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Performance Audit

Administration of the Imported Food Inspection Scheme

Department of Agriculture

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Office of the Auditor-General for Australia



Canberra ACT
10 June 2015

Dear Mr President
Dear Madam Speaker

The Australian National Audit Office has undertaken an independent performance audit in the Department of Agriculture titled *Administration of the Imported Food Inspection Scheme*. The audit was conducted in accordance with the authority contained in the *Auditor-General Act 1997*. Pursuant to Senate Standing Order 166 relating to the presentation of documents when the Senate is not sitting, I present the report of this audit to the Parliament.

Following its presentation and receipt, the report will be placed on the Australian National Audit Office's website—<http://www.anao.gov.au>.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Ian McPhee'.

Ian McPhee

The Honourable the President of the Senate
The Honourable the Speaker of the House of Representatives
Parliament House
Canberra ACT

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Abbreviations

AGIS	Australian Government Investigation Standards
Agriculture	Department of Agriculture
AIMS	Agriculture Import Management System
CDPP	Commonwealth Director of Public Prosecutions
Consignment	An entry of goods that comprises one or more lines imported by the same owner at the same time
Customs	The Australian Customs and Border Protection Service
EMC	Executive Management Committee
FICA	Food Import Compliance Agreement
FSANZ	Food Standards Australia New Zealand
FSM	Food Safety Manager
ICS	Customs' Integrated Cargo System
IFCC	Imported Food Consultative Committee
IFIS	Imported Food Inspection Scheme
Line	The lowest/single commodity description of a consignment of goods
NATA	National Association of Testing Authorities
QAP	Quarantine Approved Premises
The Code	Australia New Zealand Food Standards Code

Summary and Recommendations

Summary

Introduction

1. While Australia is a net exporter of food, around \$15 billion in processed and unprocessed food was imported in 2013–14. These imports have increased at a rate of around five per cent per annum. As food production and processing practices can vary across the world, Australian consumers may potentially be exposed to imported food contaminated by pathogenic micro-organisms or unsafe chemicals if food safety risks are not effectively managed. The harm associated with food-borne illness can be significant, for example, micro-biological contaminations from listeria can cause serious illness or death.

2. Australia is part of a bi-national arrangement involving the Australian Government, states and territories and New Zealand to manage food safety risks. Under this arrangement, the Australian Government Department of Agriculture (Agriculture) is responsible for implementing the Imported Food Inspection Scheme (IFIS) in accordance with the *Imported Food Control Act 1992* (the Act). The Scheme was established ‘to provide for the compliance of food imported into Australia with Australian food standards and the requirements of public health and safety’.¹

Imported Food Inspection Scheme

3. IFIS was primarily designed to enable risk-targeted border inspections of imported food based on domestic food standards.² Under the Act, all food imported for human consumption is categorised as either ‘risk’ or ‘surveillance’ food. Foods classified as posing a medium to high risk to human health by Food Standards Australia New Zealand (FSANZ)³ are treated as ‘risk’ category foods.⁴ All risk foods are to be referred to Agriculture for

1 *Imported Food Control Act 1992*, s. 2A.

2 Food exempt from the Scheme includes food prohibited for biosecurity reasons under the *Quarantine Act 1908*, trade samples, food imported for private consumption and food imported from New Zealand. The Trans-Tasman Mutual Recognition Arrangement between the Australian, New Zealand, and state and territory governments provides for the mutual recognition of regulatory standards across jurisdictions for goods and occupations.

3 FSANZ is a statutory authority established under the *Food Standards Australia New Zealand Act 1991*.

4 Examples of imported food classified as risk food include cheese (soft, semi-soft and fresh), peanuts and peanut products, tuna, mackerel and bivalve molluscs (clams, mussels, and oysters).

inspection at an initial rate of 100 per cent. As a producer builds up a history of compliance with Australian import requirements for a particular food, the rate of inspection reduces to a minimum of five per cent for that particular food from that producer.

