



Government of **Western Australia**
Department of **Health**

WA Food Regulation: Regulatory Food Safety Auditing – Information for Food Businesses

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Food Safety Auditing – Information for Food Businesses

1. Introduction

Certain high risk food businesses are required to have a Food Safety Program (FSP) to assist in the management of food safety hazards. This document is intended to help food businesses that have a FSP understand their responsibilities relating to the requirement to have regulatory food safety audits.

2. Does my food business require a Food Safety Program?

If your business provides food to vulnerable population (e.g. people in hospitals, aged care facilities, child care centres); or is a dairy production, dairy collection and transportation or dairy processing business you would need to implement a FSP and have it regularly audited. For more information on whether your food business is required to have a FSP you may contact your [local government](#) Food Authorised Officer or the [Department of Health](#) for further advice.

The local government or Department of Health will advise you if your food business requires an FSP.

3. If my food business does require a Food Safety Program, what next?

Food businesses need to develop a FSP that meets the requirements of Standard 3.2.1 of the Australia New Zealand Food Standards Code (*the Code*). The enforcement agency (either the local government or the Department of Health) performs a verification assessment of the FSP to assess whether the program contains the elements prescribed in Clause 5 of Standard 3.2.1. If the FSP complies with the requirements, then the appropriate enforcement agency will advise you of the initial audit frequency for the food business.

4. Following verification of my Food Safety Program, what is the next stage?

The food business shall implement their FSP and ensure that it has been audited by an appropriately approved Regulatory Food Safety Auditor (RFSA) within 6 months. **Please note that the food business is responsible for ensuring that regulatory food safety audits are completed within the timeframe specified by the appropriate enforcement agency.**

A list of approved RFSA's can be found on the [Department of Health website](#). Before an RFSA is approved by the Department of Health, the RFSA undergoes detailed checks to ensure they meet the criteria for approval. Further details are contained within the WA Food Regulation: Food Safety Auditing – Guideline for Regulatory Food Safety Auditors (on the Approval Process).

The RFSA reviews a FSP for compliance with Standard 3.2.1 and Standard 4.2.4 Primary Production and Processing Standard for Dairy Products (where applicable) of the Code and assesses the food business to ascertain compliance with the relevant Food Safety Standards (Chapter 3 of *the Code*).

5. What are Food Businesses Responsibilities within the Audit Process?

The relevant enforcement agency is not involved in the contractual arrangements between the food business and the RFSA and does not organise or schedule a regulatory food safety audit for the business. **The food business is responsible for engaging the services of an approved RFSA.**

The Department of Health maintains a list of approved RFSAs (refer to [website](#)). The list also identifies those auditors approved with specialised endorsements (e.g. heat treatment). Enforcement agencies **will only accept audit reports conducted by auditors listed on the Register.**

There is also a Code of Conduct that applies to all RFSAs approved by the Department of Health 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. Should a food business have cause to make a complaint about an RFSA then this should be raised with the appropriate enforcement agency in the first instance. If the enforcement agency is the Department of Health then email foodsafety@health.wa.gov.au or email the relevant [local government](#) who will investigate and where appropriate refer to the Department of Health.

The role of the RFSA in the audit system is to conduct regulatory food safety audits of a business's verified FSP to determine whether their FSP is implemented as documented in section 99 of the [Food Act 2008 \(WA\) \(Food Act\)](#) and continues to comply with the appropriate legislative requirements.

A food business should have the last audit report to give a new auditor on request.

The roles and responsibilities of an RFSA:

- RFSA's are approved under the Food Act to conduct Regulatory Food Safety audits according to their scope and qualification and are not Food Act authorised officers. Therefore, enforcement responsibilities continue to reside with the respective enforcement agency i.e. Local Government or Department of Health
- RFSAs conduct audits of any FSPs required to be in place by the regulations and conduct any necessary follow-up action, including further audits, as necessary, to determine if action has been taken to remedy any deficiencies in a FSP as identified during an audit
- To carry out assessments of food businesses to ascertain their compliance with the requirements of the Food Safety Standards

- RFSAs determine audit frequency and submit audit reports to the enforcement agency and the food business, in accordance with the stipulated requirements.

