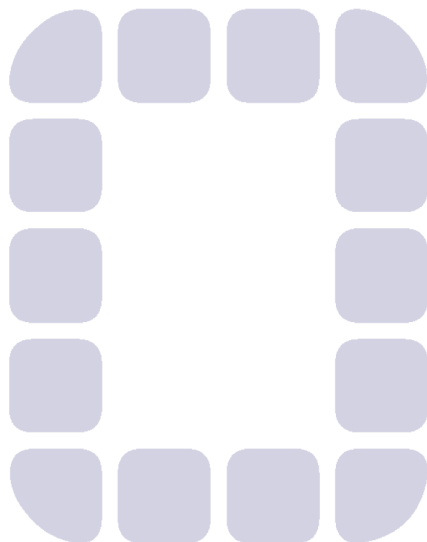
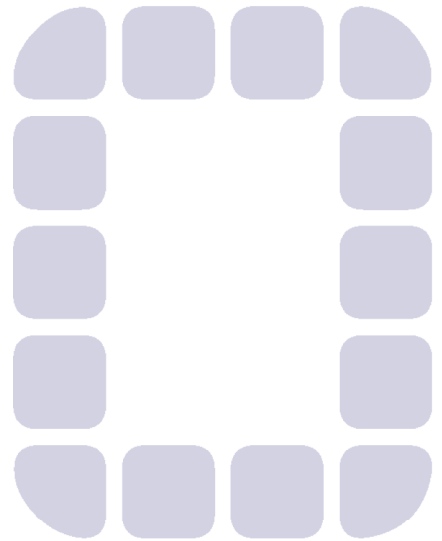
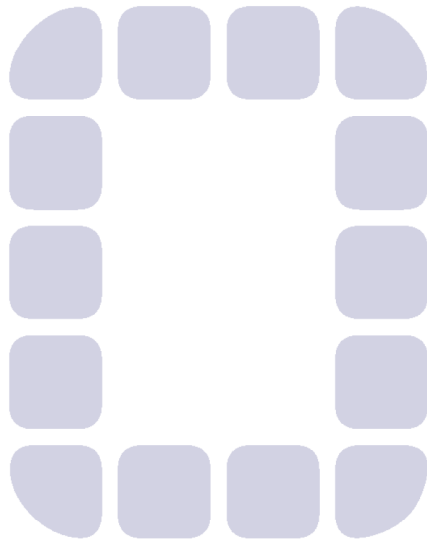
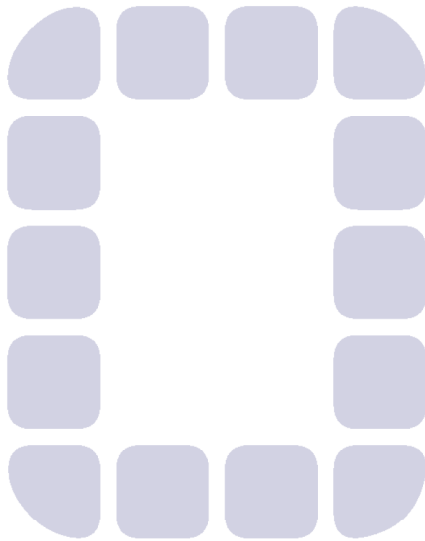


WA Food Regulation: Department of Health Management of Regulatory Food Safety Audit Policy

The Approach being taken by the Department of Health for the Management of Regulatory Food Safety Audits under the *Food Act 2008*



VERSION 01:
APPROVED:

July 2011
MANAGER
FOOD UNIT

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Department of Health Management of Regulatory Food Safety Audit Policy

1. Purpose

The purpose of this process is to provide the operational framework for managing the regulatory food safety audit process under the *Food Act 2008* (the Act).

2. Scope

This policy is applicable to Western Australia (WA) only. It is based on the National Food Safety Audit Policy and the National Regulatory Food Safety Auditor Guideline. This policy deals with the management of the regulatory food safety audit process, specifically how the Department of Health (DOH) will manage consistency in, and the integrity of, regulatory food safety auditing performed by approved regulatory food safety auditors in accordance with Part 8 of the Act.

