



WA Food Regulation: Food Safety Auditing – Guideline for Regulatory Food Safety Auditors (on the Audit and Reporting Requirements)

Version 1

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Approved by Managing Scientist - Food

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Regulatory Food Safety Auditors Guideline on Reporting Requirements

1. Introduction

This Guideline applies to the regulatory food safety audit system and to the regulatory food safety auditors (RFSAs) who audit businesses under that system. This Guideline provides a framework for RFSAs on their reporting requirements.

In addition to this Guideline there is a Code of Conduct that applies to all RFSAs approved by the Chief Executive Officer (CEO) of Department of Health (DOH) to conduct audits of food businesses. RFSAs are expected to conduct themselves with integrity, professionalism, and be accountable to the outcomes of audits they perform. The Code of Conduct provides a basis against which DOH may review, impose conditions, or revoke or suspend an RFSA's approval.

Part 8 of the *Food Act 2008 (WA)* (the Food Act) sets out requirements relating to food audits. It includes provisions for the CEO to authorise a staff member or approve an individual to be an RFSA where the CEO is satisfied that person is competent to do so, and it sets out auditing and reporting requirements. The CEO's powers under Part 8 may be delegated, in writing, to a member of staff. The CEO, acting through the DOH, is an enforcement agency as set out in the Food Regulations 2009 (Food Regulations).

2. Scope

This Guideline is applicable to Western Australia (WA) only and deals with the duties and reporting requirements of RFSAs. It is based on the National Food Safety Audit Policy, National Regulatory Food Safety Auditor Guideline and the Food Act.

3. 'WA Food Regulation: Department of Health Management of Regulatory Food Safety Audit Policy' superseded

This Guideline supersedes the previous document WA Food Regulation: Department of Health Management of Regulatory Food Safety Audit Policy (version 1- as approved by the Manager Food Unit in July 2011).

4. Objectives

The objectives of this Guideline are to provide:

- clear and consistent guidance for RFSAs on their responsibilities, the audit process and reporting requirements, prior to, and following a regulatory food safety audit;
- the framework for the reporting process of regulatory food safety audits.

5. Related documents

- [National Regulatory Food Safety Auditor Guideline \(PDF 412 KB external site\)](#)
- [National Food Safety Audit Policy \(PDF 224 KB external site\)](#)
- [WA Food Regulation: Guideline for the Management of the Regulatory Food Safety Auditing System \(PDF 336 KB\)](#)
- [WA Food Regulation: Food Safety Auditing – Guideline for Regulatory Food Safety Auditors \(on the Approval Process\) \(KB 541 KB\)](#)
- [WA Food Regulation: Food Safety Auditing – Guidelines for Enforcement Agencies \(PDF 383 KB\)](#)
- [WA Food Regulation: Food Safety Auditing – Information for Food Businesses \(PDF 273 KB\)](#)
- [WA Food Regulation: Food Safety Auditing - Code of Conduct \(PDF 288 KB\)](#)
- [Food Act 2008 Verification of Food Safety Program Guideline \(PDF 25KB\)](#)

6. Definitions

| Term | Definition |
|--------------------------------|--|
| Approval | A decision by the CEO or their delegate that they are satisfied an individual is competent to carry out the functions of an RFSA and that the individual may (with or without conditions) exercise powers as an RFSA. |
| 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 RFSA's report audit outcomes to enforcement agencies. The section 102 form for audit reports (approved by the CEO) is contained in Appendix 1. |
| 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 of food intended for sale (section 102(5) Food Act). |
| DOH | Department of Health (WA) |
| Enforcement agencies | 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 | Food Act 2008 (WA) (external site) |

| Term | Definition |
|----------------------------------|---|
| Food Business | <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> <ul style="list-style-type: none"> (a) the handling of food intended for sale; or (b) the sale of food, <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> |
| Food Regulations | <p>Food Regulations 2009 (WA) (external site)</p> |
| Food Safety Program (FSP) | <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> <ul style="list-style-type: none"> 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. |
| Food Safety Standards | <p>Defined at section 8 of the Food Act to mean: the Standards contained in Chapter 3 of the Food Standards Code.</p> |
| Food Standards Code | <p>Australia New Zealand Food Standards Code (external site) Under section 8 of the Food Act 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.</p> <p>The Food Standards Code has been adopted under Regulation 7 of the Food Regulations. The Code sets out in Chapters, the Standards that apply to food.</p> |

| Term | Definition |
|---|--|
| 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 an enforcement agency in accordance with the WA Priority Classification System approved by the CEO under section 100 of the Food Act. |
| 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 . |
| 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 food safety program with the Food Standards Code or appropriate regulation. |