4. Foods that are not classified as posing a medium to high risk by FSANZ are treated as ‘surveillance’ category foods under the Act. Five per cent of surveillance foods are to be referred to the department for inspection. If a surveillance food fails inspection, the rate of inspection for future consignments of that food from that producer is to be increased to 100 per cent and stays at this rate until a history of compliance is established.⁵

5. Under the Act, importers may also elect to enter into Food Import Compliance Agreements (FICAs) with Agriculture, which involve different regulatory arrangements. FICAs are a co-regulatory assurance arrangement that allows importers to manage their compliance with safety requirements and food standards as an alternative to IFIS inspection and testing. To qualify for a FICA, importers are required to have in place a quality assurance regime—through a food safety management system—and meet other conditions, including mandatory reporting of detections of non-compliant food. While FICA holders receive faster and more convenient clearance of their products without IFIS inspection and testing, the agreements are subject to periodic audits by Agriculture.

Administrative arrangements

6. The Australian Customs and Border Protection Service (Customs) is responsible for protecting the safety, security and commercial interests of Australians, including facilitating legitimate trade and collecting border revenue.⁶ Customs refers import consignments to the Department of Agriculture for assessment and inspection for biosecurity regulation⁷ under the *Quarantine Act 1908* and food safety regulation under the *Imported Food Control*

5 The increased rate of referral for surveillance food is achieved by the department issuing a holding order under the Act.

6 Australian Customs and Border Protection Service, *Portfolio Budget Statements*, 2014–15, p. 89.

7 Biosecurity can be defined as ‘the protection of the economy, environment and human health from the negative impacts associated with entry, establishment or spread of exotic pests (including weeds) and diseases’. See: Beale, R., Fairbrother, J., Inglis, A. and Trebeck, D. *One Biosecurity, A working partnership, The independent review of Australia’s quarantine and biosecurity arrangements*, Report to the Australian Government, 2008, p. 1.

Act 1992. Consignments of food are only to be subject to inspections under IFIS if biosecurity requirements have been met.

7. The referral of food for IFIS inspection is based on 1500 risk profiles within the Customs Integrated Cargo System (ICS).⁸ These profiles, which are created and managed by Agriculture, refer food to the Scheme when the consignment information declared by importers match certain criteria such as the tariff code, importer, supplier and country of origin codes. When there is a match against the profile, the information about the imported food consignment is electronically transferred to Agriculture's Import Management System (AIMS). Agriculture then uses this information to undertake the inspection process.

8. IFIS is administered by Agriculture's Imported Food Section based in Canberra, which comprises 10 staff within the department's Compliance Division. The food safety inspections conducted under the Scheme are undertaken by departmental staff at ports and warehouses across Australia (many of these staff members also undertake biosecurity compliance activities). These inspections consist of a visual examination to determine if the food appears safe and suitable, and an assessment of food labelling against the requirements of the Australia New Zealand Food Standards Code (the Code).⁹ In addition, private laboratories are engaged by Agriculture as 'appointed analysts' under the Act to conduct analytical testing for microbial, chemical and other contamination.

Recent developments

9. Recent public concerns about overseas food production and incidents of food-borne illness have triggered renewed interest in the regulation of food imported into Australia. In late 2014, two Parliamentary Committee reports on country of origin labelling were tabled.¹⁰ In February 2015, a private Senator's

8 Profiles are a set of risk indicators (for example, based on the importer, goods description or country of origin), that create an alert when an import declaration matches the risk indicator/s. Agriculture is responsible for managing the operation of the risk profiles that it creates.

9 The Code is developed by FSANZ.

10 These reports are: House of Representatives Standing Committee on Agriculture and Industry, *A clearer message for consumers: Report on the inquiry into country of origin labelling for food*, October 2014; and Senate Rural and Regional Affairs and Transport References Committee, *Current requirements for labelling of seafood and seafood products*, December 2014, p. 28. The Government is yet to respond to these reports.

Bill on country of origin labelling was also introduced into Parliament.¹¹ The Bill mirrors a previous Bill introduced in 2013, which lapsed at the end of the 43rd Parliament.