3. Related Policies

- a. WA Food Regulation: WA Health Regulatory Food Safety Auditor Approval Process Policy
- b. WA Food Regulation: Verification of the WA Audit Management System Policy

4. Definitions

Act	<i>Food Act 2008.</i>
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 mechanism by which regulatory food safety auditors report audit outcomes to enforcement agencies. The s 103 form (approved by the CEO) for audit reports are contained within Appendix 1 and 2.
CEO	Chief Executive Officer, Department of Health.
Code of Conduct	The <i>WA Health Regulatory Food Safety Auditor Code of Conduct</i> . This Code of Conduct can be found within Appendix 2 of the <i>WA Health Regulatory Food Safety Auditor Approval Process Policy</i> .
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	A contravention of the Act or the Code that poses an imminent and serious risk to the safety of food intended for sale or that will cause significant unsuitability of food

	intended for sale.
DOH	Department of Health Western Australia.
Enforcement Agencies	Enforcement agency has the same meaning as s 6 of the Act. As prescribed in the Regulations, the enforcement agency will either be the DOH or the appropriate local government.
Food Business	Has the same meaning as contained within s 2 of the Act.
Food Standards Code	<i>Australian New Zealand Food Standards Code.</i>
FSP	Food Safety Program.
Food Safety Standards	Standard 3.2.2 and Standard 3.2.3 of the Food Standards Code.
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.
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 regulatory food safety auditors and regulatory food safety audits in Australia. This policy is available at: http://www.health.gov.au/internet/main/publishing.nsf/Content/foodsecretariat-policydocs.htm#nfsapolicy
National Regulatory Food Safety Auditor Guideline	The Implementation Sub Committee (of the Food Regulation Standing Committee) endorsed guideline which outlines the recommended minimum elements of a regulatory auditor system to enable food regulators to demonstrate compliance with the National Food Safety Audit Policy. This guideline is available at: http://www.health.gov.au/internet/main/publishing.nsf/Content/foodsecretariat-policydocs.htm#nfsaguideline
Non-compliance	A non-compliance against the FSP, the Food Safety Standards (or if applicable Standard 4.2.4) or the Act that is not considered to pose a serious or imminent risk to food intended for sale or that will cause significant unsuitability of food intended for sale.
Priority Classification	The Priority Classification of a food business as determined by an enforcement agency in accordance with s 100 of the Act. This determination must be made in accordance with the WA Priority Classification System approved by the CEO (extract available at Table 3).
Regulations	<i>Food Regulations 2009.</i>
Regulatory Food Safety Audit	An audit arranged by a food business to satisfy the requirements imposed by s 99(2) of the Act.
Regulatory Food Safety Auditor	An auditor approved by the DOH in accordance with Part 8 of the Act.
Standard 3.2.1	Standard 3.2.1 (<i>Food Safety Programs</i>) of the Food Standards Code.
Standard 4.2.4	Standard 4.2.4 (<i>Primary Production and Processing Standard for Dairy Products</i>) of the Food Standards Code.
Validation	To scientifically confirm the effectiveness of measures controlling food safety

Verification

hazards at each Critical Control Point (CCP) or at intervals or stages of a treatment or either processes.

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.

5. Responsibilities

Responsibility for managing the regulatory audit process is split between local government enforcement agencies and the DOH. While the DOH's role is about ensuring the integrity of, and consistency in, the regulatory food safety audit system, local government enforcement agencies have a key role in relation to responding to evidence collected by regulatory food safety auditors during the regulatory food safety audit process. Enforcement agencies also have a role in reporting concerns about the conduct of regulatory food safety audits performed by approved auditors to the DOH.

Enforcement agencies are responsible for:

- Determining the Priority Classification of a food business
- Initial verification of a FSP to ascertain it contains the prescribed elements as contained in Standard 3.2.1 of the Food Standards Code
- Assigning initial audit frequencies to businesses that require regulatory food safety auditing
- Responding to audit findings where they require a compliance and/or enforcement response (i.e. where issues have been identified that relate to non-compliance with the Code)
- Investigating complaints made about food businesses by regulatory food safety auditors
- Reporting to the DOH substantiated complaints/concerns about the performance and/or capabilities of approved regulatory food safety auditors or issues that indicate breach of the Code of Conduct or the WA Regulatory Food Safety Audit Framework.

The **CEO of the DOH** is responsible for:

- Approving regulatory food safety auditor applicants
- Monitoring regulatory food safety audits and regulatory food safety auditors through review of submitted audit reports and on-site assessments of auditing ability
- Investigating complaints made against regulatory food safety auditors by a food business and/or enforcement agencies.

Regulatory food safety auditors are responsible for:

- Ensuring that regulatory food safety audits are performed in accordance with this Policy and the Code of Conduct

- Reporting auditing outcomes to the appropriate enforcement agency in a timely fashion in accordance with s 102 of the Act
- Ensuring that businesses have appropriately remedied deficiencies in their FSP as identified during the audit process.
- Making determinations as to the appropriate audit frequency of a FSP for a food business (within the applicable Priority Classification)
- Assessing a food business's compliance with the Food Safety Standards and reporting any non-compliance to the appropriate enforcement agency.

