National Food Safety Audit Policy

The national regulatory policy for the approval and management of food safety auditors and food safety audits

**August 2006**

Prepared by the Implementation Sub-Committee of the Food Regulation Standing Committee

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# Acknowledgements

The Implementation Sub-Committee Audit Working Group prepared the National Food Safety Audit Policy with assistance from affiliated staff. Members of the working group were:

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|  |  |
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# Acronyms

Table 2: Acronyms and their meanings

|  |  |
| --- | --- |
| **Acronym** | **Meaning** |
| AQIS | Australian Quarantine and Inspection Service |
| Codex | Codex Alimentarius Commission |
| FSANZ | Food Standards Australia New Zealand |
| ISO | International Organization for Standardization |
| ISC | Implementation Sub-Committee |

# 1 Introduction

The introduction of food safety programs and auditing requirements in food safety policy in Australia represents a shift in the approach of government from end-product inspection to risk-based assessment and prevention. Under the new approach, food businesses are required to identify where food safety hazards may occur in the production and handling of food, and implement systems to manage those risks. One of the roles of food regulators is to ensure that businesses identify and control their food safety hazards.

Food regulators have required risk-based management systems for primary production and export businesses in the seafood, poultry, egg, meat and dairy industries for a number of years. Food Standards Australia New Zealand (FSANZ) is working with food regulators and industry to develop and implement new nationally consistent food safety programs and risk-based food safety management systems.

Under the Food Regulation Agreement 2000, state and territory governments agreed to review their legislation against the requirements in Annex B of the Model Food Act 2000. This included provisions for the auditing of food safety programs and for the regulatory approval of food safety auditors. Food regulators have agreed to a number of measures to ensure that they implement nationally consistent food safety program requirements.

On 12 December 2003, state and territory governments decided, as a first priority, to implement mandatory food safety programs in the following sectors:

* food service businesses, which serve potentially hazardous food to vulnerable populations
* businesses involved in the production, harvesting, processing and distribution of raw oysters and other bivalves
* catering operations serving food to the general public
* producers of manufactured and fermented meat.

## 1.1 **About this document**

This document sets forth the National Food Safety Audit Policy for the management of food safety audits and food safety auditors. It focuses primarily on regulatory audits, including those conducted on behalf of regulators by approved private third-party food safety auditors.

The policy promotes national consistency in the management of food safety auditors and auditing under the health and primary industry portfolios. State and territory food regulators will use the policy as the basis for their own arrangements to support the implementation of food safety programs and food safety auditing requirements. With its national focus, the policy will simplify requirements for businesses and auditors operating in more than one state or territory in domestic markets and aims to reduce the number of food safety audits.

## 1.2 History and scope of the policy

The Food Regulation Standing Committee, at its meeting on 28 July 2004, agreed to a proposal to develop a national food safety audit implementation policy to promote consistency in the management of food safety auditors and auditing within Australia and, where possible, facilitate equivalence with New Zealand. The Implementation Sub-Committee (ISC) formed an ISC Audit Working Group to develop the policy.

The scope of the policy is limited to food safety for regulatory purposes in the health and primary industry portfolios.

The policy allows for consideration of any proposed commercial industry frameworks to achieve equivalence with legislative food safety outcomes. Australian governments will have flexibility in determining their regulatory approaches.

Please note that wherever used in this document, the term ‘auditor’ refers to a regulatory food safety auditor unless otherwise specified.

## 1.3 Consultation process

In developing the policy, the ISC sought comments from interested persons for the approval and management of food safety auditors and auditing under both health and primary industry portfolios. The submissions from the *National Food Safety Audit Implementation Framework Discussion Paper* (June 2005) and the *National Food Safety Audit Framework Consultation Paper* (May 2006) were used to inform the development of the policy.

The ISC looked at related work and consultation previously undertaken in the health and primary industry portfolios, relevant industry and concurrent complementary projects. It also drew upon work undertaken between 1998 and 2001 by the Australia New Zealand Food Authority (the predecessor of FSANZ) published in *Food Safety: An Audit System*, an information paper. The National Food Safety Auditor Competency Project (2004), and work by the National Food Industry Training Council to develop units of competency for the training and assessment of food safety auditors, were also considered.

## 1.4 Mutual recognition

Governments in Australia and New Zealand have legislated requirements for the mutual recognition of equivalent occupations. To qualify as equivalent, the occupations must be authorised under legislation and be substantially the same. The equivalency requirements among Australian states and territories are based on the *Mutual Recognition Act 1992* (Cwth). Similarly, the Trans-Tasman Mutual Recognition Arrangement, underpinned by the *Trans-Tasman Mutual Recognition Act 1997*, provides for the recognition of equivalent occupations between Australia and New Zealand. The arrangement applies to all occupations (except medical practitioners) that require some form of legislation-based registration, certification, licensing, approval, admission or other form of authorisation in order to be legally practised.