7. Responsibilities of regulatory food safety auditors

RFSAs are responsible for:

- Ensuring that regulatory food safety audits are performed in accordance with this Guideline, the Code of Conduct and the Food Act; and within the scope of their approval.
- Reporting auditing and assessment outcomes to the appropriate enforcement agency in accordance with section 102 of the Food Act
- Ensuring that business proprietors also receive a copy of the report provided to the appropriate enforcement agency and assessing whether a business has appropriately remedied deficiencies in their FSP as identified during the audit process.
- Determining whether changes are required from the current audit frequency of an FSP for a food business (within the relevant priority classification) to another audit frequency.

7.1 Duties of regulatory food safety auditors

The specific duties of an RFSA are described in section 101 of the Food Act:

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 section 102.***

The RFSA is obliged, under section 101(b), to carry out follow-up action when they have identified deficiencies in an FSP, to determine whether appropriate remedial action has been taken by the food business. Therefore, the RFSA is responsible for setting appropriate timeframes by which identified deficiencies must be addressed. (Note that the RFSA reports to the appropriate enforcement agency in the approved form within 21 days after completion of the audit). Agreement by the food business should be sought when setting any timeframes.

Follow-up action by the RFSA could include:

- 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 e.g. complete failure to have an 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 determine whether these issues have been rectified within appropriate timeframes.

Under no circumstances can an RFSA undertake enforcement action – these powers are reserved for authorised officers from the appropriate enforcement agency.

8. The audit process

8.1 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 FSP in accordance with the requirements of Standard 3.2.1 (and specific requirements of Standard 4.2.4 Primary Production and Processing Standard for Dairy Products where applicable). (The 14 days for completion of the audit starts when the RFSA is on site and not during the desk top review). Some businesses may have a Hazard Analysis Critical Control Point (HACCP) Program. The Codex HACCP system consists of seven principles. It is a documented system that has the same outcome as a Food Safety Program.

If during the desk top review, the RFSA considers that the food business has not collected sufficient evidence to demonstrate compliance with these Standards, the on-site component of a regulatory food safety audit should not be commenced.

Should this occur, the RFSA needs to report this result to the appropriate enforcement agency utilising the approved audit report form and record the result as an 'incomplete audit' (further details in Table 3).

8.2 Planning the audit

It is the responsibility of the registered food business to ensure their FSP is audited (section 99(2) of the Food Act).

The food business and the RFSA 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 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' current FSP
- Definitions of non-compliance that will be applied
- Activities (i.e. observing, record request etc.) 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 for the RFSA
- Follow-up and completion procedures.

A regulatory food safety audit must cover the full scope of the FSP. The RFSA may ask to see the food business' last report to ascertain if there are any outstanding issues.

8.2.1 Multi-sited food businesses

Irrespective of whether a food business operates from many sites, each site must maintain their own FSP and monitoring records and be audited against that FSP. The FSP can be based on a template program but it must accurately reflect how food safety issues are being managed at that particular site.

8.3 Audit teams

There may be instances where a team of RFSA's, rather than an individual RFSA, may be required to carry out a regulatory food safety audit. Under such circumstances, the lead

auditor will be required to ensure all RFSAs on the audit team are approved RFSAs and competent (have the required specialised competencies) to conduct such audits. Audit teams provide flexibility to the audit system, particularly in the case of complex audits that require technical expertise from different RFSAs.