6. Duties and Reporting Requirements of Regulatory Food Safety Auditors

6.1 Duties of Regulatory Food Safety Auditors

The specific duties of a regulatory food safety auditor are described in s 101 of the Act:

S.101: Duties of food safety auditors

A food safety auditor has the following duties –

- (a) having regard to the requirements of the regulations, to carry out audits of any food safety programs required by the regulations to be prepared in relation to food businesses;*
- (b) to carry out any necessary follow-up action, including further audits, if necessary, to determine whether 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 s 102.*

It is important to note the requirements of s 101 (b). This places an obligation on the regulatory food safety auditor, when deficiencies of a food business's FSP have been identified, to carry out whatever follow up action the regulatory food safety auditor believes is necessary to determine whether appropriate remedial action has been taken by the food business. Therefore the regulatory food safety auditor is responsible for setting appropriate timeframes by which identified deficiencies must be addressed. Agreement by the food business should be sought when setting any timeframes.

Follow-up action could include (refer to point 7.5 of this Policy for detailed information on dealing with non-compliances):

- a further audit/assessment at the food business premises to assess whether action has been taken to remedy any deficiencies of the FSP; or
- receipt of documentation from the food business demonstrating that the deficiencies have been rectified.

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

Under no circumstances can a regulatory food safety auditor undertake enforcement action – these powers are reserved for Authorised Officers only

6.2 Reporting Requirements for Regulatory Food Safety Auditors

A regulatory food safety auditor's reporting obligations are specified in s 102 of the Act. These include:

- Timeframes for submitting completed audit reports to the appropriate enforcement agency;
- Immediate notification requirements when critical non-compliances are identified; and
- The requirement that reporting must be in the approved form.

A regulatory food safety auditor must submit an audit report to the appropriate enforcement agency within 21 days of the completion of the regulatory food safety audit (s 102 (2)(b)) of the Act. A regulatory food safety audit will be considered 'complete' at the expiration of 14 days from the beginning of audit activities. This will be the case even if there are outstanding issues not addressed by the food business.

However, detection of a **critical non-compliance** during a regulatory food safety audit must result in the termination of the regulatory food safety audit. The regulatory food safety auditor will then be required to notify the relevant enforcement agency of the audit failure as soon as possible but in any event within 24 hours after the contravention comes to the regulatory food safety auditor's attention as specified in clause 6 of s 102 of the Act.

All regulatory food safety audit reports must be in the form approved by the CEO. Two forms have been approved by the CEO:

- Notification of a critical non-compliance (Appendix 2)
- Regulatory Food Safety Audit Report (Appendix 1).

It is acceptable for regulatory food safety auditors to submit their own versions of these forms (including electronic) so long as the information and wording specified in the approved forms are utilised.

Refer to point 7.4 of this Policy for further information concerning the reporting of regulatory food safety audit outcomes.

7. The Audit Process

7.1 Documentation Review

As a matter of best practice, it is recommended that a desk top review of a food business' FSP is undertaken before commencing the on-site component of a regulatory food safety audit. Such an approach determines whether the food business has collected sufficient evidence (e.g. records) to suggest it is maintaining the system in accordance with the requirements of Standard 3.2.1 of the Code (or Standard 4.2.4 if applicable). If during the desk top review, the regulatory food safety auditor considers that the food business has not collected sufficient evidence to demonstrate compliance with the requirements of Standard 3.2.1 (or Standard 4.2.4), the on-site component of a regulatory food safety audit should not be commenced.

Should this occur, the regulatory food safety auditor needs to report this result to the appropriate enforcement agency utilising the approved audit report form and record the result as an 'incomplete audit'. Refer to point 7.4 of this Policy for further details.

7.2 Planning the Audit

It is the responsibility of the registered food business to organise a regulatory food safety audit of their FSP.

The food business and the regulatory food safety auditor are responsible for organising and managing the regulatory food safety audit process. During the planning and scoping of the audit, it is recommended that the regulatory food safety auditor 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' current FSP
- Definitions of non-compliance that will be applied and the levels of non-compliance that will be used
- 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.

It is important to note that a regulatory food safety audit must cover the **full scope** of the FSP.