Food Businesses are responsible for:

- Ensuring that they operate their business in compliance with the Food Standards Code and verified/audited FSP
- Ensuring that their FSPs are prepared, implemented, maintained, monitored and audited in accordance with the appropriate audit frequency for their food business (as detailed in the WA Priority Classification system).
- Directing any complaints against RFSAs to the appropriate enforcement agency in the first instance
- Reviewing their FSP at least annually
- Notifying the appropriate enforcement agency of any change in ownership of the business (i.e. the business ceases to operate at the particular premises, the business is sold).*
- Providing on request of the RFSA written evidence that the FSP has been verified by the respective enforcement agency.
- Notifying the appropriate enforcement agency of any substantial changes to food-handling operations that may affect its priority classification.*

**There are severe penalties for failure to notify within 7 days of the change occurring.*

If your food business fails to arrange for an approved RFSA to audit your business's FSP by the scheduled date, the enforcement agency may take compliance and enforcement action.

6. How should I prepare for a Regulatory Food Safety Audit?

It is important to note that a regulatory food safety audit must cover the **full scope** of the FSP. The food business must ensure that the auditor they engage is endorsed to conduct audits for the particular business type. For example, an RFSA auditing a dairy processor must have the heat treatment competency (the competencies of each RFSA are displayed on the [Department of Health website](#)). In addition, the food business must ensure they have sufficient evidence to demonstrate compliance with their FSP.

The food business and the RFSA are responsible for organising and managing the regulatory food safety audit process. The RFSA may issue an 'incomplete audit' rating following a desk top review of a food business's FSP prior to commencing the on-site component where they consider the food business has not collected sufficient evidence to demonstrate compliance with the requirements of Standard 3.2.1 (or Standard 4.2.4) of the Code.

During the planning and scoping of the audit, it is recommended that the RFSA and the food business discuss and agree on:

- The basis of the proposed audit
- The type of audit to be conducted
- The criteria that will be used to assess the food business's current FSP
- Definitions of non-compliance that will be applied
- Activities to be conducted and responsibility for carrying out those activities
- The timing of the audit and 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.

The food business should be aware of Section 106 of the *Food Act* which states that:

- (1) *A person must not resist, obstruct or attempt to obstruct a food safety auditor in the performance of the food safety auditor's functions under this Act,*
- (2) *A person must not falsely represent, by words or conduct, that the person is a food safety auditor.*
- (3) *A person must not threaten or intimidate a food safety auditor in the performance of the food safety auditor's functions under this Act.*

There is a penalty fine of \$10,000 for any one of the above.

7. What happens following the onsite audit?

It is important for food businesses to realise that when **deficiencies** of their FSP have been identified by the RFSA, the food business has an obligation to carry out whatever follow up action the RFSA believes is necessary.

The food business should put forward a solution to address the matter within the timeframe agreed by the RFSA and provide evidence to verify that the agreed corrective measure has been implemented and its effectiveness monitored.

In some instances it may be necessary for the RFSA to conduct a follow up audit of the food business in order to obtain evidence that the non-compliance has been satisfactorily resolved and may be closed out. Alternatively receipt of documentation from the food business demonstrating that the deficiencies have been rectified may suffice. Follow up audits should only be required in circumstances where implementation of the corrective measure/s cannot be verified by another means capable of addressing the evidence requirement of the audit system.

If an RFSA submits information to the enforcement agency that they are satisfied a non-compliance has been rectified, this should negate the need for the enforcement agency to undertake a site visit.

If the issues identified during the audit relate to **non-compliance** with the Code Food Safety Standards or complete failure to have a FSP that meets the requirements of Standard 3.2.1 of the Code, these issues need to be reported by the RFSA to the appropriate enforcement agency.