The principle underlying mutual recognition is that a person registered in the first jurisdiction for an occupation is entitled, after notifying the local registration authority of the second jurisdiction for the equivalent occupation:

* to be registered in the second jurisdiction for the equivalent occupation
* pending such registration, to carry on the equivalent occupation in the second jurisdiction.

An occupation for which persons may be registered in one State is considered equivalent to an occupation for which persons may be registered in other States if the activities authorised to be carried out under each registration are substantially the same.

However, mutual recognition provisions do not affect the operation of laws that regulate the manner of carrying on an occupation in the second jurisdiction, so long as those laws:

* apply equally to all persons in the second jurisdiction who are carrying on or seeking to carry on the occupation; and
* the laws do not require different qualifications or experience before the person can carry on the occupation.

To simplify the requirements for food regulators who evaluate applicants already approved by other agencies, it is important to have agreed national benchmarks and a system that facilitates mutual recognition of food safety auditor approval requirements.

Food regulators have anticipated the challenges that the introduction of a national food safety system may present. They agree that food safety auditors should not be limited to practising within a single jurisdictional area. Application of the concept of mutual recognition has therefore been one of the drivers for developing a national policy for managing food safety auditors between jurisdictions.

Where effectively coordinated, mutual recognition provisions will facilitate the successful and efficient application and management of food safety audits and auditors across jurisdictions. Inevitably, however, these provisions will introduce complexities into the national audit system. Regulators will need to be cognisant of privacy concerns and other issues that may affect cross-jurisdictional communication and engagement of food safety auditors

## 1.5 International relevance

The Australian Quarantine and Inspection Service (AQIS) is the competent authority in Australia for provision of export certification. Where export certification is required, AQIS will be required to assure itself that importing country requirements have been met prior to issuing an export certificate. Importing countries may specify requirements that differ from those that apply nationally, such as requirements for infrastructure, food safety programs and/or the competent authority oversight of arrangements (i.e. audits and verification). AQIS will seek to use national infrastructure and standards where they exist, although it will be unable to do so where importing countries require otherwise.

# 2 Food safety program audit management framework

This section outlines the general elements of a regulatory food safety program and associated audit system. Section 3 describes the National Food Safety Audit Policy and explains how jurisdictions will administer these components consistently.

The system is presented in Figure 1 and includes:

1. Food safety auditor approval
2. Food safety audit process
3. Regulatory compliance system
4. Regulatory oversight through legislation, standards, policy and review.

The dashed lines and boxes represent elements that are likely to be interrelated.

Figure 1: Food safety program audit management framework

**This picture is figure 1, a flow chart that has 4 parts of the system; 

1) Food safety auditor approval,
2) Food safety audit process,
3) Regulatory compliance system and,
4) Regulatory oversight through legislation, standards, policy and review.

Food businesses manage food safety. The Food business develops and implements a food safety program. The Food business has the food safety program audited by an approved auditor through System 1’Food safety auditor approval’. The applicant applies for approval as a food safety auditor. The applicant is assessed against the approval criteria. The regulator approves or does not approve the auditor. If the auditor is approved they are assigned, or business contracts the auditor. 

This flows into System 3 ‘Regulatory Compliance system’. Regulators monitor competency of auditors. Regulators take remedial action. 

System 2 ‘food safety audit process’. Regulator or approved auditor reviews and assesses food safety program. Regulator or approved auditor recognises or approves food safety program. An ongoing audit continues on a determined frequency. This flows into System 3- where audit reports and outcomes are monitored by regulators. Regulators will act on non-conformances. 

Systems 1, 2 and 3 are all covered by System 4 the Regulatory oversight through legislation, standards, policy and reviews.
**

## 2.1 Food safety auditor approval

For auditors to participate in the regulatory system, regulators need to implement processes to assess the suitability of the auditors and approve them. The mechanism by which this occurs is prescribed in relevant legislation, regulation and/or policy.

The food regulator is the state, territory or Commonwealth body or statutory authority responsible for food safety legislation. These entities are either within government departments or semi-independent of government. While many are enforcement agencies, some delegate enforcement to other bodies, such as local governments.

The food safety auditor approval process is described below.

**Applicant applies for approval as a food safety auditor**—A prospective food safety auditor wishing to undertake food safety auditing as part of a regulatory system will apply to the regulator for approval to undertake audits. The application process may involve completion of an approved form; supply of relevant documentation, including demonstration of competency or provision of evidence of certification against competency standards; and payment of a prescribed fee.

**Applicant is assessed against the approval criteria**—After an application is received, the regulator will evaluate the application against specific criteria defined in either regulation or policy. The national policy sets forth the primary assessment criteria so that the standard for approval will be consistent across Australia.

**Regulator approves or does not approve auditor**—Once the assessment process is completed, the regulator makes a decision to approve or not approve the person’s application to become an auditor.