7.3 Conduct the Audit

Opening Meeting	On-site Examination	Exit Meeting
<p>Before commencing a regulatory food safety audit, the regulatory food safety auditor must communicate the objectives and intent of the audit to the food business proprietor or their designated representatives. This must be in an organised, succinct and clear manner in recognition of the time imposed on food businesses by on-site regulatory food safety audits.</p>	<p>During the on-site component of a regulatory food safety audit, a regulatory food safety auditor shall review evidence collected by the food business (e.g. records, sampling logs, documentation protocols). This evidence should demonstrate the food business' on-going compliance with its FSP to determine whether the food business is maintaining its system consistent with Standard 3.2.1 (or Standard 4.2.4).</p> <p>Regulatory food safety auditors shall also collect their own evidence from a food business during the on-site component of a regulatory food safety audit to allow them to make an objective determination as to whether the food business is maintaining its system consistent with the requirements of Standard 3.2.1 (or Standard 4.2.4).</p> <p>Evidence may be collected through interviews, independent examination of documentation and records and/or observation of activities carried out at the food business. Where any non-compliance is detected, regulatory food safety auditors should clearly document these incidences against the requirements of the Act and/or the Food Standards Code. Regulatory food safety auditors shall also inform food businesses of any non-compliances identified during the on-site audits.</p>	<p>To provide audited food businesses with the opportunity to discuss audit findings and provide further information as required, regulatory food safety auditors shall discuss audit findings with food businesses upon completion of regulatory food safety audits. During these meetings, auditors shall discuss non-compliances identified during the audit and seek comment from the food business as to how processes can be modified/implemented to address those non-compliances.</p> <p>Auditors may need to arrange further audits to verify that the corrective action proposed by the food business has been implemented to address those non-compliances.</p> <p>At the very least, regulatory food safety auditors shall obtain some form of evidence to confirm that agreed corrective measures have been implemented by the audited food business.</p> <p>Regulatory food safety auditors are required to keep records of all agreed processes to address non-compliances identified during the audit process and to subsequently report these agreed processes to the appropriate</p>

	<p>Regulatory food safety auditors must assess compliance with the Food Safety Standards.</p> <p>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 imposed on a food business proprietor or their representative during exit meetings.</p>	<p>enforcement agency in the approved audit report form.</p> <p>In circumstances where agreed processes to address non-compliances will not be completed within 14 days, the regulatory food safety auditor is required to report to the appropriate enforcement agency the agreed timeframe for rectification. The regulatory food safety auditor needs to discuss with the food business the fact that these outstanding issues will be reported.</p>
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It is important to note that 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 public health, must result in the termination of the regulatory food safety audit.

7.4 Reporting of audit outcomes

Regulatory food safety auditors are required to submit audit reports to the appropriate enforcement agency (local government or DOH) and the business being audited in accordance with provisions of Part 8 of the Act (refer to point 6.2 of this Policy). All regulatory food safety audit reports (except for the reporting of critical non-compliances) must be submitted on the approved form contained within Appendix 1 within 21 days after the completion of the regulatory food safety audit. In accordance with point 7.6 of this Policy, a regulatory food safety audit will be considered 'complete' within 14 days of the beginning of audit activities for the purposes of s 102 of the Act (reporting requirements).

Regulatory food safety auditors are required to make an overall judgement of the performance of the food business demonstrated during the audit in accordance with the categories contained within Table 1 (*Reporting Outcomes of a Regulatory Food Safety Audit and Amending Audit Frequency*) below. Any determinations in relation to regulatory food safety audit frequency adjustments must also accord with the parameters set out in Table 1.

A regulatory food safety auditor may form the opinion that a food business complies with Standard 3.2.1 and the Food Safety Standards by way of **substantial compliance** by a food business rather than the total absence of non-compliances. Thus a regulatory food

safety audit may still be deemed successful by the regulatory food safety auditor even if non-compliances are detected. **The exception to this would be where a critical non-compliance is identified.**