10. In early 2015, there were also reported cases of Hepatitis A linked to the consumption of imported frozen berries and cases of scombroid poisoning linked to imported fish products. In response to these imported food incidents, Agriculture engaged with members of the food regulation network (which had also taken action relevant to their jurisdiction) and implemented a number of measures including: increasing its inspection rates for the manufacturers of identified products; requested a formal review of the risk status of frozen berries from FSANZ; and developed new testing requirements of E. coli as an indicator of process hygiene for imported berries. These incidents have further highlighted the need to appropriately assess and target food safety risks while facilitating the efficient entry of safe and compliant products into Australia (Agriculture's responses to these incidents are discussed further in Chapters 2 and 3).

Audit objective and criteria

11. The audit objective was to assess the effectiveness of the Department of Agriculture's administration of the Imported Food Inspection Scheme.

12. To form a conclusion against this objective, the ANAO adopted the following high level criteria:

- an appropriate governance framework to support effective regulation has been established;
- sound arrangements to collect regulatory intelligence and assess compliance risks have been established;
- a compliance program to effectively monitor compliance with regulatory requirements has been implemented; and
- effective arrangements are in place to manage non-compliance.

13. The audit focused on the delivery of regulatory activities under the Act by Agriculture. The audit scope did not include an examination of the

11 The Competition and Consumer Amendment (Australian Country of Origin Food Labelling) Bill 2015 was introduced by Senator Milne on 12 February 2015.

assessment of food risks by FSANZ or the responses taken by the states and territories in relation to detections of unsafe food.

Overall conclusion

14. In 2013–14, around \$15 billion in processed and unprocessed food was imported into Australia, increasing at a rate of around five per cent per annum. The importation of food from countries with varying production and processing practices has the potential to expose Australian consumers to a broad range of food-borne illnesses if food safety risks are not effectively managed. As part of the bi-national food regulatory system established by Australia and New Zealand to manage food safety, the Department of Agriculture is responsible for implementing the Imported Food Inspection Scheme (IFIS).

15. The Scheme was designed to test whether imported food meets the same safety standards as food produced domestically through targeted border inspections. The level of inspection activity is ultimately determined by the volume of food being imported and imported food risk assessments prepared by Food Standards Australia New Zealand (FSANZ). In the six months to June 2014, 44 648 tests of imported food were undertaken as part of the inspection regime.¹² These tests included label and visual checks and laboratory tests for micro-biological and chemical contamination. The reported compliance rate was 98.5 per cent, with most (79 per cent) instances of non-compliance, referred to as ‘failing food’, due to breaches of labelling requirements.¹³

16. In the context of the legislative framework established for the regulation of imported food, Agriculture’s administration of its responsibilities under the Imported Food Inspection Scheme has been generally effective. In particular: planning for compliance monitoring is informed by food risk assessments prepared by FSANZ; regulatory activity takes into account the compliance history of producers; and actions taken are proportionate to the level of risk presented. Further, inspections are underpinned by a staff capability program, a broad range of procedural guidance material, regular

12 Department of Agriculture, *Imported Food Inspection Data Report January–June 2014*, p. 3. This is the most recent inspection data published.

13 Other causes of failing food related to the following categories: microbiological (including *E.coli*, salmonella and listeria); contaminants (including aflatoxin, histamine and iodine); and chemical (including fluoroquinolones and pesticides).

management verification of activities, and food testing is conducted by independently accredited laboratories. The department has also recently commenced initiatives to make its regulatory activities more client-focused and consistent through the re-organisation of business processes and deployment of new technologies.

17. While accepting that any border inspection regime for imported food will necessarily be risk-based, there is scope to improve aspects of Agriculture's administration of IFIS and strengthen the delivery of regulatory activities under the Scheme:

- The department is yet to establish an appropriate mechanism to gain a sufficient level of assurance that risk profiles are operating effectively and food is being referred for inspection at the prescribed rate for imported food categorised as 'risk' (100 per cent) and 'surveillance' (five per cent).
- The work practices for assessing import documentation and managing inspection activities varies across Agriculture's regional offices. As a consequence, the implementation of important inspection related activities, such as reporting the evasion of inspections and the sale of food prior to inspection, are inconsistent.
- The management of investigations in relation to serious breaches of importer requirements has been variable. The strengthening of investigation practices, particularly in relation to documenting preliminary reviews of reported incidents and appropriately planning investigations, would better position the department to respond to suspected non-compliance.
- The department is yet to develop appropriate performance measures specific to the Scheme and regularly monitor and report against these to: identify and respond to emerging trends and changes in the regulatory environment; and demonstrate to internal and external stakeholders the extent to which the Scheme is achieving its regulatory objectives.