**Auditor is assigned or business contracts auditor**—An auditor may be a second-party auditor employed (or contracted) by government, or a third-party auditor that is independent of government. When a third-party auditor is contracted by government it acts on behalf of government.

A regulator may make use of an approved auditor in a number of ways. A business may contract its own auditor to undertake audits for the regulator and other private systems directly, or the regulator may contract out its audits to approved external auditors. A food regulator can assign a regulatory food safety auditor to a food business to conduct a food safety audit. The policy gives consideration to the means by which food businesses and the public will be informed of who is approved to conduct regulatory audits.

A food business or a food regulator may also contract a third-party auditor that has been approved as a regulatory food safety auditor to conduct a regulatory food safety audit. Depending on the specific arrangements operating in a jurisdiction, a business may elect to have the food safety audits conducted by government or an approved third-party auditor.

## 2.2 Food safety audit process

To meet their regulatory obligations, businesses, having completed their food safety programs, are required to have those programs assessed and audited by an approved auditor. The means by which this is undertaken is determined by the relevant legislation, regulation or policy. The key elements in implementing regulatory audits are described below.

**Review and assessment of food safety program**—The initial consideration and audit of a food safety program is a critical component of the audit management system, regardless of whether formal ‘approval’ is given by the food regulator or approved auditor.

Once a business has completed its food safety program, it is reviewed and assessed by either an approved auditor or regulator (or both) to determine whether or not it adequately addresses food safety hazards and complies with legislated requirements. This may include a desktop review of the documented food safety program before an on-site audit. Food safety programs are also reviewed when significant changes are made to practices within the business.

**Recognition or approval of food safety program**—On the basis of the review and assessment, the regulator may require the business to submit the program for its approval. Some regulators do not formally approve food safety programs, but rely solely on the assessment and review by food safety auditors.

**Ongoing audit at determined frequency**—Following the initial assessment of the documented food safety program, the food business enters an ongoing audit cycle. An approved food safety auditor must periodically audit the implemented food safety program, at a frequency determined by the regulator, to ensure that:

* the program continues to comply with the legislated food safety program requirements
* the program is adequate to control the hazards associated with the industry and process involved
* the program has been implemented in accordance with the business’s documented system.

## 2.3 Regulatory compliance system

The food safety program/audit model facilitates greater commitment by industry in the management of food safety risks. It is dependent on ensuring that the work undertaken by auditors is of a sufficiently high standard to assess compliance with the Food Standards Code, and to adequately protect public health. The components of the regulatory compliance system are outlined below.

**Monitoring competency of auditors**—Once an auditor is approved, the regulator will establish a system to monitor the effectiveness of the auditor’s practice. The national policy recognises the critical importance of the monitoring program and associated remedial action.

**Remedial action by regulator**—Should the regulator find that the performance of the auditor is not meeting a sufficient standard, the regulator will need to take remedial action. There are a number of options available to the regulator, ranging from requiring the auditor to undergo further training to removing the auditor from the register. The national policy will address how remedial action is to be undertaken in a consistent manner across jurisdictions.

**Act on non-conformances**—An essential component of the system is the requirement for an auditor to notify the regulator or appropriate authority when food safety standards are not being met. Regulators may act on these non-conformances. The national policy will establish a consistent approach across jurisdictions.

**Monitor audit outcomes—**Regulators are responsible for ensuring that the system outcomes deliver as intended.

**Audit reports**—The results of a food safety audit are recorded in an audit report and reported to the food regulator or appropriate authority within specified timeframes.

## 2.4 Regulatory oversight

As indicated above, the operation of the food safety program system is governed by legislated standards and policies. The Food Standards Code and policy instruments such as the Model Food Act 2000 are given effect through state, territory or Commonwealth legislation. In regard to audit and auditor management:

* The regulatory approval and management of food safety auditors and audits is determined through legislation.
* Food safety legislation sets the parameters for achieving the Food Standards Code and the operation of audits and auditors.
* The National Food Safety Audit Policy is the national policy for the management of auditors and auditing. The policy applies to the system of auditors and auditing in all food regulatory practice in Australia, and therefore extends beyond the requirements of the *Food Safety Standard 3.2.1 (Food Safety Programs)*.

# 3 National Food Safety Audit Policy

The National Food Safety Policy outlined in this section represents the agreed national position for the management of food safety auditors and auditing, and the monitoring of audit outcomes.

## 3.1 Principles and objectives

### 3.1.1 Guiding principles

The guiding principles underpinning the policy are:

* a cost-effective and risk-based approach
* consideration of the special needs of small and medium-sized enterprises, and rural and remote businesses
* an open, equitable and accountable auditor management system
* auditor approval primarily based on assessment against agreed national competency standards, which allows for different entry points and is underpinned by effective education and training
* a flexible approach so that state and territory governments can implement the national audit requirements in ways that reflect their different administrative and legislative arrangements while still being cognisant of their obligations under the Food Regulation Agreement 2002
* transitional arrangements for state and territory governments with existing food safety audit management systems
* facilitation of international recognition of Australia’s audit systems and equivalence with New Zealand while balancing the needs of businesses that produce only for the domestic market.