Table 1: Audit Outcomes and Amending Audit Frequency

REPORTED AUDIT RESULT	DESCRIPTION	AUDITOR'S DETERMINATION IN RELATION TO AUDIT FREQUENCY
Incomplete audit	<p>A regulatory food safety audit is considered to be incomplete when the regulatory food safety auditor ceases (or does not begin) the audit because a FSP is not in place.</p> <p>A regulatory food safety auditor may make this determination without needing to undertake a site assessment (i.e. based on the results of a desktop audit).</p>	<p>Audit frequency to remain the same</p> <p>Enforcement agency to follow up with food business in relation to this non-compliance in accordance with their compliance and enforcement policy.</p>
Unsuccessful audit	<p>A regulatory food safety audit is unsuccessful when, in the regulatory food safety auditor's opinion, there are contraventions of the Act or the Food Standards Code that pose an imminent and serious risk to the safety of food intended for sale or that will cause significant unsuitability of food intended for sale.</p> <p>Regulatory food safety auditor to raise a critical non-compliance and notify the enforcement agency on the approved form as soon as possible but in any event within 24 hours after the contravention comes to the attention of the regulatory food safety auditor (s 102 of the Act).</p>	<p>Increase frequency of regulatory audit (within limits set by food business' Priority Classification)</p> <p>This result indicates that the food business' FSP is not effective in producing safe food. It is the responsibility of the enforcement agency to follow up with the food business in relation to the identified problems in accordance with their compliance and enforcement policy.</p>
Marginal audit	<p>A regulatory food safety audit is to be reported as indicating a marginal FSP when, in the regulatory food safety auditors opinion, the FSP has been implemented but the food business does not always follow the documented process.</p> <p>A non-compliance against specific controls within the FSP that does not meet the criteria for a critical non-compliance (i.e. does not present an imminent and serious risk to the safety of food) would</p>	<p>Increase frequency of regulatory audit (within limits set by food business' Priority Classification)</p> <p>Or audit frequency to remain the same if appropriate</p>

	automatically make the program marginal. It may take a number of non-compliances against prerequisite or support programs to make the program marginal.	
Successful audit	<p>A regulatory food safety audit is successful when the regulatory food safety auditor is confident that the system:</p> <ul style="list-style-type: none"> (1) complies with Standard 3.2.1 (and Standard 4.2.4 if applicable) (2) is adequate to control the hazards associated with the industry and process involved (3) has been implemented in accordance with the food business' documented system. <p>There may be a small number of non-compliances raised against prerequisite or support programs.</p>	<p>Audit frequency to remain the same</p> <p><u>Or</u> decrease frequency of regulatory audit (within limits set by food business's Priority Classification) if appropriate</p>
High performance audit	<p>Occurs when the regulatory food safety audit has not disclosed any contravention of the Act or the Food Standards Code (Standard 3.2.1 or Standard 4.2.4) and where the regulatory food safety auditor has a high level of confidence in the FSP. A high level of confidence can be measured in two ways:</p> <ul style="list-style-type: none"> (1) evidence of continuing compliance with the FSP (2) the food business has an effective internal food safety audit and management review process. 	<p>Decrease frequency of regulatory audit</p> <p>NOTE: The food business can not have their audit frequency decreased unless there is compliance history available to the regulatory food safety auditor and the food business has had no non-compliances identified in two previous audits.</p>

7.5 Non-compliance categories

Non-compliances detected during regulatory food safety audits of a food business' system will be classified as either:

- Critical non-compliances; or
- Non-compliances.

Table 2: Definition of Critical Non-Compliance/Non-Compliance

Critical non-compliance	Non-compliance
<p>Contraventions of legislation detected during regulatory 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.</p> <p>Critical non-compliances must be reported to the appropriate enforcement agency as soon as possible, and in any event, within 24 hours on the approved form contained in Appendix 2.</p>	<p>Where there is a non-compliance against the FSP, the Food Safety Standards (or if applicable Standard 4.2.4) or the Act that is not considered to pose a serious or imminent risk to food intended for sale or that will cause significant unsuitability of food intended for sale.</p> <p>Non-compliances are reported to the enforcement agency by means of the audit report.</p>

The regulatory food safety auditor is responsible for discussing and resolving the non-compliance with the proprietor of the food business or their representative. The regulatory food safety auditor's role in this negotiation **should not include providing the food business with the solution** to the identified non-compliance as this should be the role of the food business proprietor. The regulatory food safety auditor's role in the negotiation is limited to discussing the issue at hand and affirming that a solution offered by the food business **has the potential to address the matter**. The regulatory food safety auditor should not agree that the solution will address the matter until evidence has been supplied by the food business to verify that the agreed corrective measure has been implemented and its effectiveness monitored.

In some instances it may be necessary for the regulatory food safety auditor to conduct a second audit of the food business in order to obtain evidence that the non-compliance has been satisfactorily resolved and may be closed out. Second visits 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 a regulatory food safety auditor 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.

7.6 Reporting to Enforcement Agencies

If the non-compliance relates to a deficiency of the business' FSP, it is the responsibility of the auditor to set an appropriate timeframe for rectification and to follow-up as to how the non-compliance has been rectified.

