology).

However, if a business being audited in these sectors undertakes an activity that requires a regulatory auditor to possess a specialised auditing competency (e.g. cook chill processes and/or heat treatment processes) the regulatory food safety auditor must hold the appropriate specialised competency units (endorsements) in order to be considered competent to conduct a regulatory audit of that business.

Furthermore, attainment of competency in one of the six high risk areas does not automatically constitute attainment of competency in them all, or in more than one. Each identified high risk area is mutually exclusive and requires attainment of the individual specialised high risk audit competency unit (as necessary), all three auditing competency units, satisfactory legislative assessment (inclusive of a 'witness audit' by the food regulator), as well as possession of Certificate IV or higher in food science or related field (including 40 hours of microbiology) or equivalent, before competency may be attained.

The specialised competencies for high risk auditors are as follows.

FDFFSCC4A - Audit a cook chill process

This unit specifies the outcomes required to support a food safety audit of food safety programs that include extended life cook chill processes. The unit applies to cook chill products that are minimally heat-processed foods distributed as chilled products with a defined shelf life.

FDFFSHT4A - Audit a heat treatment process

This unit specifies the outcomes required to support a food safety audit that includes heat treatment processes designed to bring about defined logarithmic reductions in target organisms in food products. Processes covered include pasteurisation of products with a nominated refrigerated shelf life and commercially sterile, shelf-stable products.

FDFFSME4A - Audit manufacturing of RTE meat products

This unit provides specialist, technical information required for the auditing of RTE, manufactured and UCFM products. It covers the processing of RTE, manufactured and UCFM products, relevant national legislation concerning the processing of these products, and outcomes required to support an audit of a food safety program prepared for RTE and UCFM products.

FDFFSBM4A - Audit bivalve mollusc growing and harvesting operations

This unit specifies outcomes required to support an audit of food safety programs of bivalve mollusc producers. Processes concerning on-shore and wild growing, harvesting, cleaning, post-harvest handling and storage, stock movement, depuration (where applicable) and wet storage are covered. The skills and knowledge to audit the classification of growing areas are not covered.

Legislative examination, inclusive of a 'witness' audit

Before competency in any high risk activity or complex process is attained, it is strongly recommended that applicants be assessed by food regulators against the relevant legislation concerning high risk activities and/or complex processes. Part of this assessment should include a 'witness' audit, where the food regulator will evaluate the competency of the applicant during a high risk audit of the desired high risk activity/complex process. The 'witness' audit should only be conducted by a high risk activity and/or complex process regulatory auditor suitably competent in the high risk activity or complex process that is the subject of the application. This person shall also be competent to undertake skills assessments.

For example, an auditor who desires to be endorsed as competent to audit UCFM should only be assessed in a 'witness' audit by a high risk regulatory auditor that is competent in the regulatory auditing of UCFM.

Implementation arrangements for regulatory food safety auditors (all levels)

On or before 25 October 2011 all current food safety regulatory auditors are required to meet all criteria outlined in Table 1.

1.2 Approval criteria for regulatory food safety auditor applicants

It is recommended that applicants seeking appointment as regulatory food safety auditors are assessed against the following criteria:

- certification (attainment) against the audit competencies (national units of competency)
- possession of educational and technical qualifications for the auditing of medium and high risk levels
- possession of appropriate competencies for auditing of high risk activities and complex processes
- national regulatory food safety auditor code of conduct
- application of pre-approval additional provisions
- food regulator assessment of auditor competency

These criteria are the minimum that persons seeking to become regulatory food safety auditors will need to address in order to comply with the auditor approval provisions of the Policy. These criteria are expanded upon further below.

1.2.1 Training and assessment against the national units of competency

FRSC has determined that all regulatory food safety auditors must be trained and assessed as competent against the national units of competency (referred to in Table 1 as 'auditor competency'). Bodies that may conduct training and assessment are those bodies formally registered to deliver these competencies. These bodies may be personnel certification bodies (PCB) (e.g. RABQSA International) or tertiary education bodies (e.g. TAFE, registered training organisations). Upon attaining these competencies auditors may be accredited, licensed or certified as a competent auditor.

1.2.2 Possession of educational and technical qualification for the auditing of medium and high risk levels

FRSC has determined that persons seeking to conduct regulatory food safety audits in the medium and high risk levels of Table 1 must have a Certificate IV or higher in food science or related field (including 40 hours of food microbiology) in order to be considered competent to conduct such audits.

1.2.3 Possession of appropriate competencies for auditing of high risk activities and complex processes

FRSC has determined that persons seeking to conduct regulatory food safety audits of high risk activities and/or complex processes will be required to possess the relevant specialised auditing competencies (endorsements) outlined in Table 1.

Note specific comments (refer page 16) made with respect to the application of specialised auditing competencies (endorsements) to the regulatory auditing of the complex processes of food service, whereby potentially hazardous food is served to vulnerable populations and catering operations serving food to the general public.

1.2.4 Regulatory food safety auditor code of conduct

As part of the arrangements for implementing the Policy, food regulators will be required to implement a code of conduct for regulatory food safety auditors. This Code shall inform auditors of their ethical and professional responsibilities when undertaking regulatory audits. It shall also provide a basis against which food regulators may review, impose conditions, or revoke or suspend a regulatory food safety auditor's approval.

FRSC has agreed that all regulatory food safety auditors will be required to submit a signed code of conduct to their approving regulator.

Food regulators are encouraged to cover the following areas in their code of conduct:

- underlying conduct provisions
- ethical obligations
- behaviour and attitude
- conflict of interest
- receipt and giving of gifts
- use of alcohol and drugs
- commercial impartiality.

<u>Appendix A</u> outlines an example regulatory food safety auditor code of conduct. Food regulators may adopt this code or draft their own code of conduct to better reflect their own arrangements.

1.2.5 Application of pre-approval additional provisions

Food regulators acknowledge that regulatory food safety auditors are subject to significant responsibility. As such, all applications for regulatory food safety auditors shall be subject to additional pre-approval provisions that address the following issues:

- previous criminal activity
- accuracy and integrity of information provided in applications, particularly with respect to the applicant's identity, educational and training qualifications, and experience (relevant to regulatory food safety auditing).

At a minimum, food regulators should require all applications to be accompanied by a signed declaration (statement) to verify the accuracy and integrity of information provided. Food regulators should also randomly review applications to verify the accuracy and integrity of information provided.

Should a random review of an application reveal intentionally false or misleading information, the application should be subject to further investigation if not rejected outright. Furthermore, following the appointment of a person as a regulatory food safety auditor should a review reveal that significant false and misleading statements have been made to obtain approval it is quite likely that the auditor's approval may be revoked or suspended by the appointing food regulator.

Food regulators may impose additional measures to a signed statement in meeting their obligations to assess pre-approval additional provisions under the Policy. However, whatever pre-approval conditions are imposed, they should be applied fairly and equitably to all applicants.

For example, false statements/lying with respect to the declaration of previous criminal activity for specific offences (any indictable offence not eligible to become a spent conviction), should be treated equitably by all food regulators when considering regulatory auditor applicants. Whether this information was obtained from an applicant through a pre-approval criminal history check, or by random investigation following the appointment of a person as a regulatory food safety auditor (where a signed statement was used to enact pre-approval additional provisions), the outcome of providing false and misleading information should not differ.

1.2.6 Food Regulator assessment of auditor competency

Upon providing evidence that the appropriate auditing competencies have been obtained (and technical and educations qualifications if required), it is recommended that food regulators assess applicants' knowledge and understanding of the regulator's specific legislation before an approval is granted. This assessment is to verify that the prospective auditor can appropriately interpret and apply the legislation. Such an assessment should consist in part of a demonstration of practical auditing ability (i.e. 'witness' audit). It is suggested that all food regulators conduct 'witness' audits of all applicants seeking to enter their audit system, irrespective of whether the applicant is seeking to enter their systems as low, medium or high risk regulatory food safety auditors. It is further suggested that 'witness' audits are only conducted by approved regulatory auditors who are, at the very least, competent at the level of regulatory food safety auditor that is the subject of the 'witness' audit.

It is recommended that food regulators require 'witness' audits for the six high risk areas identified in Table 1 to be conducted by approved regulatory auditors that possess not only the appropriate auditing competencies and technical and educational qualifications of the high risk level, but who also have the specialised auditing competency (as required) that is the subject of the 'witness' audit.

Upon being satisfied that that the applicant possesses appropriate knowledge of the legislation and can effectively demonstrate practical regulatory auditing ability, the regulator may issue the applicant with an approval. The scope of activity of the approved regulatory auditor will be restricted to the legislation that the regulatory auditor has been assessed against. Approved regulatory auditors may not conduct regulatory audits in areas outside their scope of approval.