18. In light of recent imported food incidents, Agriculture has given preliminary consideration to legislative reforms that would better assist in the management of food incidents and also provide for systemic improvements in the regulation of imported food. The reforms under considerations would, if adopted, allow the department to: hold food pending the preparation of a risk

assessment by FSANZ; conduct compliance campaigns and intelligence gathering activities beyond risk and surveillance food inspections; and apply holding orders to allow for the establishment of new testing requirements, among other things.

19. To strengthen Agriculture's administration of IFIS, the ANAO has made three recommendations designed to: provide greater assurance over the implementation of prescribed inspection rates; improve the management of inspection related activities and investigations; and enhance performance monitoring and reporting arrangements.

Key findings by chapter

Compliance Intelligence and Risk Assessment (Chapter 2)

20. In recent years, Agriculture has worked to improve its compliance intelligence capability across its regulatory activities, with a primary focus on biosecurity regulation. The regulatory intelligence collected and retained by the department for imported food is, however, limited. Information about incidents, recalls, and breaches of state and territory food regulation are not currently retained in an integrated intelligence system. There is scope for Agriculture to better integrate its intelligence capability through the development of an IFIS compliance intelligence strategy and further strengthen its compliance information sharing arrangements with co-regulators.

21. The classification of imported food as 'risk food' by Agriculture is based on risk assessments prepared by FSANZ, which is in accordance with the legislative framework applying to imported food. There would, however, be benefit in the department making greater use of the compliance intelligence that it collects to build its understanding of the sources of compliance risk and to inform its requests to FSANZ for food risk assessments. These measures would help to ensure that the classification of food and the testing regime for particular categories of food are appropriate over time.

Monitoring Compliance (Chapter 3)

22. Agriculture provides general information on its website and provides direct guidance to importers to encourage voluntary compliance. To complement existing approaches, there would be benefit in the department targeting its communication activities to small-scale importers at risk of inadvertent non-compliance. Further, the limited take-up of FICAs

(considerably lower than expected since their introduction in 2010) suggests that the continuation of awareness activities for high-volume importers with established food safety management systems is warranted.

23. The delivery of inspection activities under IFIS is reliant on the automated referral of information from Customs' ICS to Agriculture's AIMS based on matching individual consignments with the risk profiles in ICS.¹⁴ Agriculture is, however, yet to establish a process to gain an appropriate level of assurance that risk profiles are operating effectively and food is being referred for inspection at the prescribed rate for 'risk food' (100 per cent) and 'surveillance food' (five per cent).¹⁵ In the absence of such a process, the ANAO analysed a sample of Custom's data to examine the matching of consignments to profiles, and their referral to, and receipt by, Agriculture. Of the 152 sampled profiles, all consignments referred from Customs had been received by Agriculture, including 100 per cent of risk food matches.¹⁶ The implementation of a systematic approach to monitoring the referral of food to the department under the Scheme would provide greater assurance that its level of inspections is in accordance with prescribed rates.

24. Agriculture's pre-inspection processing of food referred for inspection and the conduct of inspections is managed through an appropriate range of procedural guidance on key activities, competency requirements for staff, and regular management verifications. The department's arrangements for managing the work of laboratories are generally sound and include performance monitoring and audit processes. Overall, Agriculture has implemented suitable arrangements to monitor the importation of food under FICAs based on the assessment of manufacturer assurance certifications, food tests and the ability to trace a sample of selected consignments.¹⁷

14 These profiles are managed by the department.

15 As a profile owner, Agriculture has access to information in ICS to enable it to manage the effectiveness of its profiles. The department currently undertakes initial checks when amending profiles and conducts limited verification activities in relation to referrals of food from Customs.

16 The ANAO's analysis found that 5.8 per cent of surveillance food matches were referred to Agriculture, which exceeded the prescribed rate of five per cent.