If the non-compliance indicates non-compliance by the food business with the Act or the Food Standards Code, the appropriate enforcement agency is responsible for deciding

whether the non-compliance has been adequately rectified. The appropriate enforcement agency is also responsible for undertaking any compliance/enforcement action in relation to compliance failures by the food business.

7.7 Completion of Regulatory Audits

Regulatory food safety audits will be considered 'complete' at the expiration of 14 days, or earlier, from the beginning of audit activities for the purposes of s 102 of the Act (*Reporting Requirements*). At the end of this 14 day period, or earlier, an audit report (inclusive of agreed corrective measure(s)) must be prepared. This audit report must be submitted on the form approved by the CEO (Appendix 1) and submitted within 21 days following completion of the audit.

In circumstances where corrective measures either:

- cannot be finalised within 14 days; or
- have not been finalised by the end of the 14 day period;

the regulatory food safety auditor need only to advise the appropriate enforcement agency (in the audit report) that these issues have not been finalised. The appropriate enforcement agency may then undertake regulatory activities to ensure these issues are addressed within suitable timeframes (i.e. by issuing an Improvement Notice under s 63 of the Act).

7.8 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 food safety audit. Under such circumstances, the lead auditor will be required to ensure all regulatory food safety auditors on the audit team are competent to conduct such audits.

8. Audit Allocation

A food business is responsible for ensuring that regulatory food safety audits are completed within the timeframe specified by the appropriate enforcement agency. This includes engaging the services of an approved regulatory food safety auditor.

9. Risk Priority Classification and Audit Frequency

Enforcement agencies are responsible for determining, in accordance with the WA Priority Classification System (table 3 below):

- whether a food business is required to comply with the FSP requirements specified in Standard 3.2.1;
- the initial audit frequency of a food business; and

- the appropriate range by which the minimum audit frequency for that business can be set. This must be in accordance with the WA Priority Classification System (refer to table 3).

A **regulatory food safety auditor** may determine that the current regulatory audit frequency of a food business be adjusted. Any determination must be made with proper regard to the following matters:

- the compliance history of the food business in relation to the Food Safety Standards and the requirements of Standard 3.2.1
- any audit compliance history relevant to food safety programs established by the food business before the 23 April 2011.

Table 1 above (*Reporting Outcomes of a Regulatory Food Safety Audit and Amending Audit Frequency*) provides the basis for a regulatory food safety auditor to re-determine a particular food business' regulatory food safety audit frequency. A regulatory food safety auditor must consider this framework when making any audit frequency determination.

A regulatory food safety auditor must report to the appropriate enforcement agency that the current regulatory food safety audit frequency of a particular food business has been amended. This notification forms part of the audit report contained within Appendix 1.

Enforcement agencies must advise the Food Unit, DOH, if they believe inappropriate determinations in relation to audit frequencies are being made by a regulatory food safety auditor.

The *WA Priority Classification System* is provided in Table 3. Regulatory food safety auditors may only adjust regulatory audit frequencies in accordance with this system.

Table 3: WA Priority Classification System

Food Businesses Type	Priority Classification	Compliance Arrangements
<p>Food businesses required by the <i>Food Act 2008</i> to comply with <i>Australian New Zealand Food Standards Code Standard 3.2.1 (Food Safety Programs)</i></p> <p>This requirement extends to the following:</p> <ul style="list-style-type: none"> • Food business subject to the requirements of Standard 3.3.1 (<i>Food Safety Programs for food service to vulnerable persons</i>) of the Code 	<p>Priority 1 (P1)</p>	<p>Audit by <i>Food Act 2008</i> approved food safety auditor with qualifications suitable to the business type</p> <p>Frequency of audit</p> <p>Initial audit frequency:</p> <ul style="list-style-type: none"> ▪ Every 6 months <p>Audit frequency range:</p>

		<ul style="list-style-type: none"> ▪ maximum 3 monthly ▪ minimum 12 monthly <p>A regulatory food safety auditor may determine the audit frequency be changed in accordance with s 103 of the Act following two complete audits.</p>
<ul style="list-style-type: none"> • Food businesses subject to the requirements of Standard 4.2.4 (<i>Primary Production and Processing Standard for Dairy Products</i>) of the <i>Australian New Zealand Food Standards Code</i>. 	Priority 2 (P2)	<p>Audit by <i>Food Act 2008</i> approved regulatory food safety auditor with qualifications suitable to the business type.</p> <p>In accordance with regulation 4 of the <i>Food Regulations 2009</i>, the Department of Health is the appropriate enforcement agency for all businesses captured under Standard 4.2.4.</p> <p>Frequency of audit</p> <p>Initial audit frequency:</p> <ul style="list-style-type: none"> ▪ Standard 4.2.4 Division 2 and 3: every 12 months ▪ Standard 4.2.4 Division 4: every 6 months <p>Audit frequency range:</p> <ul style="list-style-type: none"> ○ maximum 3 monthly ○ minimum 12 monthly <p>The DOH regulatory food safety auditor may determine the audit frequency be changed in accordance with s 103 of the Act following two complete audits.</p>
Other food businesses	Not classified at this time	