For example, an approved regulatory food safety auditor with scope to audit against Parts 1-4 of the NSW Food Regulation 2004, may only conduct regulatory food safety audits in areas covered by those parts of the regulation. They may not conduct regulatory audits in areas outside these Parts until they are assessed and subsequently approved against the remaining Parts of the NSW Food Regulation 2004.

1.2.7 The food safety auditor approval process

It is recommended that regulatory food safety auditor applicants submit an application form to the food regulator. Possible requirements on such a form may include:

- full name and contact details
- evidence of attainment of audit knowledge requirements (inclusive of skill assessments)
- evidence of attainment of educational and technical requirements (required for medium and high risk auditing)
- evidence of attainment of appropriate competencies for auditing of complex and high risk processes (if required)
- signed agreement to comply with the Auditor Code of Conduct
- signed declaration stating the truthfulness of all information contained in the application
- declaration of all court-convicted offences in accordance with the limitations of the appropriate spent convictions legislation
- a statement that approval will only be granted upon satisfactory assessment against the food regulator's legislation and demonstration of appropriate auditing competency
- a statement that an applicant's approval is limited by the legislation against which the food regulator has assessed the application.

Some food regulators may require fees to accompany an auditor's application and further fees to renew an auditor's approval.

An example auditor application form is provided at Appendix B.

1.2.8 Terms of an auditor's approval

Food regulators may issue regulatory food safety auditor approvals for different terms, depending on their legislative framework. However, all auditor approvals should be finite and require renewal at a timeframe dictated by the appropriate food regulator. It is recommended that auditor approvals be no longer than four years.

1.3 Auditor register

It is recommended that food regulators list the details of all regulatory food safety auditors on a publicly available register on their website. Such a register provides industry with a ready reference to locate approved regulatory food safety auditors and also to verify the authenticity of persons claiming to be approved regulatory food safety auditors.

It is recommended that auditor registers contain the following information:

- name
- company
- contact details (phone/mobile, e-mail, postcode)
- geographical area of service
- high risk competencies attained (if applicable) and occupational limitations.
- date of approval/expiry date

Disciplinary action

Should a food regulator undertake disciplinary action against a regulatory food safety auditor, it is recommended that the food regulator notify all regulators of the action taken and the reasons why.

Following such a notification, as a matter of best practice, all food regulators should subsequently amend their respective auditor registers. For example, if a regulatory auditor is removed from a particular food regulator's register, then all other food regulators who have the auditor listed on their auditor register should also remove that auditor from their register.

1.4 Mutual recognition

The *Mutual Recognition Act 1992 (Cwlth)* is designed to remove barriers to the inter-jurisdictional flow of goods and workers in registered occupations across Australian states and territories.

The Trans-Tasman Mutual Recognition Act 1997 is closely modelled on the Mutual Recognition Act.

With respect to occupations, the mutual recognition principle allows a person registered in an occupation in one jurisdiction to apply for registration in an equivalent occupation in a second jurisdiction. When applying for work in the second jurisdiction, the person has to comply with all regulations in that jurisdiction relating to how the occupation is conducted, e.g. with respect to insurance, trust funds and registration fees. State-based regulations governing how occupations are practised within jurisdictions are exceptions to the mutual recognition principle. Mutual recognition does not override jurisdictional sovereignty.

To invoke the mutual recognition principle, a registered person must apply for registration and give details to the second jurisdiction of his or her registration in the first jurisdiction. This application must also provide the second jurisdiction with consent to access such information and particulars as is required to process the application. The second jurisdiction has one month to assess the application; however, this decision may be deferred for up to six months.

Following is an example of how the mutual recognition principle may be applied to a regulatory food safety auditor:

An approved regulatory food safety auditor who has elected to **only** be assessed against Parts 1-4 of the NSW Food Regulation 2004 (Dairy Food Safety Scheme) applies to Dairy Authority South Australia to conduct regulatory audits under the Primary Produce (Food Safety Schemes) Dairy Industry Regulations 2005. The auditor applies under the Mutual Recognition Act 1992, to transfer his/her registration from New South Wales to South Australia. The issue of equivalence for the mutual recognition application becomes the similarity/difference of the two legislative instruments that control the operation of dairy industries within the two states.

The same auditor cannot claim, under mutual recognition, competency to audit food products captured under the Primary Produce (Food Safety Schemes) Meat Industry Regulations 2005, as the auditor has not been approved by the NSW Food Authority against Part 5 of the NSW Food Regulation 2004 (Meat Food Safety Scheme).

Please click here for further information on mutual recognition legislation.

2.0 Managing the audit process

2.1 Inspection and audit

Inspection is used to assess compliance with a prescriptive standard and where no requirements for keeping documents or records are required. The Policy defines inspection as follows:

The examination of food or systems for control of food, raw materials, processing and distribution, including in-process and finished product testing, to verify that they conform to regulatory requirements.

Audit is an assessment of systems. Where a business is required by legislation to maintain an approved food safety management system, audit is a tool that may be used by food regulators and regulatory food safety auditors to assess whether the business is maintaining its system in accordance with the approval granted to it by the food regulator. The Policy defines audit as follows:

A systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled.

2.2 Duties and reporting requirements of regulatory food safety auditors

2.2.1 Duties of regulatory food safety auditors

The specific duties of a regulatory food safety auditor are described in the approving food regulator's legislation.

As a guide, Section 67 of the Model Food Provisions are provided for information:

A food safety auditor has the following duties:

- a. to carry out audits of any food safety programs required by the regulations to be prepared in relation to food businesses having regard to the requirements of the regulations
- b) to carry out any necessary follow-up action, including further audits, if necessary, to check to see if action has been taken to remedy any deficiencies of any such food safety program identified in an audit
- c) to carry out assessments of food businesses to ascertain their compliance with requirements of the Food Safety Standards
- d) to report in accordance with Section 68.

2.2.2 Reporting requirements for regulatory food safety auditors

Reporting requirements for regulatory food safety audits conducted by regulatory food safety auditors are described in the approving food regulator's legislation and/or policies and reporting templates developed under that regulator's audit system. These requirements may differ between regulators. Where a food regulator specifies particular reporting requirements for regulatory food safety audits (e.g. reporting template), regulatory food safety auditors working in that audit system must comply with those requirements. All regulatory food safety auditors are required to submit audit reports to the approving food regulator and the business that has been audited within the timeframe stipulated in the approving food regulator's legislation or other arrangement. As a guide, the Model Food Provisions suggests that audit reports should be submitted to the food regulator and the business within 21 days of the completion of the audit.

Identification of critical non-conformances during regulatory food safety audits generally requires the regulatory food safety auditor to notify the relevant food regulator within a timeframe stipulated in the food regulator's legislation. As a guide, the Model Food Provisions suggest that such notification should occur within 24 hours.

Section 68 of the Model Food Provisions is provided below as a potential reference for regulatory food safety auditor reporting requirements.

Reporting requirements:

- 1) A food safety auditor must report in writing to the appropriate enforcement agency the results of any audit or assessment carried out by the food safety auditor for the purposes of this Act.
- 2) A report under subsection (1) must:
 - a) be in the prescribed form
 - b) be submitted to the appropriate enforcement agency within 21 days after the completion of the audit or assessment
 - c) take account of any action taken before the submission of the report to remedy any deficiency identified by the food safety auditor.
- 3) A food safety auditor must indicate in a report of an audit under subsection (1):
 - a) whether or not the food safety auditor is of the opinion that the food business is being carried on in compliance with the requirements of the regulations relating to food safety programs
 - b) any such requirements that the food safety auditor is of the opinion are being contravened in relation to the food business and the manner in which they are being contravened.
- 4) A food safety auditor must indicate in a report of an assessment under subsection (1):
 - a) whether or not the food safety auditor is of the opinion that the food business is being carried on in compliance with the provisions of the Food Safety Standards
 - b) any such provisions that the food safety auditor is of the opinion are being contravened in relation to the food business and the manner in which they are being contravened.
- 5) A food safety auditor must report any contravention of this Act, the regulations relating to food safety programs, or the Food Safety Standards that comes to the food safety auditor's attention in the course of carrying out an audit or assessment for the purposes of this Act:
 - a) that is an imminent and serious risk to the safety of food intended for sale
 - b) that will cause significant unsuitability of food intended for sale, as soon as possible but in any event within 24 hours after the contravention comes to the food safety auditor's attention.
- 6) A food safety auditor must report in writing to the appropriate enforcement agency, giving reasons, if the food safety auditor considers that the priority classification of a food business that has been audited by the food safety auditor should be changed.
- 7) A copy of a report provided to the appropriate enforcement agency in relation to an audit or assessment must be given to the proprietor of the food business concerned.

It is considered that compliance with Section 68 Clause (3) (a) and Clause (4) (a) of the Model Food Act may be demonstrated through substantial compliance during a regulatory audit, rather than the total absence of non-conformances.