It is the responsibility of the enforcement agency to undertake follow up action (including any necessary compliance or enforcement response) to ensure that these issues have been rectified within appropriate timeframes.

The detection of a **critical non-compliance** during a regulatory food safety audit, or the detection of a number of non-compliances that collectively indicates that there is an **imminent and serious risk to the safety of food intended for sale; or that will cause significant unsuitability of food intended for sale**, the RFSA must immediately inform the appropriate enforcement agency (within 24 hours). The enforcement agency will follow up with the relevant food business in relation to the identified problems and will take appropriate compliance and enforcement action.

RSAs are required to submit audit reports to the appropriate enforcement agency (local government or Department of Health) and provide a copy for the food business.

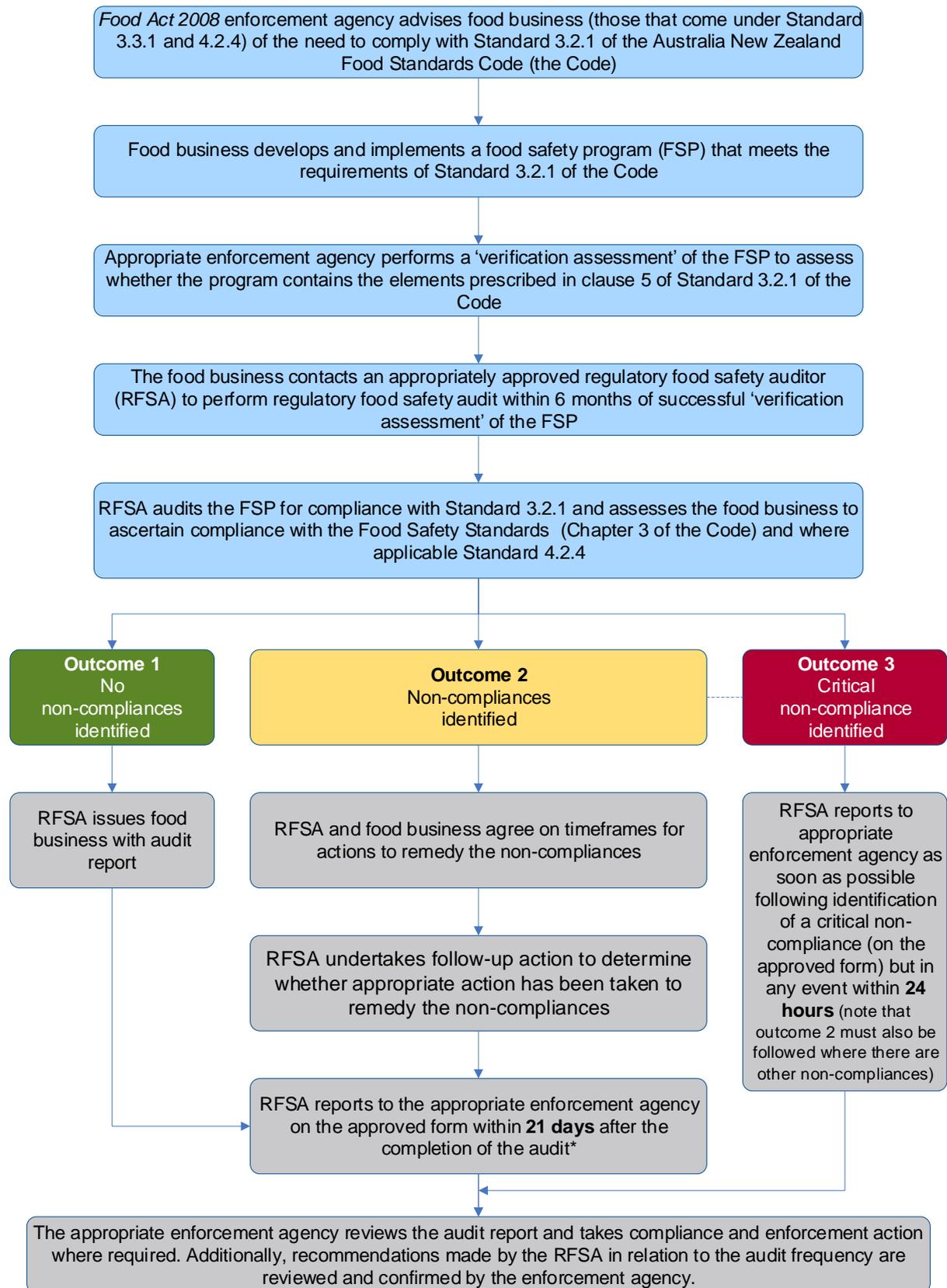
All regulatory food safety audit reports must be submitted on an approved form within 21 days (or 24hrs for the reporting of critical non-compliances) after the completion* of the regulatory food safety audit.