17 The importer of the frozen berries linked to reported cases of Hepatitis A in February 2015 was operating under a FICA. Agriculture had most recently audited the importer on 1 December 2014. The audit identified that the producer of the frozen berries was compliant with an internationally recognised food processing safety standard (British Retail Consortium), with certification provided by the United Kingdom Assurance Service on 21 August 2014.

Responding to Non-compliance (Chapter 4)

25. Once identified, failing food (that is, food found not to be safe or compliant with domestic standards) is to be re-labelled, destroyed, re-exported or downgraded to stock feed, under the supervision of Agriculture. Overall, Agriculture has instituted appropriate responses to failing food identified through its physical inspection and laboratory testing regime. There is, however, scope for the department to improve on the timeliness of issuing holding orders to reduce the risk that further consignments of unsafe or non-compliant food are released without inspection. Further, the varying inspection workflow monitoring practices that are in place across regions increase the risk of inconsistent regulatory decision-making. In particular, the department's reporting of the sale of food prior to inspection, was incomplete and inconsistent. In the two years to June 2014, there were 120 instances of food sold prior to inspection in the South East Region, yet only seven of these (5.8 per cent) incidents had been formally reported in accordance with procedural requirements. By contrast, the South West Region had 22 instances of food sold prior to inspection with 19 incidents reported (86.4 per cent).

26. In responding to identified or reported serious non-compliance, Agriculture has established a requirement for a preliminary review to be undertaken to assist in determining whether an investigation is to be commenced. The department's preliminary reviews of reported incidents were not, however, appropriately documented in 40 per cent of the cases examined by the ANAO, which ultimately limits the transparency of the review process and adversely impacts on the efficient allocation of investigation resources. Once investigations were commenced, 59 per cent were discontinued, 13 of which related to investigations where preliminary reviews had not been fully documented.¹⁸

27. The establishment of appropriate plans and routine monitoring arrangements underpin the effective delivery of investigation activities. Of the 41 investigations examined by the ANAO, only nine cases had an investigation plan developed and three were subject to regular reviews in accordance with the minimum standards established in the Australian Government

18 The main reasons for discontinued investigations were 'no offence detected', 'resolved through discussion with management' and 'insufficient evidence'. These reasons were similar to those underpinning decisions not to proceed to investigation on preliminary review of 40 of the 81 reported incidents.

Investigation Standards (AGIS).¹⁹ Re-enforcing to staff the importance of implementing procedures, coupled with strengthening the management of investigations, would better support timely completion, the preparation of briefs of evidence, and ultimately, Agriculture's implementation of its graduated response to non-compliance.

Governance Arrangements (Chapter 5)

28. Overall, appropriate administrative arrangements are in place to support the delivery of regulatory activities under IFIS, including well-established lines of responsibility between the national office and the regional office network. While staff capability is managed through a specialised training and competency accreditation program, continued effort will be required to help ensure that regional locations are able to efficiently meet the demand for inspection services and that regulatory activities are delivered in a consistent manner.

29. The effective delivery of IFIS is heavily reliant on the IT systems that support the Scheme, in particular the entry workflow management system (AIMS) that receives referrals from Customs ICS, allocates tests and manages inspection related information. In general, core workflow functions are appropriately supported by the department's IT systems. A key limitation of AIMS is, however, its inability to produce exception reports, such as reporting on consignments referred, but yet to be inspected. Regional offices had adopted a range of spreadsheets to address this limitation, which as noted earlier, has impacted on the consistency of the delivery regulatory activities.

30. In general, Agriculture's monitoring and reporting of its regulatory activities relates to its biosecurity compliance activities, with monitoring and reporting in relation to IFIS primarily limited to the periodic tracking of operational activities. The establishment of an appropriate set of IFIS-specific performance measures would better position the department to: identify and respond to trends and changes in the regulatory environment; and measure and report on the extent to which it is achieving regulatory objectives.

19 The AGIS establish the minimum standards for entities conducting investigations relating to the programs and legislation they administer. The AGIS apply to all entities required to comply with the *Public Governance, Performance and Accountability Act 2013* (which includes Agriculture).

Summary of entity response

31. Agriculture's summary response to the proposed report is provided below, with the full response provided at Appendix 1.