Appendix 1: Regulatory Food Safety Audit Report

Food Act 2008 Regulatory Food Safety Audit Report

Section 102 Approved Form

Version 01: June 2011

To be submitted to the appropriate enforcement agency within 21 days after the completion of a regulatory food safety audit/assessment by the regulatory food safety auditor

Section A: Food Business Details	
Registered Trading Name of Food Business	
Proprietor Name	
Business Address	
Business Type	
Priority Classification	
Address of premises where the audit was performed	
Responsible person for food business premises audited	
Enforcement Agency	

Section B: Auditor Details	
Name	
Contact details	Phone: Mobile: Email:
Approval scope	

Section C: Audit Details			
Is this the first audit?	Yes/No	If 'No', date of previous audit	
Review of previous audit report/ Food Act 2008 regulatory assessment report/regulatory action (i.e. s. 63 improvement notice)	Are there outstanding issues? <i>please detail</i>		
Date/s of Audit		Total Time of Audit include start/finish times	

Section D: Regulatory Food Safety Auditor Declaration

Following completion of the regulatory food safety audit, I am of the opinion that:

The food business is being carried on in compliance with the requirements of the Standard 3.2.1 of the *Food Standards Code* in relation to the FSP (refer to 'Verification of Food Safety Program Guideline' for assistance with determining compliance): YES NO

<p>IF NO, I am of the opinion that the following requirements are being contravened:</p>	<p align="center">Details of the manner in which they are being contravened:</p>

The food business is being carried on in compliance with the provisions of the Food Safety Standards (Chapter 3 of the *Australian New Zealand Food Standards Code*): YES NO

<p>IF NO, Details of non-compliance</p>	<p>Food Safety Standards Reference</p>

Section E: Audit Summary

Reference Number (FSP or FSS)	Activity audited (Receiving, Storage, Preparation, Cooking, Holding Transport Display, Support Programs, Training, Food Recall and Records)	Compliant Y/N	Evidence/reasons for compliance or details of non-compliance (Identify positive aspects of the audit as well as non-compliances)

Section F: Management of non-compliances

Actions taken/agreed to be undertaken by the food business to remedy any identified non-compliances

NON-COMPLIANCE OBSERVED	CORRECTIVE ACTION Action taken or proposed to be taken for each non-compliance	CLOSE OUT DATE	EVIDENCE SIGHTED

Section G: Auditor Conclusion and Recommendations

Overall, the performance of the business in the audit has been assessed as:

Refer to Appendix 1 for detailed explanation of categories

High Performance Successful Marginal Unsuccessful Incomplete

As such, determine that the audit frequency of the food business should be changed:

YES NO

New audit frequency: _____ **This is an:** INCREASE/DECREASE *(please circle one)*

This determination is made with regard to the compliance history of the food business concerned in relation to its food safety program and the requirements of the Food Safety Standards.

If yes, provide details of the reasons why the audit frequency change is recommend:

Auditor Signature:

Auditor Name:

Date:

This form must be forwarded to the appropriate enforcement agency within 21 days after the completion of the audit

Appendix 2: Regulatory Food Safety Audit Report – Notification of Critical Non-Compliance

Food Act 2008 Regulatory Food Safety Audit Report

Section 102 (5) Approved Form: Notification of Critical Non-Compliance

Version 01: June 2011

To be submitted to the appropriate enforcement agency within 24 hours by a regulatory food safety auditor following the finding of a contravention that 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.