8.4 Conduct the audit

Table 1: Audit process

| Opening Meeting | On-site Examination | Exit Meeting |
|---|--|---|
| <p>Before commencing a regulatory food safety audit, the RFSAs must communicate the objectives and intent of the audit to the food business proprietor or their designated representatives (some of this may have already been done in the desktop review). 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, an RFSAs 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 FSP consistent with Standard 3.2.1 (and Standard 4.2.4 where applicable).</p> <p>RFSAs 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 FSP consistent with the requirements of Standard 3.2.1 (and Standard 4.2.4 where applicable).</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.</p> <p>RFSAs must assess compliance with the FSP and the Food Safety Standards.</p> <p>(Where any critical non-compliance is detected, RFSAs should clearly document these incidents against the requirements of the Food Act, the Food Regulations relating to FSP or Food Safety Standards and report to the appropriate enforcement agency within 24 hrs).</p> <p>It is suggested that RFSAs 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</p> | <p>To provide audited food businesses with the opportunity to discuss audit findings and provide further information as required, RFSAs shall discuss audit findings with food businesses upon completion of the on-site component of the regulatory food safety audit. During these meetings, RFSAs 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>RFSAs may need to arrange further audits/assessments 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, RFSAs shall obtain some form of evidence (e.g. through interviews, photos, examination of records) to confirm that agreed corrective measures have been implemented by the audited food business.</p> <p>RFSAs 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 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 RFSAs is required to report to the appropriate enforcement agency the agreed timeframe for rectification. The RFSAs needs to discuss with the food business the fact that these outstanding issues will be reported however the RFSAs will take into</p> |

| | | |
|--|---|---|
| | business proprietor or their representative during exit meetings. | account any action taken before the submission of the report to remedy any deficiency identified by the RFSA. |
|--|---|---|

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 indicate 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 regulatory food safety audit should continue to identify any further non-compliances including critical non-compliances.

For further guidance on minimum requirements for conducting a regulatory food safety audit refer to Appendix 3.

A flow chart of the regulatory food safety audit process is in Appendix 4.

9. Reporting of audit outcomes

9.1 Reporting requirements for regulatory food safety auditors

An RFSA's reporting obligations are specified in section 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.

Non-compliance categories

Non-compliances detected during regulatory food safety audits of a food business' FSP 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 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>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 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.</p> <p>Non-compliances are reported to the enforcement agency by means of the audit report.</p> |

Where there is no critical non-compliance:

An RFSA must submit an audit report to the appropriate enforcement agency **within 21 days after the completion of the audit or assessment** (section 102(2)(b) of the Food Act). The report must take account of any action taken before the submission of the report to remedy any deficiency identified by the RFSA (section 102 (2)(c)).

A regulatory food safety audit will be considered 'complete' within 14 days or earlier from the beginning of audit activities. This will be the case even if there are outstanding issues not addressed by the food business.

Where critical non-compliance is detected:

The RFSA should carry on the regulatory food safety audit to identify any further critical non-compliances and non-compliances.

The RFSA will then be required to notify the relevant enforcement agency of the unsuccessful audit as soon as possible but in any event within 24 hours after the contravention comes to the RFSA's attention as specified in section 102(6) of the Act.

All regulatory food safety audit reports must be in the form approved by the CEO. It is acceptable for RFSA's to submit their own versions of these forms so long as the information and wording specified in the approved forms detailed below are utilised. Two forms have been approved by the CEO:

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

RFSA's must immediately notify the DOH of:

- changes to their certification or qualifications
- unintentional or suspected breach of the Code of Conduct e.g. conflicts of interest.

RFSA's must immediately notify the relevant enforcement agency of:

- threats, intimidation, bribery
- complaints
- identification of critical food safety issues i.e. critical non-compliances
- unsuccessful audits (further details in Table 3).

RFSA's are required to submit audit reports to the appropriate enforcement agency (local government or DOH, as specified) and provide a copy to the business being audited in accordance with provisions of Part 8 of the Act (refer to point 9.1 of this Guideline). All RFSA reports (except for the reporting of critical non-compliances) must be submitted on the approved form in Appendix 1 within 21 days after the completion of the regulatory food safety audit.

RFSA's are required to make an overall assessment of the performance of the food business demonstrated during the audit in accordance with the categories contained within Table 3 (Audit Outcomes and Amending Audit Frequency). Any determinations in relation to regulatory food safety audit frequency adjustments must also accord with the parameters set out in Table 3 with recommendations for change being reported to the enforcement agency (section 102(7) of the Food Act).

An RFSA may form the opinion that a food business complies with Standard 3.2.1 (and specific requirements of Standard 4.2.4 where applicable) 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 RFSA even if contraventions are detected. The exception to this would be where a critical non-compliance is identified.