A regulatory audit may still be deemed acceptable by the regulatory food safety auditor even if minor or major non-conformances are detected. The exception to this recommendation is critical non-conformances.

Detection of a critical non-conformance during a regulatory audit, or a collection of a number of major non-conformances constituting a critical non-conformance (this will depend on the specific food regulator's legislation or audit management system), should result in the termination of the audit and the regulatory food safety auditor failing the business.

The auditor will then likely be required to notify the relevant food regulator of the audit failure within the timeframe stipulated in the food regulator's legislation.

Refer to section 2.3.4 of this Guideline for further information concerning the reporting of regulatory audit outcomes.

2.3 The audit process

2.3.1 Documentation review

As a matter of best practice, it is recommended that a desk top review of a business's approved food safety management system is undertaken before commencing the on-site component of a regulatory food safety audit. Such an approach determines whether the business has collected sufficient evidence (e.g. records) to suggest that it is maintaining the system in accordance with the approval provided by the food regulator. If during the desk top review, the regulatory food safety auditor considers that the business has not collected sufficient evidence to demonstrate compliance with the approval of the system provided by the food regulator, it is recommended that the on-site component of a regulatory food safety audit not be commenced.

2.3.2 Planning the audit

It is suggested that the scope of a regulatory food safety audit, and the criteria used to determine whether the business has implemented its system in accordance with the approval granted by the food regulator, be determined before commencing the on-site component of the audit. This is likely to be a specific requirement of a regulator's audit system due to the time impost placed upon businesses by regulatory food safety audits. During the planning and scoping of the audit, it is recommended that the regulatory food safety auditor determine:

- the basis and purpose of the audit
- the type of audit to be conducted
- the criteria that will be used to assess the business's current food safety management system
- definitions of non-conformance that will be applied and the levels of non-conformance that will be used
- activities to be conducted and responsibility for carrying out those activities
- the timing of the audit
- a timetable for conducting the audit
- resource requirements for conducting the audit
- personnel required to conduct the audit
- compliance history
- reporting requirements
- follow up and completion procedures.

2.3.3 Conduct the audit

Opening meeting

Before commencing a regulatory food safety audit, it is suggested that the auditor communicate the objectives and intent of the audit to the food business proprietor or their designated representatives in an organised, succinct and clear manner in recognition of the time impost placed on food businesses by onsite regulatory audits.

On-site examination of the business's food safety program

It is recommended that during the on-site component of a regulatory food safety audit, a regulatory food safety auditor should review evidence collected by the business (e.g. records, sampling logs, documentation protocols) that demonstrates its on-going compliance with its approved system to determine whether the business is maintaining its system consistent with its approval and with the version that underwent desk top audit.

It is further recommended that regulatory food safety auditors collect their own evidence from a business during the on-site component of a regulatory food safety audit to allow them to make an objective determination as to whether the business is maintaining its system consistent with the food regulator's approval. Evidence may be collected through interviews, independent examination of documentation and records and/or observation of activities carried out at the business. Where a non-conformance is detected, auditors should clearly document these incidences against the requirements of the appropriate legislation. Auditors should further inform businesses of any non-conformances identified during on-site audits.

It is suggested that regulatory food safety auditors review findings from on-site audits against legislative requirements before initiating exit meetings with the food business. This approach ensures all audit objectives have been met and reduces the time impost on a food business proprietor or their representative during exit meetings.

Exit meetings with food businesses

To provide audited businesses with the opportunity to discuss audit findings and provide further information as required, it is strongly recommended that regulatory food safety auditors discuss audit findings with food businesses upon completion of regulatory food safety audits. During these meetings, it is further recommended that auditors discuss non-conformances identified during the audit and seek comment from the business as to how processes can be modified/implemented to address those non-conformances. Auditors may need to arrange further audits to verify that the corrective action proposed by the food businesses has been implemented. At the very least it is strongly suggested that regulatory food safety auditors be required to obtain some form of evidence to confirm that agreed corrective measures have been implemented by audited businesses.

It is also recommended that the audit systems of all food regulators require regulatory food safety auditors to keep records of all agreed processes to address non-conformances identified during regulatory food safety audits. These records should require the auditor to obtain evidence from the business to verify that agreed corrective measures have been implemented. It is further recommended that these records are submitted to the food regulator and the business as part of the audit report, and that the regulatory food safety audit remain open until this information is received.

2.3.4 Reporting of audit outcomes

As discussed in Section 2.2.2, regulatory food safety auditors are required to submit audit reports to the appropriate food regulator and the business being audited in accordance with the appropriate food regulator's legislation. These arrangements may also be prescribed in documentation other than legislation that forms part of the food regulator's audit system.

It is recommended that regulatory food safety audit reports address the following as a minimum:

- the date(s) of the audit
- the name and signature of the auditor(s)
- the name and address of the food business audited
- the scope and objectives of the audit, including audit type, and whether it is a scheduled or follow-up audit
- information regarding non-conformances raised during the audit
- copies of records relating to non-conformances, if applicable
- information regarding changes in the business's food handling activities that may affect its risk priority classification
- a statement of compliance on which to base future audit frequency. If a variation to audit frequency is proposed, sufficient information should be included in the audit report to substantiate the proposed variation.

As also mentioned in Section 2.2.2, reporting requirements for critical non-conformances are likely to differ from requirements for submitting audit reports. It is likely that the legislation of all food regulators will require critical non-conformances (i.e. issues found in businesses, which in the auditor's opinion constitute an imminent and serious risk to public health and safety), to be reported to food regulators within 24 hours.

2.3.5 Non-conformance categories and reporting

Subject to terminology used within a food regulator's audit system, it is likely that non-conformances detected by regulatory food safety audits of a business's approved system will be classified as critical non-conformances or non-critical non-conformances. The regulatory audit systems of some food regulators may further classify non-critical non-conformances into minor non-conformances or major non-conformances. Advice in this Guideline is confined to critical non-conformances or non-critical non-critical non-conformances.

Critical non-conformances are defined by the Policy as contraventions of legislation detected during food safety audits that present a serious or imminent risk to the safety of food intended for sale, or that will cause significant unsuitability to the food intended for sale. Under these circumstances, the food regulator's audit system is likely to require that the regulatory auditor notify the food regulator within 24 hours.

Non-conformances detected during regulatory food safety audits where there is no imminent risk to public health and safety or risk of significant unsuitability to the food intended for sale, may be referred to as non-critical non-conformances. In this situation, the food regulator's audit system is not likely to require that the auditor notify the regulator of the non-conformance until the audit report is complete and has been submitted to the appropriate food regulator and food business.

For non-critical non-conformances, it is likely that the regulator's audit system will place responsibility for discussing and resolving the non-critical non-conformance on the regulatory food safety auditor and the proprietor of the business or their representative. It is strongly recommended that the auditor's role in this negotiation not include providing the business with the solution to the identified non-conformance as this should be the role of the business proprietor.

The auditor's role in the negotiation should be limited to discussing the issue at hand and affirming that a solution offered by the business has the potential to address the matter. The auditor should not agree that the solution will address the matter until evidence has been supplied by the business to verify that the agreed corrective measure has been implemented.

In some instances it may be necessary for the regulatory food safety auditor to conduct a second audit of the business in order to obtain evidence that the non-conformance has been satisfactorily resolved and may be closed out. It is recommended that second visits only be required in circumstances where implementation of the corrective measure/s cannot be verified by another means capable of addressing the evidence requirement within a food regulator's audit system.

2.3.6 Completion of regulatory audits

Regulatory food safety audits should only be closed out when all planned activities are concluded and an audit report (inclusive of agreed corrective measure(s) and evidence to verify implementation of these measures) has been provided to the appropriate food regulator and the food business. A guideline competency template for auditing a food safety program is provided in <u>Appendix D</u> for example purposes.

2.4 Audit teams

There may be instances where a team of regulatory food safety auditors, rather than an individual regulatory food safety auditor, may be required to carry out a regulatory audit. Under such circumstances, the lead auditor of the audit team will be required to ensure all regulatory food safety auditors on the audit team are competent to conduct such audits. For example, a large dairy manufacturer that has a number of different production lines and production technologies may require an audit team to conduct a regulatory food safety audit of its business rather than just one regulatory food safety auditor. This is due to the dairy manufacturer having a large number of milk pasteurisers on site as well as receiving areas and storage bays to receive and store unpasteurised milk from the farm. Such a site will require regulatory food safety auditors with the high risk competency 'audit a heat treatment process' to audit the pasteurisers, whereas the storage bays and receiving areas may be audited by auditors who do not possess this high risk competency unit.