The Department of Agriculture (the department) considers the report and findings provide a basis for further improvements to the risk-based management of imported food under the Imported Food Inspection Scheme (IFIS). As noted in the report, imported food is currently estimated to have an overall compliance rate of 98.5 per cent, with most (79 per cent) instances of non-compliance due to breaches of labelling requirements.

The department has committed to reforms of the IFIS in response to growing levels of trade in food and community expectations of both government and importers that were expressed during the Hepatitis A Virus incident linked to imported berries.

The department is working closely with Food Standards Australia New Zealand which is reviewing its risk assessment advice that was previously provided to the department. This will inform the department's risk management strategies under the IFIS to mitigate the risk posed by certain imported food.

Recommendations

Recommendation No. 1
Paragraph 3.22

To gain appropriate assurance that imported food is referred for inspection in accordance with prescribed rates, the ANAO recommends that the Department of Agriculture implement a systematic approach for monitoring the operation of risk profiles and the referral of imported food for inspection under the Imported Food Inspection Scheme.

Agriculture's response: *Agreed*

Recommendation No. 2
Paragraph 4.45

To improve the management of inspection-related activities and responses to non-compliance under the Imported Food Inspection Scheme, the ANAO recommends that the Department of Agriculture:

- a) implement nationally standardised procedures for the management of inspection workflow;
- b) reinforce to staff the importance of consistently applying existing procedures for the reporting of incidents of serious non-compliance;
- c) appropriately document its preliminary reviews of reported serious incidents; and
- d) develop plans for each investigation into reported incidents.

Agriculture's response: *Agreed*

**Recommendation
No. 3**

Paragraph 5.56

To inform management and stakeholders of the effectiveness of the regulatory activities under the Imported Food Inspection Scheme, the ANAO recommends that the Department of Agriculture:

- a) develop appropriate performance measures for the Scheme; and
- b) report against these measures on the extent to which objectives are being achieved.

Agriculture's response: *Agreed*

Audit Findings

1. Introduction

This chapter outlines the framework for the regulation of food imported into Australia and the role of the Department of Agriculture in implementing the Imported Food Inspection Scheme under the Imported Food Control Act 1992.

International trade

1.1 A key driver of globalisation and economic development over the past 50 years has been the rapid growth of international trade. Australia's integration into the world economy has grown dramatically following the adoption of trade liberalisation and other measures. As trade has increased, so too has economic growth and employment. However, the world-wide movement of goods also comes with risks to domestic industries, human and animal health, and the environment. These risks arise from the introduction of exotic pests, diseases and food that is unsafe for human consumption.²⁰

1.2 While Australia is a net exporter of food, in 2013–14, a total of \$14.9 billion in processed and unprocessed food was imported into the country, amounting to six per cent of total imports, representing a trend growth rate of five per cent per annum.²¹ Australia's main food imports are processed fruit and vegetables, processed seafood, soft drink and cordials, with New Zealand the major source of imports, followed by the United States, China and Singapore.

Food safety risks

1.3 Food production and processing practices can vary across the world, particularly in relation to the use of certain drugs, such as antibiotics, and hygiene and storage standards. Food safety risks include contamination by pathogenic micro-organisms and their toxins, unsafe chemicals or chemical residues, and physical factors (Table 1.1 provides further details on risk factors).

20 Recent pest and disease incursions have included European house borer, tramp ants, sugar cane smut, currant-lettuce aphid and equine influenza. These incursions have resulted in significant costs to the \$46.7 billion agricultural sector and the national economy. In 2002, the Productivity Commission estimated the cumulative loss to the national economy arising from a foot and mouth disease outbreak to be around \$2 to \$3 billion in Gross Domestic Product for a contained outbreak, rising to between \$8 and \$13 billion for a 12 month outbreak. Productivity Commission, *Impact of a foot and mouth disease outbreak on Australia*, Research Report, AusInfo, Canberra, 2002, p. xviii.