Table 3: Audit outcomes and amending audit frequency

| REPORTED AUDIT RESULT | DESCRIPTION | RFSA'S DETERMINATION IN RELATION TO AUDIT FREQUENCY |
|-------------------------------|--|--|
| Incomplete audit | <p>A regulatory food safety audit is considered to be incomplete when the RFSA ceases (or does not begin) the audit because an FSP is not in place.</p> <p>An RFSA 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 non-compliance with food business (including breaches of Food Act) in accordance with their compliance and enforcement policy.</p> |
| Unsuccessful audit | <p>A regulatory food safety audit result is unsuccessful when:</p> <p>in the RFSA's opinion, there are contraventions of the Food Act, the regulations relating to FSPs 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>Or</p> <p>a collection of a number of deficiencies that clearly indicate the FSP is not being implemented that constitute a critical non-compliance 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>RFSA 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 RFSA (section 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 audit result when, in the RFSA's opinion, the FSP has been implemented but the food business does not always follow the documented process (i.e. inconsistent compliance with FSP).</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 or that will cause significant unsuitability of food intended for sale) would automatically make the program marginal. It may take a number of non-compliances against prerequisite or support programs to make the program marginal.</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> |

| | | |
|-------------------------------|--|---|
| Successful audit | <p>A regulatory food safety audit result is successful when the RFSA is confident that the FSP:</p> <ol 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 against prerequisite or support programs.</p> | <p>Audit frequency to remain the same</p> <p>Or 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 detected any contravention of the <i>Food Act</i> or the Food Standards Code (Standard 3.2.1 or Standard 4.2.4) and where the RFSA has a high level of confidence in the FSP. A high level of confidence can be measured in two ways:</p> <ol 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 (within limits set by food business's Priority Classification) if appropriate*</p> |

***NOTE: The food business cannot have their audit frequency decreased unless there is compliance history available to the RFSA and the food business has had no non-compliances identified in two previous audits.**

The RFSA is responsible for discussing all non-compliances with the proprietor of the food business or their representative. The food business proprietor, not the RFSA, is responsible for providing and identifying a solution to any non-compliances. The RFSA'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 (if that is the case).

If the food business produces evidence that a corrective measure has been implemented and is successful in addressing the non-compliance, the RFSA can confirm the solution appears appropriate.

In some instances it may be necessary for the RFSA 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 an RFSA submits information to the enforcement agency that they are satisfied a non-compliance has been rectified, this may negate the need for the enforcement agency to undertake a site visit.

9.2 Follow-up of non-compliances

Deficiencies with the FSP prior to 21 days

For non-compliances that relate to **deficiencies of the business' FSP**, it is the **responsibility of the RFSA** to set an appropriate timeframe for rectification and to follow-up within 21 days as to how the non-compliance has been rectified.

Non-compliances with the legislation and deficiencies with the FSP after 21 days

For non-compliances that relate to the **Food Act or the Food Standards Code (i.e. are not deficiencies with the FSP)**, and **non-compliances that relate to deficiencies in the FSP after the 21 days 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.

Note: Enforcement agencies may require an RFSA to send hand written notes, checklists and computer-based documents of regulatory food safety audits conducted. This may be as a result of a Freedom of Information request, a Ministerial Directive or as part of the enforcement agency's activities e.g. verification program.

9.3 Completion of regulatory audits

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 RFSA should include this detail in their audit report submitted to the enforcement agency. 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 section 63 of the Food Act).

10. Audit allocation

A food business is responsible for ensuring that regulatory food safety audits are completed within the specified audit frequency set by the appropriate enforcement agency (i.e. audited within and not beyond the specified frequency). This includes engaging the services of an approved RFSA.

11. Priority classification and audit frequency

Under the Food Act section 100 enforcement agencies are responsible for determining, in accordance with the WA Priority Classification System (table 4):

- 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.

An RFSA may determine that the current regulatory audit frequency of a food business be adjusted, in accordance with section 103(2) of the Food Act. 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 where applicable Standard 4.2.4) and the requirements of Standard 3.2.1
- any audit compliance history relevant to the FSP, established by the food business.

Table 3 (Audit Outcomes and Amending Audit Frequency) provides the basis for an RFSA to re-determine a particular food business' regulatory food safety audit frequency. An RFSA must consider this framework when making any audit frequency determination.