Section A: Food Business Details	
Registered Trading Name of Food Business	
Proprietor Name	
Business Address	
Business Type	
Priority Classification	
Address of premises where the audit was performed	
Responsible person for food business premises audited	
Enforcement Agency	

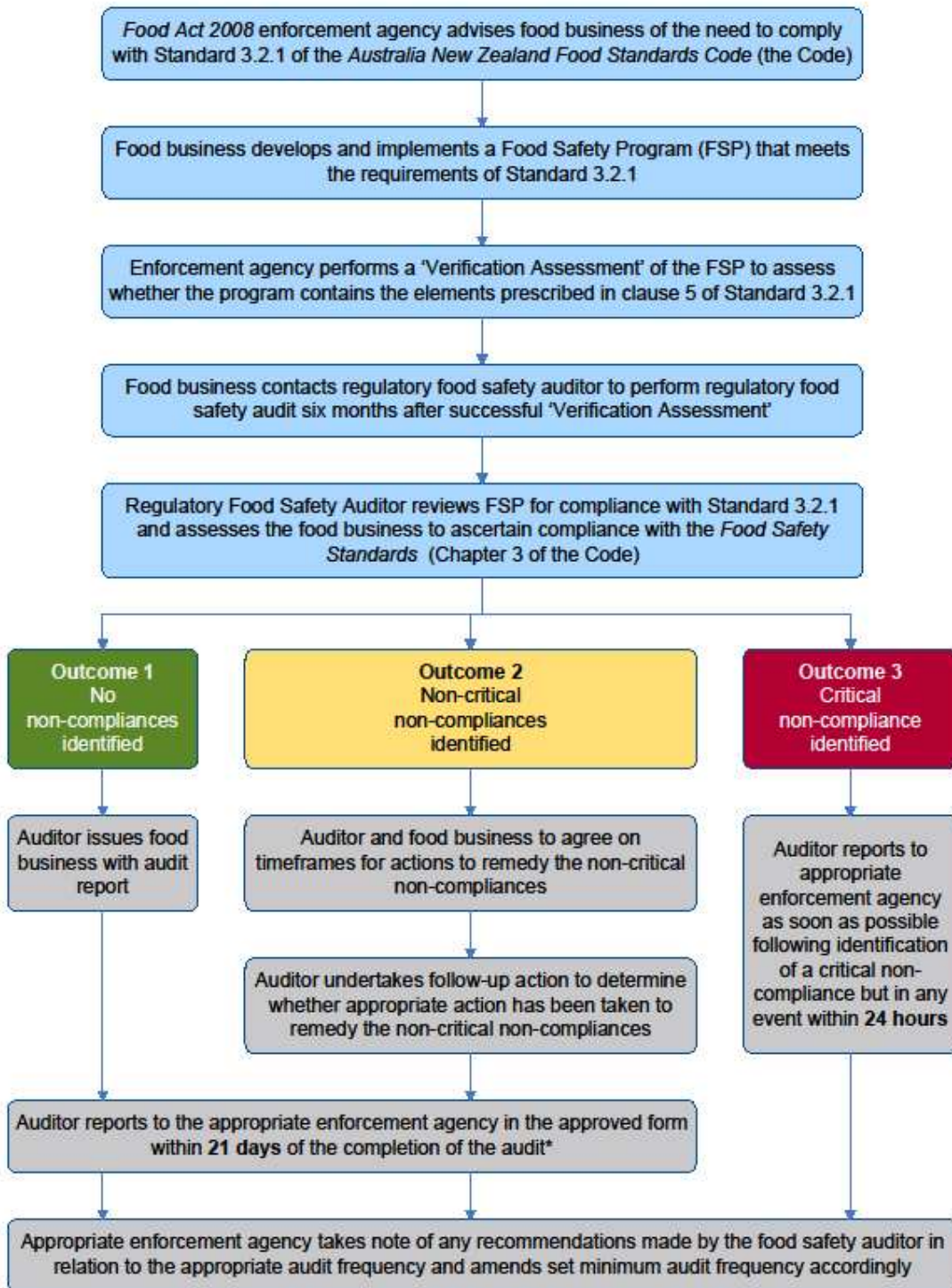
Section B: Auditor Details	
Name	
Contact details	Phone: Mobile: Email:
Approval scope	

Section C: Details of Critical Non-Compliance	
<p>During the course of carrying out an audit/assessment at the above mentioned food business premises, I am of the opinion that there is a contravention of the <i>Food Act 2008</i>, the <i>Food Regulations 2009</i> and/or the Chapter 3 of the Australia New Zealand Food Standards Code (Food Safety Standards):</p>	
<input type="checkbox"/> that is an imminent and serious risk to the safety of food intended for sale	<input type="checkbox"/> will cause significant unsuitability of food intended for sale
<p><i>Please provide details over page</i></p>	
Auditor Signature	
Date	

Details of Critical Non-Compliance

Reference Number (FSP or FSS)	Activity audited	Details of non-compliance

Appendix 3: 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**

Delivering a Healthy WA