2.5 Audit allocation

The allocation of timing of regulatory food safety audits (i.e. whether businesses are advised of audits ahead of time) is a matter that rests with the approving food regulator and may or may not be subject to the regulator's legislation.

2.6 The role of the food regulator in the audit process

As part of establishing regulatory audit management systems, food regulators are required to establish management systems to respond to audit findings, monitor the activities of approved regulatory food safety auditors, and if required, approve food safety management systems. It is suggested that the audit management system established by a food regulator:

- contains measures to enable the approval of a business's food safety management system before it may enter a routine audit cycle. These measures may be imposed through conditions of legislative administration such as licensing, accreditation or registration.
- assigns audit frequencies to businesses that require regulatory auditing
- requires the approval of regulatory food safety auditor applicants
- monitors regulatory food safety audits and regulatory food safety auditors through review of submitted audit reports and on-site assessments of auditing ability
- investigates complaints made against auditors by food businesses and complaints made by auditors against food businesses
- defines what constitutes a direct or indirect interest in a food business.

Further detail on the role of the food regulator in the audit system in provided in Chapter 3.

2.7 Risk priority classification and audit frequency

It is suggested that the National Risk Profiling Framework (NRPF) developed by FRSC may be used as an aid to assist the process of assigning risk levels to food businesses that require regulatory auditing. Further detail on the NRPF may be found at the <u>FRSC website</u>.

The process of assigning an audit frequency to businesses in the low, medium or high risk levels of the national regulatory food safety auditor framework (refer to Table 1) will likely be dictated by a food regulator's legislation or other arrangement used by the regulator to perform this function (e.g. a policy document).

Table 2 provides an example for assigning audit frequencies to the low, medium and high risk levels. The low risk level is assigned an initial audit frequency of 18 months, whereas the medium risk level is assigned an initial audit frequency of 12 months and the high risk level an initial audit frequency of six months. Under this example, following the initial audit, a business's future audit frequency may subsequently vary according to their audit performance, with good audit performance rewarded with a lower audit frequency and poor audit performance leading to closer monitoring by means of more frequent audits. Table 2 provides an example only.

 Table 2 - Relationship between audit frequency and food business risk classification*

 Audit frequency (every x months)

Priority Classification Status	Initial audit	Maximum	Minimum
Low	18	12	24
Medium	12	6	18
High	6	3	12

* This table is based on information derived from the ANZFA document *The Priority Classification System for Food Businesses.*

It is the food regulator's responsibility to assign a priority classification status to a food business as a basis for determining that business's initial audit frequency. Upon deciding the priority classification status of a food business (and its associated audit frequency), it is likely that the food regulator's governing legislation will require the food regulator to notify the business of its decision in writing. It is also likely to be the food regulator's responsibility to amend a business's priority classification status (and audit frequency) as required, and notify the food business in writing of the amended status. Situations where it would likely be necessary to amend a business' priority classification status would include expansion of a business that previously was a butcher only).

It is also likely to be the responsibility of the food regulator to amend the audit frequency of a food business within an assigned priority classification status as required. This decision may or may not be influenced by information provided by regulatory food safety auditors in audit reports. Once again, should a regulator make a decision to increase or decrease the regulatory audit frequency of a business, it is suggested that the business be notified in writing.

3.0 Managing the approved regulatory food safety auditor

A robust management system that includes all parts of the regulatory audit system will need to be implemented by food regulators as part of their responsibilities to the audit process. This management system should include procedures and processes for monitoring and reviewing the performance of regulatory food safety auditors against performance indicators, procedures for applying disciplinary procedures to regulatory food safety auditors and measures to ensure regulatory food safety auditors are informed of changes to a food regulator's audit management system. Such processes will be on-going and will require an investment in resources by food regulators.

It is recommended as a minimum, with respect to the management of regulatory food safety auditors, that the audit management systems maintained by food regulators include provisions for:

- maintaining requirements for regulatory auditor approval
- having the regulatory food safety auditor notify the food regulator of any direct or indirect interest they may have in a food business that they have been requested to audit
- procedures that examine whether regulatory food safety auditors are undertaking audits in accordance with the governing legislation and other elements within a food regulator's audit system. Such procedures would examine issues such as reporting requirements, check audits and review of submitted audit reports
- instituting appropriate procedures to manage any complaints received about regulatory food safety auditors and/or apply disciplinary procedures
- indemnity and insurance coverage for second party (contract) and third party auditors
- approval certificates.

Suggested practices that food regulators may implement to demonstrate compliance with these requirements are described in further detail in this chapter.

3.1 Maintain the requirements for approval

It is recommended that food regulators implement arrangements within their own audit management systems to enable regulatory food safety auditors to be kept informed of changes to the respective regulator's audit system. These changes may include, but are not limited to: legislative changes, such as increases in the number of industry sectors to be subject to regulatory auditing, or changes to particular arrangements within an existing legislative instrument used by the regulatory food safety auditors; and amendments to reporting documentation used by regulatory food safety auditors (e.g. reporting templates).

It is further recommended that food regulators require regulatory food safety auditors to re-certify against a food regulator's code of conduct each time their approval is renewed.

It is suggested that regulatory food safety auditors be made responsible for maintaining certification against the audit knowledge competencies as outlined in Table 1 of this Guideline.

Regulatory food safety auditors should also be responsible for maintaining a minimum level of regulatory auditing activity during their prescribed period of approval under a food regulator's audit system. There may be a minimum quantity of activity required from a regulatory food safety auditor to maintain an approval. Regulatory food safety auditors are requested to contact their approving food regulator for further information.

3.2 Conflict of interest

It is strongly recommended that food regulators implement arrangements within their audit management systems to address potential conflict of interest issues. It is likely that food regulator's legislation stipulates such a requirement. These arrangements should prevent regulatory food safety auditors from conducting regulatory audits in businesses where it may be argued that a conflict of interest exists. It is further recommended that regulatory food safety auditors upon discovering that a potential conflict of interest exists be required to notify the relevant officer of the food regulator (person with responsibility for audit activities) as soon as possible. The food regulator shall subsequently determine whether the auditor may continue to conduct the regulatory audit of that business.

Potential conflict of interest situations are listed below.

- The auditing of a business where a regulatory food safety auditor has provided specific direction to that business in how to manage food safety risks associated with its approved system, which may or may not have included drafting the business's food safety management system. Situations where a regulatory food safety auditor has provided general food safety advice to a business, providing this advice does not include or provide specific direction to the food business in how to manage a food safety risk associated with its approved system, should not be considered a conflict of interest situation.
- Arranging food safety training or participating as a food safety trainer for a company during which specific solutions to food safety risks associated with the company's approved system are discussed or provided. It should be noted that discussing non-conformances identified during a regulatory audit should not be considered a conflict of interest. It should be further noted that a conflict of interest is not considered to occur where such information is limited to generic information freely available in the public domain, and company-specific solutions are not provided or discussed.
- Where the regulatory food safety auditor has a direct financial interest in the food business to be audited. It should be noted that remuneration provided to an auditor for auditing a food business does not constitute a conflict of interest.
- Preferential treatment of a person, organisation or interest (including, but not limited to, pecuniary, commercial, political or religious) during a regulatory audit as a result of a regulatory food safety auditor's previous association with that person, organisation or interest.
- Where the regulatory food safety auditor, or a close family member or associate of the auditor, has a direct relationship with a direct competitor of the food business being audited. In this situation, the proprietor of the food business should be notified of the relationship and allowed to decide whether the regulatory food safety auditor may continue to conduct the audit of their business. Should the proprietor refuse the auditor, the auditor should inform the appropriate food regulator, who shall subsequently determine an appropriate course of action.

Failure to declare a potential conflict of interest to the appropriate food regulator should result, in the very least, a review of the regulatory food safety auditor's approval if not suspension or cancellation. Further information on conflict of interest is contained in the example regulatory auditor code of conduct (refer to Appendix A).

3.3 Confidentiality

It is strongly recommended that a food regulator's audit management system should oblige regulatory food safety auditors to keep all information gathered during audits on food businesses confidential. Such information may arise from, but is not limited to, the following sources:

- desk-top audits
- on-site audits
- the presentation of audit results to a food business
- any agreed outcomes arising from the presentation of audit results to a food business
- audit reports.

A possible means of obtaining auditor compliance with this requirement is to include measures within the regulatory auditor code of conduct. Refer to the example auditor code of conduct in <u>Appendix A</u>. The example code states that auditors must maintain the confidentiality of all commercially sensitive or any other information provided in confidence. Should regulatory auditors disclose such information without appropriate consent, it is recommended that food regulators review, suspend or cancel the auditor's approval.

3.4 Monitoring the activity of approved regulatory food safety auditors

It is recommended that regulatory audit management systems include sufficient provisions to enable food regulators to determine whether regulatory food safety auditors are conducting audits in accordance with the appropriate legislation, and in compliance with any relevant non-legislative provisions (e.g. using an appropriate reporting template).