Under section 102(7) an RFSA must report in writing to the appropriate enforcement agency, giving reasons, if the RFSA considers that the priority classification of a food business that has been audited by the RFSA should be changed. This notification forms part of the audit report contained within Appendix 1. The enforcement agency will review

the determination and amend the priority classification accordingly (Food Act section 100(4)) and advise the food business of their updated priority classification and audit frequency.

Local government enforcement agencies must advise the DOH, if they believe inappropriate determinations in relation to audit frequencies are being made by an RFSA.

The *WA Priority Classification System* is provided in Table 4. RFSA's may only adjust regulatory audit frequencies in accordance with this system.

Table 4: WA Priority Classification System

The CEO of the Department of Health, under section 100(2) of the *Food Act 2008*, has approved the following as the priority classification system in WA for the purposes of the application of the requirements relating to food safety programs:

| Food Businesses Type | Priority Classification | Compliance Arrangements |
|--|-------------------------|---|
| <p>Food businesses required by the <i>Food Act 2008</i> to comply with Australian New Zealand Food Standards Code Standard 3.2.1 (Food Safety Programs)</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 (Food Safety Programs for food service to vulnerable persons) of the Food Standards Code | <p>Priority 1 (P1)</p> | <p>Audit by Food Act approved RFSA 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>An RFSA may determine that the audit frequency be changed in accordance with section 103 of the Food Act.</p> <p>The audit frequency can only be decreased if the food business has had no non-compliances identified in two previous audits.</p> |
| <ul style="list-style-type: none"> Food businesses subject to the requirements of Standard 4.2.4 (Primary Production and Processing Standard for Dairy Products) of the Food Standards Code. (Division 4) | <p>Priority 1 (P1)</p> | <p>Audit by Food Act approved RFSA's with qualifications suitable to the business type.</p> <p>In accordance with regulation 4 of the Food Regulations, the Department of Health is the appropriate enforcement agency for all businesses captured under Standard 4.2.4.</p> <p>Frequency of audit:</p> <ul style="list-style-type: none"> Initial audit frequency: 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>An RFSA may determine that the audit frequency be changed in accordance with section 103 of the Act.</p> <p>The audit frequency can only be decreased if the food business has had no non-compliances identified in two previous audits.</p> |
| <p>Other food businesses not classified yet</p> | <p>Priority 2 (P2)</p> | <p>Not classified at this time</p> |

| | | |
|--|------------------------|--|
| <ul style="list-style-type: none"> Food businesses subject to the requirements of Standard 4.2.4 (Primary Production and Processing Standard for Dairy Products) of the Food Standards Code. (Division 2 and 3) | <p>Priority 3 (P3)</p> | <p>In accordance with regulation 4 of the Food Regulations, the Department of Health is the appropriate enforcement agency for all businesses captured under Standard 4.2.4.</p> <p>Frequency of audit:</p> <ul style="list-style-type: none"> Initial audit frequency: Standard 4.2.4 Division 2 and 3: every 12 months <p>Audit frequency range:</p> <ul style="list-style-type: none"> Maximum 6 monthly Minimum 24 months <p>An RFSA may determine that the audit frequency be changed in accordance with section 103 of the Act.</p> <p>The audit frequency can only be decreased if the food business has had no non-compliances identified in two previous audits</p> |
|--|------------------------|--|

Approved and signed

Dr Michael Lindsay
EXECUTIVE DIRECTOR
ENVIRONMENTAL HEALTH DIRECTOR
Public and Aboriginal Health Division
As the Delegate of the Chief Executive Officer

Appendix 1: Food Act 2008 Regulatory Food Safety Audit Report

Section 102 Approved Form

Version 02: June 2021

Completed report is to be submitted to the appropriate enforcement agency within 21 days of audit being completed by RFSA; provide copy of completed report to food business proprietor.