*A regulatory food safety audit will be considered 'complete' within 14 days of the beginning of audit activities for the purposes of section 102 of the Act (reporting requirements).

8. Further information

- [National Regulatory Food Safety Auditor Guideline \(PDF 412 KB external site\)](#)
- [National Food Safety Audit Policy \(PDF 224 KB external site\)](#)
- [WA Food Regulation: Food Safety Auditing – Guidelines for Regulatory Food Safety Auditors \(on the Audit and Reporting Requirements\) \(PDF 526 KB\)](#)
- [WA Food Regulation: Food Safety Auditing – Guideline for Regulatory Food Safety Auditors \(on the Approval Process\) \(PDF 541 KB\)](#)
- [WA Food Regulation: Food Safety Auditing - Code of Conduct \(PDF 288 KB\)](#)
- [Food Act 2008 \(external site\)](#)
- [Australia New Zealand Food Standards Code \(external site\)](#)

Flowchart of the regulatory food safety audit process



***NOTE: Regulatory food safety audits will be considered complete within 14 days or earlier from the beginning of audit activities**

Glossary

Term	Definition
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.
Audit Report	The report required under section 102 of the Food Act by which RFSAs report audit outcomes to enforcement agencies.
CEO	The Chief Executive Officer of the department of the Public Service principally assisting in the administration of the Food Act (section 8). The CEO of the Department of Health is the “Director General”.
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.
Critical non-compliance	Contraventions of the Food Act, regulations relating to food safety programs, or the Food Safety Standards detected during regulatory food safety audits that present an imminent and serious risk to the safety of food intended for sale; or that will cause significant unsuitability to the food intended for sale (section 102(5) Food Act)
Enforcement agency	As defined in section 8 of the Food Act, an enforcement agency is (a) the CEO; or (b) a local government; or (c) a person or body, or a person or body within a class of persons or bodies, prescribed by the regulations for the purposes of this definition; As prescribed in the Regulations, depending on the circumstances, an enforcement agency will be either the CEO or a local government.
Food Act	<i>Food Act 2008 (WA)</i> (external site)