Food regulators should ensure their audit management system includes processes that:

- measure the impartiality and independence displayed by regulatory auditors while conducting regulatory audits
- monitor a regulatory food safety auditor's maintenance of confidentiality during regulatory audits
- allow for the investigation of complaints concerning a regulatory food safety auditor's activities or a regulatory auditor's conduct during a regulatory audit
- monitor a regulatory food safety auditor's performance in conducting regulatory audits, e.g. check audits* and regular reviews of audit reports and non-conformance notices.
- * The Policy defines a check audit as follows:

An action taken to verify the effectiveness of a previous audit, including a full audit or a partial audit; it may be used to assess the performance of an auditor or be part of monitoring to assess whether a regulatory system is achieving its objectives.

Check audits may be undertaken by a food regulator immediately following a regulatory audit to verify that comments made in the auditor's report are accurate or by randomly accompanying an auditor during an audit of a food business.

It is suggested that check audits examine a regulatory food safety auditor's ability to:

- conduct desk-top reviews of a business's approved system
- plan a regulatory audit
- review evidence gathered by the business to suggest compliance with its approved system
- gather their own evidence during the on-site component of a regulatory audit
- apply interpretative skills with respect to evidence supplied by the business, or evidence they have gathered, in order to generate an opinion as to whether the business is carrying on its system in accordance with the approval provided by the appropriate food regulator
- apply interpretative skills to ascertain whether the priority classification status assigned to the business is still appropriate, or whether the regulatory auditor should suggest to the food regulator that it amend the priority classification status assigned to the business;

- communicate and negotiate with the business, both during the audit and during the opening and exit meetings
- manage the time impost placed upon a business by the regulatory audit process.

It is recommended that food regulators review a random percentage of audit reports as part of the monitoring process. Such reviews should consider whether the auditor:

- completes audit reports in compliance with agreed reporting templates
- completes audit reports within appropriate timeframes
- makes appropriate conclusions from the evidence gathered and reviewed during the on-site component of the audit with respect to the business's compliance with its approved system
- appropriately identifies and classifies non-conformances within the business's approved system during the regulatory audit. Part of this assessment will include a review of the evidence obtained by the auditor to verify that the business has implemented the agreed corrective measure(s).

3.5 Appeals, complaints and disputes

During regulatory food safety audits it is likely that disagreements will arise between regulatory food safety auditors and business proprietors or their representatives with respect to audit findings and decisions. In the event of such disagreements (where the issue cannot be resolved by the auditor), it is recommended that a food regulator's audit management system require regulatory food safety auditors to notify food business proprietors of their rights of appeal to an auditor's findings and decisions. The system should further require the auditor to notify the appropriate food regulator of the dispute at the earliest possible opportunity (depending on the severity of the dispute).

The audit management system should also require the proprietor to pursue the matter directly with the appropriate food regulator. In this situation, it is suggested that the food regulator's audit management system require the auditor, as part of their audit report to describe the nature of the dispute and the agreed outcome(s) if possible. If the dispute is of a sufficiently serious nature or it cannot be resolved it is recommended that the auditor not undertake further regulatory food safety auditing work at the business until the food regulator has investigated the dispute.

Examples of issues that may be disputed during a regulatory food safety audit include:

- interpretation and application of legislation
- the level of non-conformance raised during regulatory audits (critical versus non-critical)
- the need for an auditor to re-visit a business to ensure it has implemented agreed corrective measures
- a decision by the auditor to recommend to the food regulator that a business's audit frequency should be increased due to poor audit performance
- a decision by the auditor to recommend to the food regulator that a business's priority classification status be amended to one with a higher audit frequency.

With regard to complaints received about the behaviour of a regulatory food safety auditor while conducting a regulatory audit, it is recommended that food regulators provide for the following processes in their audit management systems:

- mandatory notification to the food regulator, on all occasions, where a complaint has been made against a regulatory food safety auditor concerning behaviour displayed during a regulatory audit. This should, include the nature and circumstances of the complaint
- investigation and management of complaints
- an appeal by an auditor against a decision made by a food regulator arising from a complaint
- management of the outcome of an appeal.

There may also be situations where a regulatory food safety auditor considers that a food business, subject to a regulatory food safety audit, has not appropriately cooperated during the audit process. Under such circumstances, should a regulatory food safety auditor's ability to conduct a regulatory audit not be compromised, the food regulator's audit management system should require the auditor to provide a written report describing the nature and circumstances of the alleged incident, (in addition to the normal audit report). The food regulator may then investigate and inform the auditor of the outcome.

Where a regulatory food safety auditor's ability to appropriately conduct a regulatory food safety audit is compromised by the behaviour of a person(s) in a business subject to a regulatory audit, the regulator's audit management system should allow the auditor to cease the audit immediately and inform the appropriate food regulator in writing as soon as possible of the nature and circumstances of the incident that caused the audit to be prematurely ended. The food regulator shall subsequently investigate.

3.6 Auditor disciplinary procedures

Food regulators may apply disciplinary procedures to regulatory auditors under certain circumstances, including the imposition of additional conditions an auditor's approval, or the suspension, downgrading or revoking of an auditor's approval. It is likely that the appropriate food regulator's legislation will contain specific provisions to this effect.

The grounds by which food regulators may apply disciplinary procedures to regulatory food safety auditors will probably be described in a food regulator's legislation. Grounds by which a food regulator may apply disciplinary procedures to regulatory auditors may also be contained within the regulator's auditor code of conduct. The model auditor code of conduct at Appendix A provides advice as to when such procedures may be warranted.

Examples of circumstances that may result in disciplinary procedures being applied to a regulatory food safety auditor include:

- accepting gifts from food businesses during regulatory audits
- providing false or misleading statements to a food regulator in a signed statement provided as part of an auditor's initial approval
- continuing a regulatory audit in a circumstances where the food regulator has confirmed that a conflict of interest is known to exist
- providing deliberately false and misleading information in regulatory audit reports submitted to food regulators
- making of public statements with respect to the findings of a regulatory audit without the express permission of the relevant officer of the appropriate food regulator
- using alcohol and illegal drugs while conducting regulatory audits
- using legal or prescription drugs in a deliberately irresponsible manner while undertaking regulatory audits
- acting inappropriately while conducting regulatory audits.

3.7 Insurance and indemnity

Food regulators will not be vicariously liable for the negligent acts of second party (contract) or thirdparty regulatory auditors. It is recommended that a food regulator's audit management system require regulatory food safety auditors to hold an adequate level of professional indemnity insurance before they are approved to conduct regulatory audits.

3.8 Certificates of approval

On approval, food regulators may issue regulatory food safety auditors with certificates of approval. If an approval certificate is issued by an approving food regulator, it is suggested that it contain the following information:

- food regulator's name
- name of the Act under which the approval has been issued
- name, photograph and signature of the person who has been issued the approval
- date of expiry of the approval
- scope of the approval
- signature of the person who has issued the approval and the role played by that person when issuing the approval
- any conditions as may be imposed by the food regulator.

Food regulators may request regulatory food safety auditors to carry their certificate of approval (e.g. ID card) when conducting regulatory audits. If it is mandatory under a food regulator's audit system for an approved auditor to carry their certificate of approval when conducting regulatory audits, it is suggested that auditors be provided with the choice of wearing their approval in visible sight or displaying their approval upon request.

3.9 Auditing of food businesses that operate from more than one site

There are a number of food businesses across Australia that are franchised or operate from a number of different business sites. Such businesses may have different food safety management systems on each site, or have one system approved for use across all sites.

Irrespective of whether a food business operating from more than one site chooses to use one system or a different system at each site, regulatory food safety auditors must ensure businesses are managing their approved system within their scope of approval.

4.0 Summary

The Guideline sets out possible arrangements that food regulators may implement to demonstrate compliance with the Policy.

The Policy was endorsed by the Australia New Zealand Food Regulation Ministerial Council in October 2006, with food regulators being given five years in which to implement it (expires 25 October 2011).

This Guideline provides food regulators with advice on the following issues:

- a national regulatory food safety auditor framework, based on a model derived from a pragmatic alignment of the Policy with the industry National Food Safety Auditor Scheme and the Ministerial Policy Guideline for Food Safety Management in Australia: Food Safety Programs.
- processes and procedures for food regulators to adopt to further facilitate a nationally consistent approach to the approval of regulatory food safety auditors
- operational matters likely to be encountered whilst regulatory food safety audits are being undertaken
- processes and procedures to monitor the activity and behaviour of regulatory food safety auditors.

The Guideline, by providing advice that may be incorporated into a food regulator's audit management system is designed to assist in harmonising arrangements for regulatory food safety auditors and regulatory food safety audits across Australia (one of the principal objectives of the Policy).