### 3.1.2 Objectives

The main objectives of the policy are:

* to promote national consistency in managing auditors and auditing
* to provide assistance to food regulators implementing regulatory food safety audit management systems, including supporting greater sharing of resources
* to simplify the requirements for businesses and auditors operating in more than one jurisdiction
* to facilitate the recognition and acceptance by industry of minimum core regulatory requirements.

## 3.2 Management of food safety auditors

As noted above, a person wishing to undertake regulatory food safety auditing must apply to the regulator for approval. All regulatory food safety auditors must meet the requirements outlined in this section.

Regulator auditor management focuses on the principles and processes required to ensure that appropriate and competent people are approved under legislation to undertake food safety audits. The process also focuses on the integrity and consistency of a national system to manage regulatory food safety auditors.

### 3.2.1 Regulatory auditor classification

There is only one category of regulatory auditor and no classification by sector or industry type. All regulatory auditors will have to be capable of undertaking systems and compliance audits in all sectors. However, an auditor will be required to have endorsements by the regulator to undertake audits of certain complex or high-risk processes. The list of required endorsements will be agreed nationally, and will be finalised in the implementation phase of the policy.

The ‘scope of practice’ of an auditor will be limited by the legislation under which the auditor is approved. For example, auditors approved by primary production agencies under primary production legislation will only be allowed to undertake audits within that regulatory system.

Provisional auditors will not be accepted. Only auditors that meet all the evaluation criteria will be approved. A ‘provisional’ classification will not form part of the Australian regulatory system.

Auditors currently operate across jurisdictions, and the policy encourages the continuation of this practice. An auditor wishing to operate in more than one jurisdiction will be required to apply to the relevant regulators.

### 3.2.2 Auditor evaluation

The system for the evaluation of regulatory food safety auditor applicants should be rigorous, fair, consistent and nationally recognised. An approval process that meets these criteria will produce nationally consistent outcomes and facilitate mutual recognition between food regulators. It is agreed that regulators may either conduct the evaluations themselves or use the services of a personnel certification body. The decision to approve regulatory food safety auditors is made by the relevant food regulator.

As the ultimate responsibility and accountability for the approval of auditors rests with the food regulator, food regulators have the ability to evaluate regulatory food safety auditor applicants prior to their approval. If auditors are evaluated by an external organisation, food regulators will not be limited to engage a particular certification body and will be able to choose from a variety of organisations. Personnel certification bodies, such as RABQSA International Inc. and like organisations, are currently in existence.

The criteria that a body will be required to meet to evaluate auditors will be agreed nationally and will be finalised in the implementation phase of the policy.

### 3.2.3 Evaluation criteria

The decision to approve food safety auditors is made by the food regulator. To be approved, an auditor must have complied with all of the evaluation criteria. Food regulators have agreed to a national set of criteria to guide the evaluation of regulatory food safety auditors and to ensure consistency between jurisdictions. The elements for the evaluation and subsequent approval of regulatory food safety auditors are illustrated in Figure 2. Before a person is approved as a regulatory food safety auditor, he or she must meet specific minimum criteria, which include:

* auditor competence (general)
* auditor competence (specialised)
* regulator’s system requirements
* additional provisions.

Figure 2: Evaluation criteria

***This picture is a diagram of a triangle split into 3 sections. The biggest section is at the bottom. It is labelled auditor compliance (skills and knowledge). There is a divide between auditors’ specialised competence and general competence; this is to evaluate an auditor ‘s competency based on regulator agreed competency standards.

The second part or middle section of the triangle is labelled the Regulator's system requirements. This is for understanding a regulator's specific requirements such as legislation and reporting requirements. 

The top and last part of the triangle is labelled additional provisions. This is for meeting suitability checks, adhering to code of conduct, meeting verification requirements and has a history of practise.***

#### 3.2.3.1 Auditor competence

Auditor competence relates to appropriate skills and knowledge. Regulatory food safety auditors must have general competence to undertake systems and compliance audits. Therefore, every auditor must be competent to assess whether a food safety program or food safety management system is effective in controlling the identified food safety hazards and ensuring the production of safe and suitable food. Food safety regulators will evaluate general and specialised auditor competence based on agreed competency standards.

Although there is only one category of regulatory food safety auditor, auditors of specialised, critical and/or high-risk processes (i.e. those that are critical to public health and safety and require technical knowledge to audit competently, such as pasteurisation and cook/chill processes) must demonstrate specialised competencies. Regulators will evaluate the competence of the regulatory food safety auditors who will audit these specialised processes.