<p>Food Business</p>	<p>As defined in section 10 of the Food Act, a “food business” is “a business, enterprise or activity (other than a business, enterprise or activity that is primary food production) that involves —</p> <p style="padding-left: 40px;">(a) the handling of food intended for sale; or (b) the sale of food,</p> <p>regardless of whether, subject to section 6, the business, enterprise or activity concerned is of a commercial, charitable or community nature or whether it involves the handling or sale of food on one occasion only”.</p> <p>Note that dairy primary producers are also a ‘food business’ in accordance with Regulation 6 of the Food Regulations which prescribes that any food production activity to which a standard in Chapter 4 of the Australia New Zealand Food Standards Code (Food Standards Code) applies is not primary food production for the purpose of section 10.</p>
<p>Food Safety Program (FSP)</p>	<p>As defined at section 103(1) Food Safety Program means, “for a food business, the food safety program required by the regulations to be prepared for the food business”.</p> <p>Standard 3.2.1 states a food safety program must -</p> <p style="padding-left: 40px;">a) systematically identify the potential hazards that may be reasonably expected to occur in all food handling operations of the food business; b) identify where, in a food handling operation, each hazard identified under paragraph (a) can be controlled and the means of control; c) provide for the systematic monitoring of those controls; d) provide for appropriate corrective action when that hazard, or each of those hazards, is found not to be under control; e) provide for the regular review of the program by the food business to ensure its adequacy; and f) provide 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.</p>
<p>Food Safety Standards</p>	<p>Defined at section 8 of the Food Act to mean: the Standards contained in Chapter 3 of the Food Standards Code.</p>
<p>Food Standards Code</p>	<p><u>Australia New Zealand Food Standards Code</u></p> <p>Under section 8 of the Food Act 2008 means the Australia New Zealand Food Standards Code as defined in the Commonwealth Food Standards Australia New Zealand Act 1991 and as adopted or incorporated by the regulations. The Food Standard Code has been adopted under Regulation 7 of the Food Regulations. The Code sets out in Chapters, the Standards that apply to food.</p>

List of Approved Regulatory Food Safety Auditors in WA	The list of regulatory food safety auditors, as required by section 105 of the Food Act, to be prepared and maintained by the CEO. The publicly available list of RFSAs in WA is located on the Department of Health website
National Food Safety Audit Policy	The policy endorsed by the Australian and New Zealand Food Regulation Ministerial Council on 25 October 2006 for the approval and management of RFSAs and regulatory food safety audits in Australia. This policy is available on the Food Regulation website (external site)
Non-compliance	A non-compliance against the FSP, the Food Safety Standards (or if applicable Standard 4.2.4) or the Food Act that is not considered to pose an imminent and serious risk to food intended for sale or that will cause significant unsuitability of food intended for sale. Compare to “critical non-compliance”.
Priority Classification	The Priority Classification of a food business as determined by the appropriate enforcement agency in accordance with the <i>WA Priority Classification System</i> approved by the CEO under section 100 of the Food Act.
the Regulations	Food Regulations 2009 (WA)
Regulatory Food Safety Audit	An audit (by an RFSA) arranged by a food business proprietor to satisfy the requirements imposed by section 99(2) of the Food Act. Regulatory food safety audit means an evaluation, by an RFSA, of a food business’ verified food safety program or other aspect of a food business to determine compliance with relevant aspects of the Food Act, the Food Regulations and associated policies applicable in WA.
Regulatory Food Safety Auditor (RFSA)	A food safety auditor approved or authorised by the CEO in accordance with Part 8 Division 1 of the Food Act. RFSA means a person formally approved or authorised by the CEO to conduct audits of food businesses or other premises requiring food safety audits (e.g. any business required by the Food Standards Code to implement a food safety program that complies with Standard 3.2.1 i.e. hospitals, child care centres etc.).
Regulatory Food Safety Auditor - Code of Conduct	Sets out standards of conduct that all RFSAs are required to demonstrate in their practice as RFSAs, and all RFSAs are required to commit to abide by the Code of Conduct as a condition of their approval. The Code of Conduct imposes an obligation on RFSAs to notify the CEO of any direct or indirect interest in any food business (section 96 of the Food Act). The RFSA Code of Conduct can be found on the Department of Health website (PDF 288 KB) .

Standard 3.2.1	Standard 3.2.1 (Food Safety Programs) of the Food Standards Code (external site)
Standard 4.2.4	Standard 4.2.4 (Primary Production and Processing Standard for Dairy Products) of the Food Standards Code (external site)
Verification	The application of methods, procedures, tests and other tools for evaluation, in addition to monitoring, to determine compliance of the food business's FSP with the Food Standards Code or appropriate regulation.

This document can be made available in alternative formats on request for a person with a disability.

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