21 Department of Foreign Affairs and Trade, *Composition of Trade Australia 2013–14*, p. 59.

Table 1.1: Risk factors for imported food

Microbiological Factors	Chemical Factors	Physical Factors
Bacteria (infectious and toxin-producing)	Environmental contaminants	Metal
Protozoa and helminths	Food additives and processing aids	Glass
Viruses	Naturally occurring toxins	Stones
Moulds	Nutritive substances	Plastics
	Dietary macro-components	Wood
	Agricultural and veterinary chemicals	Bone and bone fragments
	Packaging contaminants	
	Allergens	
	Novel food and ingredients	
	Prions	
	Nanoscale materials	

Source: Food Standards Australia New Zealand.

1.4 The harm associated with the realisation of food risks can be significant. Microbiological contaminations from *e. coli*, *listeria monocytogenes* and *salmonella* can cause serious illness or death. Incorrect labelling of food containing allergens, such as nuts, milk or eggs, also has the potential to cause fatalities. The transmission of bovine spongiform encephalopathy (BSE or ‘mad cow disease’) through beef products, while rare, can also be fatal.²²

1.5 While seeking to facilitate and maximise the benefits of international trade, governments have recognised the importance of managing the negative impacts associated with the entry, establishment and spread of pests, diseases and unsafe food. Trade rules, such as the World Trade Organization’s *Agreement on the Application of Sanitary and Phytosanitary Measures*, recognises the role of governments in adopting science-based measures for the protection of human, animal, plant life and health.²³ In line with these measures, the *Quarantine Act*

22 Food Standards Australia New Zealand, *The Analysis of Food-Related Health Risks*, FSANZ, 2009, p. 35.

23 WTO, *Agreement on the Application of Sanitary and Phytosanitary Measures*, Final Act of the Uruguay Round of Multilateral Trade Negotiations, Marrakesh on 15 April 1994.

1908 and the *Imported Food Control Act 1992* frame the biosecurity and human health regulation of food imports into Australia.²⁴

Food regulation system

1.6 Australia is part of a bi-national regulatory arrangement involving the Australian Government, states and territories and New Zealand to manage food safety risks. State and territory health and food regulatory bodies, and through them, local government authorities, are responsible for ensuring that food (both imported and domestically produced), which is available for sale within their jurisdictions, is safe for human consumption and meets the Australia New Zealand Food Standards Code (the Code). The Code is developed by Food Standards Australia New Zealand (FSANZ).²⁵

1.7 Once it has cleared consignments of imported food, the Australian Customs and Border Protection Service (Customs) may refer consignments to the Department of Agriculture (Agriculture) for assessment and inspection under biosecurity regulation. The *Quarantine Act 1908* establishes the requirement that all imports into Australia must comply with biosecurity conditions for entry²⁶, with permits and conditions, import source restrictions, and government certificates and inspections used to manage biosecurity risks.²⁷

1.8 The inspections conducted by Agriculture under the *Imported Food Control Act 1992* (the Act) focus on the safety of imported food for human consumption and compliance with the Code and are only to be applied once imported food has cleared biosecurity requirements for entry. According to the Act, imported food poses a risk to human health if it has been manufactured or transported under conditions that render it dangerous or unfit for human consumption or if it contains:

- pathogenic micro-organisms or their toxins;

24 Beale, R., Fairbrother, J., Inglis, A. and Trebeck, D. *One Biosecurity, A working partnership, The independent review of Australia's quarantine and biosecurity arrangements*, Report to the Australian Government, 2008, p. 3. The Beale Review defined biosecurity as 'the protection of the economy, environment and human health from the negative impacts associated with entry, establishment or spread of exotic pests (including weeds) and diseases' (p. 1).

25 FSANZ is a statutory authority established under the *Food Standards Australia New Zealand Act 1991*.

26 On 27 November 2014, the Australian Government introduced the Biosecurity Bill 2014 into Parliament to replace the *Quarantine Act 1908*, as part of its broader program to strengthen and modernise biosecurity regulation.

27 Examples of biosecurity risks include animal material (hair, fur, skin, faeces, shells, blood), live animals (birds, rodents and reptiles) and plant pathogens (fungi, nematodes, bacteria, viruses).