Figure 2 illustrates the relationship between auditor competence, auditor evaluation and criteria for auditor approval for regulatory purposes. Regulatory auditor competency will be demonstrated by the following elements:

* assessment as competent to meet regulator-agreed competency standards
* certification by a regulator-agreed certification body or bodies or by a regulator
* assessment as competent to undertake systems and compliance audits
* possession of relevant high-risk industry technical knowledge, when appropriate.

The Department of Agriculture, Fisheries and Forestry and the Agri-Food Industry Skills Council collaborated with industry to develop national food safety auditor training standards through the national vocational education and training framework. The food safety auditor units of competency will be incorporated into the food processing industry training package and can be viewed at the [National Training Information Service website](http://training.gov.au/) and at the [Agri-Food Industry Skills Council website](http://www.agrifoodskills.net.au/).

Food regulators will use these standards as the basis for training and assessing the competence of food safety auditors. They will also consider other competency standards in the approval of auditors by means of a statement of attainment. A statement of attainment may be achieved by undertaking training to obtain the competencies, or by recognition of current competency or by recognition of prior learning.

#### 3.2.3.2 Regulator’s system requirements

Each food regulator will determine a regulatory food safety auditor’s ability to meet the regulator’s specific requirements.

Food safety auditors will demonstrate that they meet those requirements based on the following criteria:

* knowledge of jurisdictional legislation under which they will be auditing
* knowledge of the regulator’s audit management system
* knowledge of the regulatory requirements.

#### 3.2.3.3 Additional provisions

Food regulators recognise that ethical and professional conduct of regulatory food safety auditors is important because of the responsibility auditors hold in assisting the regulator in protecting public health. A regulatory food safety auditor that does not comply with professional conduct provisions may jeopardise the integrity of the regulatory audit system and put public health at risk.

Additional provisional requirements will be demonstrated by the following elements:

* understanding of professional conduct
* meeting suitability checks (e.g. criminal history checks, security checks and child protection checks if required) agreeing to comply with the National Code of Conduct (including conflict of interest declarations and confidentiality provisions)
* meeting verification requirements
* having a history of practice.

Food regulators will establish arrangements to manage inappropriate professional conduct, complaints, appeals and disputes in relation to regulatory food safety auditors during the implementation phase of the policy.

### 3.2.4 Registers of food safety auditors

Each food regulator will publish its own register of approved regulatory food safety auditors on its website, and include links to all other food regulator registers of food safety auditors. The purpose of the registers is to inform businesses and the community of who has been approved to audit food businesses on behalf of regulators. They will also identify those auditors approved with specialised endorsements. Regulators will only accept audits conducted by auditors listed on the registers.

The postcodes of auditors will be included on the registers to provide assistance in locating an auditor. The registers of auditors will enable industry to engage approved regulatory food safety auditors and allow food regulators in other jurisdictions to confirm the status of auditors.

### 3.2.5 Maintaining standards of practice

Once approved, regulatory food safety auditors must be able to demonstrate that they maintain their standards of practice as auditors. Standards of practice may be easily monitored if a renewal process is in place for auditor approvals.

Approved regulatory food safety auditors must demonstrate that they continue to be competent and remain up to date based on the following principles:

* Auditors need to demonstrate recency of practice.
* Auditors must remain up to date with the relevant legislation and the regulator’s audit management system.
* When there have been important changes to legislation or a regulator’s audit management system, auditors may be required to demonstrate knowledge of the changed requirements, or be required to make a declaration that they will abide by the new requirements.

These principles are based on criteria that regulatory food safety auditors are required to demonstrate in order to obtain and maintain approval. Regulators will nationally standardise the minimum requirements and frequency for evaluating whether auditors are remaining up to date, competent and suitable.

Assessment of an auditor’s competence and standard of practice is an ongoing process. To ensure the integrity of the audit system, competency must be assessed not only at the approval phase but should be supported by a program that regularly verifies competency to ensure the integrity of the audit system.

Regulatory food safety auditors must be able to demonstrate that they maintain their standards of practice as auditors before being re-approved by:

* Demonstrating that they continue to be competent and remain up to date.
* Demonstrating recency of practise. This may be demonstrated by producing an audit log and/or evidence of witnessed audits indicating competence. An applicant may also produce documentation from a personnel certification body (accepted by regulators) to verify ongoing professional development. Regulators may accept evidence from suitable organisations, such as personnel certification or professional bodies, to prove an auditor has remained up to date and competent.
* Remaining up to date with relevant legislation and with the regulator’s management system. When there have been important changes to legislation or a regulator’s audit management system, auditors may be required to demonstrate knowledge of the changed requirements, or be required to agree to keep abreast with legislative change and abide by the new requirements.

### 3.2.6 Code of conduct

All regulatory food safety auditors will be required to agree to abide by a code of conduct before they will be approved.