ISC acknowledges the suggested processes and procedures described in the Guideline may be subject to change as further developments in the national food regulatory system arise, e.g. amendments to the priority classification of food businesses into low, medium and high risk levels of the national regulatory food safety auditor framework. It is ISC's intention to update the Guideline with such information as it emerges, so food regulators should ensure they continue to use the most recent version of the Guideline.

In developing the Guideline, ISC drew upon work by the Australia New Zealand Food Authority (the predecessor to FSANZ) between 1998 and 2001 published in the information paper *Food Safety: An Audit System.* This Guideline is also informed by the National Food Safety Auditor Competency Project (2004). Work undertaken by the National Food Industry Training Council and the Agri-Food Industry Skills Council in developing national units of competency for the training and assessment of food safety auditors was also considered in the drafting of the Guideline.

Some elements of the Policy are not covered by the Guideline, namely the process for the review of the implementation plan for the Policy and the strategies for regulatory auditing of businesses in remote and regional areas ISC intends to develop discussion papers on these issues

Appendix A – Example of a National Regulatory Food Safety Auditor Code of Conduct

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National Auditor Code of Conduct

1.0 Purpose and application of the Code

1.0.1 Purpose

This Code applies to all auditors approved by the food regulator to conduct audits of food businesses. Such persons are expected to conduct themselves with integrity, professionalism, and be accountable to the outcomes of audits they perform.

This Code has been drafted with respect to measures pertained in clauses 65-72 of the *Model Food Act.*

1.0.2 Application

This Code applies to all approved auditors.

Auditors should:

- Familiarise themselves with this Code.
- Familiarise themselves, and comply with all legislation, concerning auditors, audits, audit performance and the legislation to which they are auditing.

Any approved auditor failing to comply with this Code may have their approval immediately suspended or cancelled by the appropriate food regulator.

2.0 Definitions

"actual conflict of interest" when a food regulator would conclude that an auditor's ability to conduct an audit has been compromised by their private or business interests in the client's business.

"apparent conflict of interest" when a food regulator would consider the private or business interests of an auditor may interfere, unduly benefit, or disadvantage their ability to conduct a fair audit of a client's business.

"approval" is a term used to describe an auditor that has been approved by a food regulator.

"approved" means a person authorised by a food regulator to conduct audits. The scope of food businesses an auditor may audit, and any other specific conditions concerning an auditor's approval, will form part of that auditor's approval.

"audit" means an evaluation of a business's approved food safety management system or other aspect of a food business to determine compliance with relevant aspects of Acts, regulations and policies applicable in the jurisdiction where the auditor has an approval to conduct audits.

"auditor" means a person formally approved by a food regulator to conduct audits of food businesses or other premises requiring food safety audits (e.g. primary production farms, hospitals, child care centres and other premises providing food for retail sale). All auditors must be approved by the food regulator to conduct audits.

"food regulator" means the local, state, territory or Commonwealth Government regulator with responsibility for food regulation in that state or territory.

"food business" means a business, enterprise or activity that involves:

- a) the handling of food intended for sale, or
- b) the sale of food,

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

For the purposes of this definition business, enterprise or activity includes a factory, manufacturer, production, entity processing, transporter, store, producer, farm and those businesses that are licensed, accredited or registered or under suspension by a food regulator.

"code" means this Code of Conduct

"commercially sensitive information" means information:

- a) provided to an auditor by a food business during an audit of the business where the business's commercial interests may be impacted
- b) information provided by someone else other than the business concerning some aspect of the business's audit, where the business's commercial interests may be affected;

Where upon receipt of the information the auditor has been requested to not disclose the information.

"food safety management system" is a general term referring to any risk-based food safety management system, including legislated food safety programs and HACCP plans. Where such systems refer to legislated food safety programs equal to Standard 3.2.1 of the Australia New Zealand Food Standards Code, a food safety program means a system that:

- a) systematically identifies the potential hazards that may be reasonably expected to occur in all food handling operations of the food business
- b) identifies where, in a food handling operation, each hazard identified under paragraph (a) can be controlled and the means of control
- c) provides for the systematic monitoring of those controls
- d) provides for appropriate corrective action when that hazard, or each of those hazards, is found not to be under control
- e) provides for the regular review of the system by the food business to ensure its adequacy
- f) provides for appropriate records to be made and kept by the food business demonstrating action taken in relation to, or in compliance with, the food safety program.

"gifts" means any item offered by:

- a) an employee of a food business
- b) any other person acting on behalf of a food business, or in the interests of a food business

to solicit favourable treatment during an audit, or offered to an auditor in response to a finding of a non-conformance during an audit of a food business. This includes findings of a legislative nature and findings in relation to food safety programs. The offer of money to an auditor (bribery) by parties listed in a) or b) is considered a gift.

"illegal drug" means a habit-forming medicinal or illicit substance

"official information" means information:

- a) provided to an auditor by a food regulator
- b) provided by another party acting on behalf of a food regulator*, where upon receipt of the information, the auditor is requested to not disclose the information.

*When a party claims to be acting on behalf of a food regulator, the auditor shall not accept the information from that party until the legitimacy of that party has been established.

"relevant officer" means the person employed and authorised by a food regulator to manage audit activities within a food regulator's jurisdiction.

3.0 Underlying Conduct Provisions

Auditors shall:

- conduct audits with diligence, professionalism and integrity
- provide a copy of all audit reports to the food regulator and immediately inform the food regulator of all notifiable non-conformances detected during audits, in compliance with measures dictated in the *Model Food Act*
- always act fairly and equitably
- comply will all relevant legislation and policies
- avoid real or apparent conflicts of interest
- In the event of a conflict of interest arising during an audit, declare this conflict to the food regulator as soon as possible to enable the food regulator to determine the appropriate course of action
- always show respect to all people involved in the regulatory audit process
- only conduct regulatory audits once approved by the appropriate food regulator
- only conduct audits in the jurisdiction where they are approved to do so, unless approved by the food regulator of another jurisdiction to conduct audits in that jurisdiction (Auditors found practicing outside their jurisdiction of approval without having a formal approval from the appropriate food regulator of that jurisdiction are in breach of this Code)
- not audit food businesses outside their scope of practice
- not behave in a manner that compromises the food regulator
- assist food regulators with enforcement activity taken by the regulator as a result of the auditor's auditing activities including but not limited to, providing statements of evidence for matters concerning legal prosecutions (Auditors shall not be responsible for paying costs associated with the activity of a food regulator)
- not seek or accept recompense from any client for failure to implement appropriate action in relation to a finding of non-conformance detected during an audit. This includes, but is not limited to non-conformances of legislative nature.

4.0 Ethical obligations

4.0.1 Respect for persons

Auditors shall behave fairly and without undue favouritism, patronage or prejudice displayed toward any person associated with a food business.

4.0.2 Respect for the dignity, rights and views of others

Auditors shall not let their personal beliefs influence the outcomes of audits they perform. Auditors shall not use abusive, obscene or threatening language or behaviour towards any person associated with the food business. Physical and/or verbal violence against any person during the audit process is considered a breach of this Code.

4.0.3 Natural justice

Auditors will follow the principles of procedural fairness (natural justice) when making decisions. The principles of procedural fairness require an auditor to:

- provide an opportunity for both sides of an issue to be heard and considered before a decisions is made
- not allow any personal interest associated with an audit or a person associated with a food business to influence an audit outcome
- act in good faith while conducting audits
- provide sound reasons to support decisions made while conducting audits.

4.0.4 Health, welfare and safety concerns

Auditors shall conform with all aspects of occupational health and safety legislation appropriate to the jurisdiction in which they have been approved to conduct audits (including the health and safety policies of food businesses that an auditor has been requested to audit). Auditors shall further respect the health, safety and welfare of all persons and/or animals associated with a food business while conducting audits at that business, as well as ensure their own health, safety and welfare is not unlawfully put at risk while conducting audits.

4.0.5 Equal Employment Opportunity (EEO)

Auditors shall act in accordance with EEO legislation pertinent in the jurisdiction they are approved to conduct audits.

4.0.6 Discrimination

Auditors shall not unlawfully discriminate against any employee of a food business, or other person associated with a food business, or member of the general public while conducting regulatory food safety audits. Issues covered by "unlawfully discriminate" include, but are not limited to discrimination based on sex, colour, race, religious or other personal belief, or other issue listed in antidiscrimination legislation in the jurisdiction in which the auditor has been approved to conduct audits. This does not include recommendations made by an auditor to an employee of a food business concerning the employee's duties should they be afflicted with a condition or illness capable of affecting food safety (e.g. salmonellosis).