| Section A: Food Business Details | | | |
|---|---------------------------------------|-------|--------|
| Registered Trading Name of Food Business | | | |
| Proprietor Name | | | |
| Business Address | Tel: | | Email: |
| | Fax: | ABN | ACN |
| | Description and type of food business | | |
| Priority Classification | | | |
| Address of premises where the audit was performed | | | |
| Responsible person for food business premises audited | Name | | |
| | Position | | |
| | Email | Phone | |
| Enforcement Agency | | | |
| Audit scope | | | |

| Section B: Auditor Details | | |
|--------------------------------|---------|--------------|
| Name | | |
| Contact details | Phone: | Work address |
| | Mobile: | |
| | Email: | |
| Approval scope and expiry date | | |

| Section C: Audit Details | | | |
|---|--|---------------------------------|---|
| Is this the first audit? | Yes/No | If 'No', date of previous audit | |
| Review of previous audit report conducted under Part 8 of the Food Act/ enforcement agency regulatory assessment report/regulatory action (conducted under Part 6 of the Food Act e.g. section 63 improvement notice) | Are there outstanding issues? <i>please detail</i> | | |
| Date/s of Audit (and if applicable follow up) | Start time | Finish time | Time off site (desktop audit / reporting) |
| | | | Total time |

Section D: Regulatory Food Safety Auditor Summary

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 following where appropriate:

Standard 3.2.1 of the Food Standards Code in relation to the FSP (refer to 'Verification of FSP Guideline' for assistance with determining compliance)

| | | |
|--|---|---|
| <input type="checkbox"/> YES <input type="checkbox"/> NO | Non-compliances (number) <input type="checkbox"/> <i>(if critical non-compliance provide details on 'Notification of Critical non-compliance form')</i> <input type="checkbox"/> observations* | Critical Non-compliances (number) <input type="checkbox"/> |
|--|---|---|

Standard 4.2.4 Primary Production and Processing Standard for Dairy Products

**Note: Under regulation 8 of the Food Regulations 2009 Clause 15 of Std 4.2.4 does not apply to goats milk*

| | | |
|--|---|---|
| <input type="checkbox"/> YES <input type="checkbox"/> NO <input type="checkbox"/> N/A | Non-compliances (number) <input type="checkbox"/> <i>(if critical non-compliance provide details on 'Notification of Critical non-compliance form')</i> <input type="checkbox"/> observations* | Critical Non-compliances (number) <input type="checkbox"/> |
|--|---|---|

Standard 3.2.2 Food Safety Practices and General Requirements (for premises where Standard 3.3.1 or Standard 4.2.4 Division 4 applies)

| | | |
|--|---|---|
| <input type="checkbox"/> YES <input type="checkbox"/> NO | Non-compliances (number) <input type="checkbox"/> <i>(if critical non-compliance provide details on 'Notification of Critical non-compliance form')</i> <input type="checkbox"/> observations* | Critical Non-compliances (number) <input type="checkbox"/> |
|--|---|---|

Standard 3.2.3 Food Premises and Equipment (for premises where Standard 3.3.1 or Standard 4.2.4 Division 4 applies)

| | | |
|--|---|---|
| <input type="checkbox"/> YES <input type="checkbox"/> NO | Non-compliances (number) <input type="checkbox"/> <i>(if critical non-compliance provide details on 'Notification of Critical non-compliance form')</i> <input type="checkbox"/> observations* | Critical Non-compliances (number) <input type="checkbox"/> |
|--|---|---|

FOOD BUSINESSES MUST ENSURE THEY PROVIDE CLEAR OBJECTIVE EVIDENCE OF CORRECTIVE ACTIONS TO THE RFSA (WITHIN 14 DAYS AFTER THE COMPLETION OF THE AUDIT) TO ENABLE THE RFSA TO ASSESS CORRECTIVE ACTIONS AND REPORT NON-COMPLIANCES TO THE ENFORCEMENT AGENCY WITHIN 21 DAYS.

*observations (e.g. work already in progress, highlighting issues likely to become a problem in the future)

If No – details of non-compliance

**Food Safety Standards/ standard 4.2.4/
FSP Reference**

Section E: Audit Findings and non-Compliance Register

| Reference Number (FSP or FSS, or standard 4.2.4) | Activity audited (Receiving, Storage, Preparation, Cooking, Cooling, rethermalisation, hot and cold Holding, Transport, Display, Serving, post service collection waste management, Cleaning, Dishwashing, Support Programs, Training, Food Recall and Records etc.) | Compliant Y/N Observations | 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, Recommendations and Declaration

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

Refer to Table 3 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 FSP and the requirements of the Food Safety Standards.