The code of conduct will make reference to the misconduct provisions and provides regulators with a mechanism to review auditor conduct. Penalties for violations may include suspension or cancellation of approvals. The code of conduct addresses the following issues:

* ethical obligations (e.g. fairness, respect, procedural fairness, occupational health and safety, equal employment opportunity, discrimination, confidentiality, harassment and victimisation)
* behaviour (e.g. attitude, communication, and avoiding intimidating or offensive behaviour)
* standards of dress (e.g. clean, appropriate and meeting bio-security requirements)
* appropriate use of alcohol and drugs
* handling conflicts of interest
* acceptance of benefits (e.g. procedure for acceptance of gifts and reporting of attempts to bribe)
* use of official information and public comment
* falsification of audit outcomes.

### 3.2.7 Disciplinary action and notification of misconduct

A regulator that establishes that the performance of an auditor is unsatisfactory or has breached the code of conduct, may remove the auditor’s approval. As auditors may operate in a number of jurisdictions, decisions made by one regulator must be taken into account by all other regulators. It is agreed, in principle, that:

* All regulators will establish a consistent approach to taking disciplinary action against food safety auditors.
* All regulators will exchange information regarding disciplinary action taken against regulatory food safety auditors. This information will only be shared between regulators for the purposes of administering legislation and will not be available to the general public.
* When a regulator removes a food safety auditor from its register of approved auditors, all jurisdictions will remove that auditor from their registers.

The Implementation Sub-Committee is aware that there may be legislative impediments to the sharing of such information and to the use of information by one regulator regarding disciplinary action taken by another regulator in determining an auditor’s status. These legal issues will be addressed during the implementation phase of the policy.

## 3.3 Management of food safety audits

The National Food Safety Audit Policy identifies the food safety audit process as an interaction between the regulatory food safety auditor, the regulatory compliance system, food businesses and legislation (see Figure 1). To ensure that the audit process is nationally consistent and to assist auditors who work in more than one jurisdiction, approved auditors and food regulators need to apply common terms and definitions to the audit process, regardless of the jurisdiction in which they practise.

### 3.3.1 Reporting non-conformances

As already agreed in section 68 of the Model Food Act 2000:

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:
   1. be in the prescribed form, and
   2. be submitted to the appropriate enforcement agency within 21 days after the completion of the audit or assessment, and
   3. 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):
   1. whether or not the food safety auditor is of the opinion that the food business is being carried on in compliance with the requirements of the regulations relating to food safety programs, and
   2. 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):
   1. whether or not the food safety auditor is of the opinion that the food business is being carried on in compliance with the provisions of the Food Safety Standards, and
   2. 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:
   1. that is an imminent and serious risk to the safety of food intended for sale, or
   2. 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.

1. 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.
2. 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.

Regulators may wish to develop additional levels of non-conformances and associated notification timeframes; however, as a minimum, the above has been agreed.

### 3.3.2 Frequency of audits

All jurisdictions have agreed to work together to implement nationally consistent food safety audit frequencies for legislated food safety programs.

Regulators will align the frequency of regulatory food safety audits with the business risk profile and the business’s compliance history. Business risk profiles will be developed through the ISC’s work on food safety management.

### 3.3.3 Audit teams

On occasion it may be necessary for an audit to be conducted by a team. An audit team is composed of auditors with specialist knowledge who are directed by and assist the lead auditor.

Audit teams provide flexibility to the audit system, particularly in the case of complex audits that require technical expertise from different auditors.

Audit teams are permitted when the competencies to audit the business can be shared and no single auditor has all the specialised (high-risk process) competencies required. All auditors in the audit team must be approved regulatory auditors. Each approved auditor must have the competencies required to audit the specific part or parts of the food business to which he or she is assigned.

### ***3.3.4 Audit terms and definitions***

The following terms and definitions will be employed consistently across jurisdictions to describe regulatory food safety audits.

Table 3: Audit terms and definitions

|  |  |
| --- | --- |
| Terms | Definitions |
| auditor review | a general term for review of an auditor’s performance which may include a range of monitoring mechanisms, such as investigation of complaints, review of documentation and client interviews |
| check audit | 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 |
| compliance audit | an assessment of whether a business is complying with its internal food safety program |
| corrective action | an action taken by a food business/primary food producer to rectify a non-conformance or systems deviation to ensure ongoing compliance with its legislated food safety program and relevant regulatory scheme |
| corrective action request | a formal notification to a food business/primary food producer requesting the rectification of a non-conformance or systems deviation to ensure ongoing compliance with the legislated food safety program and relevant regulatory scheme |
| critical non-conformance | a contravention of legislation that presents an imminent and serious risk to the safety of food intended for sale, or that will cause significant unsuitability of food intended for sale |
| follow-up audit | a review in response to audit findings that identified areas of concern |
| initial audit | the first full examination of a food safety program to ensure its adequacy and implementation, including desk and on-site auditing |
| inspection | 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 |
| non-conformance | a deficiency or a failure of a food business to comply with its legislated food safety program or relevant regulatory scheme  Note: Food regulators may develop sub-definitions of non-conformance as major or minor non-conformance consistent with their existing legislation. |
| regulatory system monitoring | a general term for activities to ascertain if a regulatory audit system is achieving its objectives; this may involve using a range of mechanisms, including auditor review and food safety program review |
| systems audit | the periodic review of a food safety program to ensure that the food safety management system continues to be effective in controlling the identified food safety hazards and ensuring the production of safe and suitable food |

## 3.4 Monitoring audit outcomes

All food regulators will incorporate systems to monitor the performance of auditors, and the effectiveness of food safety programs. An auditor’s performance may be reviewed through a range of monitoring mechanisms, such as check audits, investigation of complaints, review of documentation and client interviews.