4.0.7 Sexual harassment

Auditors shall not sexually harass any employee of a food business, or other persons associated with a food business, or member of the general public while conducting audits. Sexual harassment means any behaviour that would be deemed by a reasonable person to be of a sexual nature. Auditors should understand that sexual harassment is defined by the recipient of the behaviour. Food regulators shall investigate all occasions where an auditor is reported to have behaved in a "sexual manner" while conducting a regulatory food safety audit.

4.0.8 Workplace harassment

Auditors shall not behave in a manner considered by employees of a food business, other persons associated with the food business, or any member of the general public, as being offensive, abusive, obscene, threatening or belittling or demonstrate any other type of behaviour considered to be a breach of the food regulator's own employee behavioural standards or policies for approved food safety auditors. Auditors should note this requirement applies to both verbal and physical behaviour. Statements made in the relation to the potential consequences of not implementing advice concerning non-conformances, is not considered to be threatening behaviour.

4.0.9 Confidentiality

Auditors are required to maintain confidentiality in relation to the nature of processes and practices (and any complaints associated with either) of food produced at businesses they have been requested to audit.

Strict confidentiality is also required from auditors when dealing with any allegation of discrimination, workplace harassment or sexual harassment, whether the allegation concerns themselves, another auditor, or any other person associated with a food business where they may be required to conduct an audit. A breach of confidentiality is deemed a breach of this code.

4.0.10 Victimisation or reprisal

Auditors shall not threaten, or act to the detriment of any person. To do so is considered a breach of this code.

5.0 Behaviour and attitude

During an audit, an auditor shall:

- conduct themselves in a positive manner with a positive attitude to policies and directions provided by the food regulator
- maintain an open and honest approach with all parties involved in the audit, and maintain an appropriate level of communication whilst conducting audits or dealing with audit outcomes
- treat audit participants fairly, equitably and consistently, and follow criteria, policies and processes when making decisions concerning audit findings
- respect all persons when conducting audits, irrespective of their ideas and/or modes of operation
- avoid inappropriate behaviour when conducting audits including behaviour perceived to be intimidating, hostile or offensive and not responding in kind to intimidating or threatening behaviour displayed to them during an audit. In the event of such behaviour, an auditor shall immediately suspend the audit and directly inform the relevant officer of the food regulator.

6.0 Dress standards

Auditors shall conform to a standard of dress suitable for the work to be undertaken. Auditors shall dress respectably in clean clothes and ensure the professionalism of all food safety auditors is not compromised by the standard of their dress.

Auditors shall comply with industry-specific or client-specific dress requirements while conducting audits at a food business, including compliance with any required bio-security protocols.

Auditors shall produce identification verifying themselves to be approved food safety auditors on demand. It is preferred that auditors have identification verifying their approval clearly visible at all time when conducting audits, but it is not mandatory for auditors to follow this practice.

7.0 Alcohol and drugs

Auditors shall not:

- smoke on the premises of a food business in any area other than that deemed by the proprietor of the premises to be a smoking area
- at any time, consume substances (e.g. alcohol, illegal drugs) capable of altering their behaviour or ability to competently conduct food safety audits. To do so is considered a breach of this Code which may result in the immediate cancellation of an auditor's approval
- use legal drugs obtained on prescription or direct purchase, in any way other than in direct compliance with the prescribing doctor's or manufacturer's direction.

8.0 Conflicts of interest

Auditors, must at all times, avoid conflicts of interest. In the event of an auditor learning that an actual or apparent conflict of interest exists, the auditor shall immediately inform the relevant officer of the food regulator. Following investigation, the relevant officer will inform the auditor whether they may continue to audit the food business.

Examples of situations that are considered to constitute an actual or apparent conflict of interest include:

- The auditing of a business where a regulatory food safety auditor has provided specific direction to the business in how to manage food safety risks associated with its approved food safety management system, which may or may not include having drafted the business's food safety management system. The provision of general food safety advice to a business, providing this advice does not include or provide specific direction to the food business on how to manage a food safety risk associated with its approved food safety management system, should not be considered a conflict of interest situation.
- Arranging food safety training or participating as a food safety trainer in sessions where company specific solutions to food safety risks associated with a company's approved food safety management system are discussed or provided. It should be noted that discussing nonconformances identified during a regulatory food safety audit do not constitute a conflict of interest. It should be further noted that a conflict of interest in not considered to occur where such information is limited to generic information freely available in the public domain, and company specific solutions are not provided or discussed.
- Food businesses where the regulatory food safety auditor has a direct financial interest. It should be noted that remuneration provided to an auditor for auditing a food business does not constitute a conflict of interest.
- Preferential treatment of a person, organisation or interest (including, but not limited to, pecuniary, commercial, political or religious interests) during a regulatory food safety audit as a result of a regulatory food safety auditor's previous association with that person, organisation or interest.
- Food businesses where the regulatory food safety auditor, or a close family member or associate of the auditor, has a direct relationship with a direct competitor of the business being audited. In this situation, the proprietor of the food business should be notified of the relationship and allowed to decide whether the regulatory food safety auditor may continue to conduct the audit of their business. Should the proprietor refuse the auditor, the auditor should inform the appropriate food regulator who will then decide on an appropriate course of action.

Failure to declare a conflict of interest may result in the suspension or cancellation of an auditor's approval by the food regulator.

9.0 Acceptance of benefits

Any auditor found to accept gifts, where the intent in offering the gift may reasonably be perceived to be an attempt to influence an audit outcome, and/or a response to a non-conformance finding, will be subject to immediate investigation by the food regulator. Such an investigation may lead to the suspension or cancellation of the auditor's approval. The investigation may further lead to criminal prosecutions being commenced against the auditor.

Benefits do not include refreshments such as tea and coffee or basic meals such as sandwiches provided to an auditor while conducting an audit of a food business.

An auditor must notify the relevant officer of the food regulator immediately should any attempt be made by a client to offer a gift to the auditor, where the intent of offering the gift may reasonably be perceived to be an attempt to influence an audit outcome, and/or a response to a non-conformance finding.

10.0 Official information and public comment

Commercially sensitive information and official information provided to an auditor shall not be used by an auditor to gain advantage for themselves, another person or organisation.

An auditor shall not make public statements or be interviewed by the media on matters concerning audits, clients, the food regulator or other government body associated with the food regulator's activity, unless provided with express written permission by the relevant officer of the food regulator. If provided with such permission, any statement made by an auditor will only discuss facts and shall at no time include the auditor's opinion on the Act, regulation or policies being implemented in the jurisdiction in which they are approved to conduct audits.

11.0 Falsification of results

Any auditor found to deliberately provide false information on audit reports will have their approval immediately suspended or cancelled.

12.0 Declaration of compliance with, and understanding of, the National Food Safety Auditor Code of Conduct

I declare that I have read, understand and will comply with all aspects of the National Food Safety Auditor Code of Conduct when undertaking regulatory food safety audits as an approved food safety auditor.

I agree that failure to comply with this Code of Conduct may result in the non-issue of my approval to conduct regulatory food safety audits or the immediate suspension or cancellation of my existing approval to conduct regulatory food safety audits.

Name (Print).....

Signature.....

Date.....

Appendix B - Sample application form for approval as a regulatory food safety auditor

1. CONTACT DETAILS

These details will be made available on the Approved Auditor Register

Full name:

Postal address:

Post code:

Telephone number:

Mobile number:

Facsimile number:

E-mail address:

Web site:

2. EMPLOYMENT DETAILS
Employment arrangements (tick box):
Self-employed Sub-contracting Audit company employee
Business name:
Trading Name (if applicable):
Postal address:
Post code:

3. CURRENT AUDIT CERTIFICATION

Please attach all evidence of your qualifications

Certifying organisation:

Certification number:

Expiry date:

Auditor level:

□ No

Do you currently have auditor registration in any other State or Territory of Australia?

□ VIC □ QLD □ SA □ TAS

 \Box WA \Box NT \Box ACT \Box Overseas:

(State Country)

4. AUDITING EXPERIENCE

List your main auditing experience – include contact details of employers or clients. Provide specific details of experience in auditor level(s) listed in Section 3.

5. DO YOU WISH TO BE ENDORSED FOR HIGH RISK INDUSTRY SECTORS?

- \Box Yes please go to Q6
- □ No please go to Q7

6. WHAT AUDIT ENDORSEMENTS ARE YOU APPLYING FOR?

☐ Heat treatment

Cook chill

☐ Manufacture of ready-to-eat products

Oysters and Bivalve Molluscs Production and Processing

7. DETAILS OF OTHER QUALIFICATIONS

Please attach all evidence of your qualifications.

Relevant tertiary education (including details of the minimum 40 hours of microbiological

training if applying for high risk process auditing):

HACCP training qualifications:

Other relevant auditing qualifications:

Other relevant qualifications or training:

If you require further room for your response, please attach a separate sheet.