If yes, provide details on the determination of the audit frequency change:

To enable a decision to be made on the performance of the food business' food safety program and implementation, the RFSA confirms that (tick as appropriate):

- I have reviewed records and food safety system documents
- I challenged staff competence, skills and knowledge
- I reviewed food production and service (if applicable) during the audit process
- I reviewed facilities and work practises in accordance with the standards

In addition, as an RFSA I acknowledge and affirm the following:

- I have no conflict of interest with the auditee at this time that has not been declared to the Department of Health
- The audit report reflects accurately my review of the audited site and practices performed at the time and date of the report.
- The contents of this review shall remain confidential to the extent permitted by law.

RFSA Signature:

RFSA Name:

Signature of responsible person for food business premises audited:

Date:

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

Approved and signed

Dr Michael Lindsay
EXECUTIVE DIRECTOR
ENVIRONMENTAL HEALTH DIRECTOR
Public and Aboriginal Health Division
As the Delegate of the Chief Executive Officer

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

Food Act 2008 Regulatory Food Safety Audit Report Section 102 (5) and (6) Approved Form: Notification of Critical Non-Compliance Version 02: June 2021

Form to be completed if RFSA becomes aware, during an audit, of a contravention of the Food Act, the regulations relating to food safety programs, or the Food Safety Standards that: (a) is an imminent and serious risk to the safety of food intended for sale; or (b) will cause significant unsuitability of food intended for sale.

Form must be provided to the enforcement agency within 24 hours of the contravention coming to the RFSA's attention. Copy of completed form must be given to proprietor of food business.

| Section A: Food Business Details | | | |
|---|---------------------------------------|-------|-------|
| Registered Trading Name of Food Business | | | |
| Proprietor Name | | | |
| Business Address | Tel | | Email |
| | Fax | ABN | ACN |
| | Description and type of food business | | |
| Priority Classification | | | |
| Address of premises where the audit was performed | | | |
| Responsible person for food business premises audited | Name | Phone | |
| | Position | Email | |
| Enforcement Agency | | | |
| Audit scope | | | |

| Section B: Auditor Details | |
|--------------------------------|--|
| Name | |
| Contact details | Phone: Mobile: Email: Work address: |
| Approval scope and expiry date | |

| Section C: Details of Critical Non-Compliance | |
|---|---|
| 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 regulations relating to FSPs, or the Food Safety Standards and where applicable Standard 4.2.4 Primary Production and Processing Standard for Dairy Products | |
| <input type="checkbox"/> that is an imminent and serious risk to the safety of food intended for sale, or | <input type="checkbox"/> will cause significant unsuitability of food intended for sale |
| <i>Please provide details over page</i> | |
| RFSA Signature | Date |

| Reference Number (FSP or FSS) | Activity audited | Details of Critical Non-Compliance |
|-------------------------------|------------------|------------------------------------|
| | | |

Approved and signed

Dr Michael Lindsay
EXECUTIVE DIRECTOR
ENVIRONMENTAL HEALTH DIRECTOR
 Public and Aboriginal Health Division
 As the Delegate of the Chief Executive Officer