Regulators will nationally standardise the minimum requirements and frequency for evaluating whether auditors are remaining up to date, competent and suitable. All jurisdictions will incorporate verification activities into their audit management systems to assess the competence of approved food safety auditors. This may be achieved at the renewal stage.

The monitoring of activities to ascertain if a regulatory audit system is achieving it objectives is referred to as ‘regulatory system monitoring’. Regulatory system monitoring includes a range of mechanisms, including auditor review and food safety program review.

Auditor review is a verification activity that assesses the competence of an approved food safety auditor; food safety program review verifies the appropriateness of a food safety program.

## 3.5 Industry’s role

Industry will likely realise benefits if they take up the challenges in the policy and recognise regulatory audits as part of their commercial audit systems. These benefits may include a reduction in the number of audits performed and a decrease in audit costs.

The National Food Safety Audit Policy represents an opportunity to minimise audit duplication and industry cost. To be acceptable for regulatory third-party auditing, existing food safety programs must include and address the food regulatory requirements.

For a third-party audit to be acceptable to an enforcement agency in a particular jurisdiction:

* the food business’s food safety program must address legislated requirements
* the audit must be undertaken by an auditor appropriately approved under the jurisdiction’s legislation
* the audit must be undertaken and reported according to the enforcement agency’s requirements.

Regulators will accept audits by approved third-party auditors where the audits are part of a regulatory third-party audit program implemented in the relevant jurisdiction.

Food regulators recognise the importance of industry quality systems that incorporate food safety elements (for example, Freshcare). However, the policy does not propose a mechanism for recognising or endorsing these industry quality systems, per se.

These arrangements provide opportunities for regulatory audits to be combined with third-party non-regulatory audits and thereby reduce audit costs to some food businesses.

# 4 Implementation of the policy

Regulators have agreed that the policy will be implemented in their jurisdictions within five years from the date of its approval.

While the policy sets the direction for the consistent implementation of food safety auditor regulation, and audit practice, the details will be worked through as part of the implementation process. An implementation plan will be developed that will identify resource requirements, accountabilities and timeframes. The ISC will be responsible for overseeing the progress of the plan’s development. The implementation plan will address:

* review of policy after implementation, including reviewing and advising on:
  + changes to regulatory food safety auditor approval criteria and audit categories in light of experience
  + auditing implementation issues and national consistency
  + system integrity and review
* workforce capacity issues
* development of a code of conduct
* audit reports and non-conformance notification, including:
  + notification timeframes for non-conformances
  + nationally agreed minimum criteria and format of audit reports
* mutual recognition, including:
  + recognition of food safety programs approved or assessed in another state or territory
  + mutual recognition between jurisdictions
  + recognition of multi-sited businesses operating across state and territory borders;
  + mutual recognition under the Trans-Tasman Mutual Recognition Arrangement; further liaison and development are required to address equivalence with New Zealand’s system for food safety auditors
* legal issues, including the legal implications of coordinating and resolving disciplinary action
* implementation of national units of competency for food safety auditors, including
  + scope of specialist endorsements
  + competencies for specialised endorsements
* criteria for personnel certification bodies to undertake certification
* duration of auditor approval and process for re-approval.

# 5 Glossary

This glossary provides guidance on some of the terms used in the National Food Safety Audit Policy and is not intended to be a complete reference source. Its purpose is to guide food regulators in the selection of audit terms and definitions in order to achieve greater consistency. The terms included have been developed on either an international or national level. Please note that auditing terms included in the Model Food Act 2000 have not been included in this list as state and territory governments have already agreed to use them where practical.

Stakeholders are reminded that constraints may apply to the auditing of food businesses that export food.