8. PERSONAL HISTORY INFORMATION

In the last 12 months:

1. Have you been convicted of any criminal offence in any state, territory or federal court?

Yes 🗌 No 🗌

If yes, please provide details of the offence.

2. Have you previously been denied approval to undertake the role of a food safety auditor, or had an auditing accreditation or registration suspended or cancelled by any licensing authority in Australia? If yes, attach a detailed explanation.

Yes 🗌 No 🗌

9. PERSONAL INDEMNITY INSURANCE

Do you or your employer have personal indemnity insurance? Yes \Box No \Box

If yes, please provide:

Name of insurer:

Policy number:

10. FEES		
Annual application fee	\$xxx.xx	Must be paid with this application and is non- refundable. Successful applicants will be invoiced this fee. Payment must be made before full auditor approval is granted each year.

11. PAYMENT I have attached a cheque or money order for \$xxx.xx payable to food regulator I want to pay \$xxx.xx by credit card Cardholder's name: Card type: Visa

Mastercard Bankcard

Card number:

11. PAYMENT

Signature: Expiry date:

12. AUDITOR IDENTIFICATION REQUIREMENTS

Please sign your name within the confines of the box below using BLACK INK. Your signature will be scanned and will appear on your auditor identification card.

Please print your name below:

Please provide four colour passport photos one of which will be scanned onto your auditor identification card.

13. PROTECTING YOUR PRIVACY

Personal information collected and held by the food regulator may be used in order to provide approval and audit services, administer and manage administration systems, and inform you of our services and requirements. For more information on how we protect your privacy, please contact your local food regulator.

14. CHECK YOUR APPLICATION		
Please check that you have completed all sections of this form and have attached the required payments and documentation.		
Please do not provide original copies of any documentation as non- approved applications may be destroyed after a period of 24 months		
$_\square$ Signed and dated the declaration (Section 15)		
$_\Box$ Completed the application form		
$_\square$ Payment of \$xxx.xx by cheque or money order or completed and signed the		
credit card details		
$_\Box$ Evidence of relevant tertiary education		
_ Evidence of HACCP training/qualifications		
$_\Box$ Evidence of other qualifications		
$_\Box$ Details of audit experience		
$_\Box$ Details of food industry experience and expertise		
_ Signature block (for ID card – Section 12)		
$_\Box$ Four colour passport photographs (for ID card – Section 12)		

15. DECLARATION

I, (clearly print full name)

being the applicant, apply for approval as an authorised food safety auditor under the food regulator's legislation, and confirm that:

- I have read, understood and agree to comply with the food regulator's Code of Conduct for Food Safety Auditors
- I understand that a 100 point identity, criminal record, qualifications and client check will be undertaken as part of the application process by the food regulator
- I have examined the application form and all supporting documents that I am submitting and declare to the best of my knowledge this information is true, correct and complete
- I understand that the application fee is non-refundable
- I note that I will be required to participate in at least one annual training session at my own expense.

Signature:		
Date:		
	Applications to be sent to food regulator; PO Box	
	Any Inquiries? Please contact the food regulator at	

Word	Meaning
Acceptable	Means the food is not unsafe or unsuitable.
Aid	To promote the course of accomplishment of; facilitate.
Audit	A systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which audit criteria are fulfilled.
Compliance	Refers to a state when persons, food businesses or primary producers are operating within the regulatory requirements that apply to that person, food and associated inputs, food business or primary producer.
Compliance plan	The component of an implementation model that describes how compliance to the full extent of a standard will be demonstrated and/or measured. These measures may be regulatory or non- regulatory.
Consistent	Constantly adhering to the same principles.
Critical non-conformance	A non-conformance of a business's approved food safety program that has substantial or immediate significance and is likely to result in, or has resulted in, unacceptable food.
Enforcement	Means to impose a course of legal action against a food business, e.g. prosecution or cancellation of a business's registration with a food regulator.
Exception report	A report that is generated following identification of a critical non-conformance.
Food business	Means a <i>"business, enterprise or activity</i> that involves:
	a) the handling of food intended for saleb) the sale of food,
	regardless of whether the business, enterprise or activity concerned is of a commercial nature or whether it involves the handling or sale of food on one occasion only.
	For the purposes of this definition, a business, enterprise or activity includes a factory, manufacturer, production, entity processing, transporter, store, producer, farm and those businesses that are licensed, accredited or registered or under suspension by a food regulator.
Food regulator	Bodies of the Commonwealth of Australia, the Government of New Zealand, or states and territories within Australia responsible for food safety legislation. These organisations may be part of government departments or be semi- independent of government and, while many are enforcement agencies, some may delegate enforcement responsibility to other bodies such as local governments.
Food safety program	A general term referring to any risk-based food safety management system, including legislated food safety programs and HACCP plans.

Appendix C – Glossary of key ISC terms

Word	Meaning
Food Standards Code	Food Standards Code means the Australia New
	Zealand Food Standards Code as defined in the
	Australia New Zealand Food Authority Act 1991.
Implementation model	The deliverable provided by the Implementation
	Model Working Group describing how measures
	prescribed in standards will be implemented in
	jurisdictions by food regulators. Implementation
	models may be composed of any combination,
	singular use or differing emphasis of any of the
	following:
	compliance plans
	response plans
	reference materials
	support materials.
Implementation process	
Implementation process	The process undertaken by the Implementation Model Working Group to develop an
	implementation model for a standard.
Monitoring	Includes activity undertaken either by audit,
in or into in the second se	inspection, surveillance or alternative methods
	to ensure compliance with the Food Standards
	Code.
Reference materials	Research and/or evidence gathered by food
	businesses and/or food regulators to assist the
	process of developing implementation models,
	or to assist the process of constructing evidence
	to support measures proposed to indicate
	compliance with a food regulator's compliance
	plan.
Regulation	A rule or order, as for conduct, prescribed by a
	food regulator; a governing direction or law.
Regulatory Impact Statement	The prescribed form for the presentation of an
	impact assessment associated with the
	development of regulatory proposals. Under the
	COAG Principles and Guidelines for National
	Standard Setting and Regulatory Action by Ministerial Councils and Standard-Setting
	<i>Bodies</i> , an impact assessment is required for all
	regulatory proposals and should provide
	information on the following:
	Ŭ
	the appropriateness or otherwise of
	government regulatory action in any
	particular circumstance
	the most effective form that government intervention might take to achieve a
	intervention might take to achieve a
	 desired objective the relative social costs and benefits of
	the relative social costs and benefits of regulation
	who in the community will reap the bonefite or insur the costs of regulation
	benefits or incur the costs of regulation
Response plan	The component of an implementation model that
	describes enforcement and emergency
	provisions available to food regulators that may
	be used in the event of non-compliance to a
	standard.
Standard	
Standard	Standard made under the Food Standards
Standard	Australia New Zealand Act 1991 after the commencement of Part 1 of Schedule 1 to the

Word	Meaning
	Australia New Zealand Food Authority
	Amendment Act 2001; or
	a standard that has been adopted, or taken to have been adopted, by a former Council under the <i>Food Standards Australia New Zealand Act</i> <i>1991</i> before the commencement of Part 1 of Schedule 1 to the <i>Australia New Zealand Food</i> <i>Authority Amendment Act 2001</i> ; or
	a standard that is included in the Food Standards Code.
	However, neither of the following is taken to be part of a standard:
	 text identified as an editorial note, which may include reference to guidance material.
	- text identified as an example.
Standards development	The process undertaken by Food Standards Australia New Zealand to develop standards.
Support materials	Guidance developed by food regulators to assist food businesses understand their obligations to a food regulator's compliance and/or response plan, e.g. an industry information flyer providing guidance on implementing regulatory requirements.
Surveillance	A watch kept over a food business or sector.
Tool	An instrument, for performing or facilitating an operation.
Unsuitable	Food is unsuitable if it:
	 a) is damaged, deteriorated or perished to an extent that affects its reasonable intended use
	 b) contains any damaged, deteriorated or perished substance that affects its reasonable intended use
	 c) is the product of a diseased animal, or an animal that has died otherwise than by slaughter, and has not been declared by or under another Act to be safe for human consumption
	 contains a biological or chemical agent, or other matter or substance, that is foreign to the nature of the food.
Validation	Means to scientifically confirm the effectiveness of measures controlling food safety hazards at each CCP or at intervals or stages of a treatment or either processes.
Verification	The application of methods, procedures, tests
	and other tools for evaluation, in addition to monitoring, to determine compliance of the food business's food safety program with the Food Standards Code or appropriate regulation.

Appendix D – Audit a food safety program guideline competency standard

(as listed in the ANZFA document Food Safety: An audit system).

This appendix is provided for auditor and food regulator information and advice only.

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 the English language, literacy and technical skills 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. An auditor shall have the 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 an 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.