Appendix 3 Minimum requirements for conducting a regulatory food safety audit

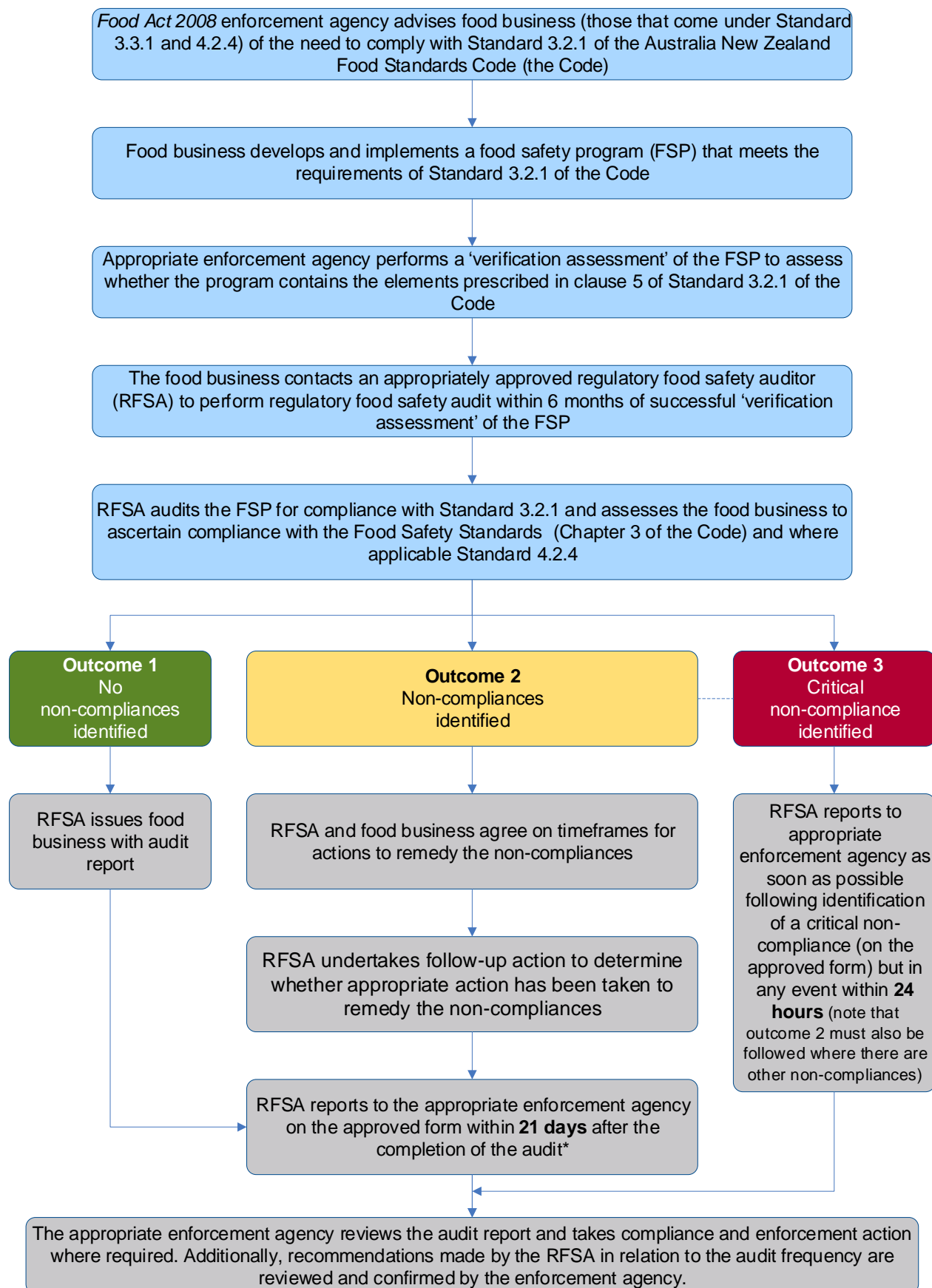
| Audit activity | Minimum requirement |
|--|--|
| <p>Entry meeting Conducted at the start of the audit</p> | <ul style="list-style-type: none"> • appropriate management must be present • introduce RFSA and show RFSA identification card • check FSP is available and onsite • check monitoring records are available, up to date and onsite. • detail the scope of the audit • check that the food business holds a current food business registration • review any changes to activities conducted at the food business that may affect their priority classification • review changes to approved activities or processes • review FSP amendments • previous audit report reviewed and discussed • review of previous enforcement action taken by the enforcement agency • previous non-compliances reviewed and discussed (non-compliances not addressed will be escalated) • determine number of fulltime equivalent employee food handlers at the facility. |
| <p>Conducting the audit</p> | <ul style="list-style-type: none"> • review non-compliances and enforcement action to verify that corrective action has been effective. This is performed in conjunction with the inspection of the food business. • review of FSP to confirm currency and accuracy including: <ul style="list-style-type: none"> ○ flow charts, ○ hazard analysis and control points, ○ validation of critical limits, finished product specifications, ○ monitoring records, product testing results, and verification records. • review of the food business and observation of processing and manufacturing practices • review of food safety support programs • review of audit elements • identify non-compliances and critical non-compliances • complete audit report and notes. |

Exit meeting

Conducted at completion of the audit

- appropriate management present
- audit summary and result (high performance, successful, marginal, unsuccessful, incomplete)
- review non-compliances,
- agree close out timeframes for non-compliances raised at audit
- inform proprietor or person in charge of audit frequency
- check all information is recorded on report
- check food business is fully aware of what information will be communicated back to the enforcement agency
- management to sign audit report
- audit records should detail persons present at entry and exit meetings.

Appendix 4 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**

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

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