Table 4: Glossary of some terms used in the National Food Safety Audit Policy

| **Term** | **Definition** | **Source** |
| --- | --- | --- |
| audit | a systematic, independent and documented process for obtaining evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled | ISO 19011 |
| audit client | the person or organisation requesting the audit; this may be the regulator, industry organisation, corporate customer or auditee | ISO 19011 |
| audit conclusions | the outcome of an audit provided by the auditor, or audit team, after consideration of the audit objectives and the audit findings | ISO 19011 |
| audit criteria | a set of policies, procedures or requirements that specify the parts of the food safety management system required to be audited by the audit client within the agreed scope of the auditee’s business | ISO 19011 |
| audit evidence | records, statements of fact or other information that is relevant to the audit criteria | ISO 19011 |
| audit findings | the results of the evaluation of the collected audit evidence against the audit criteria | ISO 19011 |
| auditee | the organisation (i.e. business) being audited | ISO 19011 |
| auditing frequency | the frequency of auditing determined by the appropriate enforcement agency, or a food safety auditor, in accordance with the Model Food Act | FSANZ |
| auditor | a person with the competence to conduct an audit  *Note: Wherever used in this document, the term ‘auditor’ refers to a regulatory food safety auditor unless otherwise qualified.* | ISO 19011 |
| first-, second- and third-party auditor | first-party auditors are involved in internal auditing of the food business; second-party auditors are auditors employed (or contracted) by the government; and third-party auditors are private and independent of the government | FSANZ, *Food Safety: An Audit System* |
| certification | the procedure by which official certification bodies and officially recognised bodies provide written or equivalent assurance that foods or food control systems conform to requirements; certification of food may be, as appropriate, based on a range of inspection activities, including continuous on-line inspection, auditing of quality assurance systems, and examination of finished products | Codex |
| competence | demonstrated ability to apply knowledge and skills |  |
| competency standards | an industry- or regulator-determined specification of performance that sets out the skills, knowledge and attributes needed to operate effectively in employment; competency standards are made up of units of competency and are an endorsed component of a training package |  |
| critical control point (CCP) | a step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level | Codex |
| cross-jurisdictional | between or across food regulators and/or Commonwealth, state and territory governmental agencies; for example, AQIS and quasi-governmental organisations such as Safe Food Production Queensland |  |
| food regulators | state, territory or Commonwealth bodies 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 |  |
| 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*. |  |
| HACCP | hazard analysis critical control points, a system which identifies, evaluates and controls hazards that are significant for food safety | Codex |
| HACCP plan | a document prepared in accordance with the principles of HACCP to ensure control of hazards that are significant for food safety in the segment of the food chain under consideration | Codex |
| hazard | a biological, chemical or physical agent in, or condition of, food with the potential to cause an adverse health effect | Codex |
| hazard analysis | the process of collecting and evaluating information on hazards and conditions leading to their presence to decide which are significant for food safety and therefore should be addressed in the HACCP plan | Codex |
| jurisdiction | a state, territory or Commonwealth government |  |
| Model Food Provisions | a term used interchangeably with the term ‘Model Food Act Provisions’ agreed to by the Council on Australian Governments on 3 November 2000 |  |
| monitor | the act of conducting a planned sequence of observations or measurements of control parameters to assess whether a critical control point is under control | Codex |
| official accreditation | the procedure by which a government agency having jurisdiction formally recognises the competence of an inspection and/or certification body to provide inspection and/or certification services | Codex |
| official inspection systems and official certification systems | systems administered by a government agency having jurisdiction that is empowered to perform a regulatory or enforcement function or both | Codex |
| officially recognised inspection systems and officially recognised certification systems | systems that have been formally approved or recognised by a government agency having jurisdiction | Codex |
| qualitative risk assessment | a risk assessment based on data which, while forming an inadequate basis for numerical risk estimations, nonetheless, when conditioned by prior expert knowledge and identification of attendant uncertainties, permits risk ranking or separation into descriptive categories of risk | Codex |
| quantitative risk assessment | a risk assessment that provides numerical expressions of risk and indication of the attendant uncertainties | Codex: 1995 export consultation definition on risk analysis |
| risk | a function of the probability of an adverse health effect and the severity of that effect, consequential to a hazard or hazards in food | Codex |
| risk analysis | a process consisting of three components: risk assessment, risk management and risk communication | Codex |
| risk assessment | A scientifically based process consisting of the following steps: (i) hazard identification, (ii) hazard characterisation, (iii) exposure assessment and (iv) risk characterisation | Codex |
| risk assessment policy | documented guidelines on the choice of options and associated judgements for their application at appropriate decision points in the risk assessment process such that the scientific integrity of the process is maintained | Codex |
| risk characterisation | the qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterisation and exposure assessment | Codex |
| risk communication | the interactive exchange of information and opinions concerning risk and risk management among risk assessors, risk managers, consumers and other interested parties, including an explanation of risk assessment findings and the basis of risk management decisions | Codex |
| risk profile | a description of a food safety problem and its context | Codex |
| system owner | the organisation responsible for implementing a food safety management system, including management of the audit system; food regulators are considered to be system owners | Bill McBride, Food Safety Auditor Competency: Proposed National Competency Criteria and Management Systems |
| validation | obtaining evidence that the elements of the HACCP plan are effective | Codex |
| verification | the application of methods, procedures, tests and other tools for evaluation, in addition to monitoring, to determine compliance with the HACCP plan | Codex |