- micro-organisms indicating poor handling;
- non-approved chemicals or chemical residues;
- approved chemicals, or chemical residues, at greater levels than permitted;
- non-approved additives;
- approved additives at greater levels than permitted; and
- any other contaminant or constituent that may be dangerous to human health.²⁸

1.9 The Act provides the legislative framework for the operation of the inspection regime for imported food—the Imported Food Inspection Scheme (IFIS).

Imported Food Inspection Scheme

1.10 The Department of Agriculture (Agriculture) has had primary responsibility for the inspection of imported food for biosecurity and food safety since 1990.²⁹ The *Imported Food Control Act 1992* provides the legislative basis to enable targeted border inspections of imported food based on domestic standards. These standards are developed by FSANZ and set out in the Code. The Code outlines a series of:

- general food standards, including acceptable labelling, additives and contaminants, and food product standards for categories of food, such as meat, fruits and dairy products;
- food safety standards applying to practices, premises and equipment; and
- primary production and processing standards for categories of food.³⁰

1.11 Inspections under IFIS are primarily focused at the border. When a consignment of food has been selected for inspection, the inspection involves a visual and label assessment and may also include sampling the food for laboratory testing for contaminants, depending on the risk profile of the

28 Section 3(2), *Imported Food Control Act 1992*.

29 Prior to 1990, imported food was generally subject to end-product testing by state and territory authorities.

30 Australia New Zealand Food Standards Code.

particular food.³¹ The inspection regime under IFIS applies to imported food that has been classified, on advice from FSANZ, as ‘risk food’ and ‘surveillance food’ and food imported under Food Import Compliance Agreements.³²

Food risk categories

Risk foods

1.12 Risk food is subject to ‘test and hold’ direction and is not to be released for sale until test results are known. Consignments of risk food that fail inspection and, therefore, do not meet Australian standards or are determined to be unsafe cannot be imported. These foods must be brought into compliance otherwise the food is to be re-exported or destroyed. In those cases where a producer’s or importer’s consignments fail inspection, subsequent consignments from the producer/importer are to be subject to 100 per cent testing of that product until a history of compliance is re-established. Examples of tests applied to risk food are outlined in Table 1.2.

Table 1.2: Examples of tests applied to risk food

Food Type	Hazard	Tests Applied
Cheese—soft, semi-soft and fresh	Micro-organisms	E.coli, listeria monocytogenes, salmonella
Peanuts and peanut products, pistachios and pistachio products	Aflatoxin	Aflatoxin
Beef and beef products	Bovine spongiform encephalopathy (BSE)	National competent authority certificate from a country permitted to trade and includes mandatory declaration
Seafood—bivalve molluscs such as clams, cockles, mussels, oysters, pipi and scallops	Biotoxins and micro-organisms	Paralytic shellfish poisons, domoic acid, E.coli, listeria monocytogenes

Source: Department of Agriculture.

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- 31 A consignment is a unit of imported food referred for inspection under IFIS that comprises one or more batches imported by the same importer at the same time and described by a single line on an import entry.
- 32 Clause 8, *Imported Food Control Regulations 1993*. Food not covered under the Scheme includes food prohibited for biosecurity reasons under the *Quarantine Act 1908*, trade samples, food imported for private consumption and food imported from New Zealand. The Trans-Tasman Mutual Recognition Arrangement between the Australian (Commonwealth), state and territory governments and the Government of New Zealand provides for the mutual recognition of regulatory standards across the jurisdictions for goods and occupations.

Surveillance food

1.13 Surveillance food is all other food subject to the Scheme that has not be classified as risk food. As surveillance food is not considered to pose a medium to high risk to human health, it is subject to a 'test and release' direction and can be distributed for sale before test results have been received. If there are adverse test results, the relevant state or territory food regulator is to be advised, with a recall initiated where considered necessary. Any action, such as a recall or withdrawal, taken in relation to goods released by an importer is to be at the importer's expense. Examples of food-specific tests applied to surveillance food are outlined in Table 1.3.

Table 1.3: Examples of tests applied to surveillance food

Food type	Hazard	Tests Applied
Milk and cream concentrated powders, including powdered infant formula	Micro-organisms	Salmonella
Fish	Chemical	Malachite green, nitrofurans (including furaltadone, nitrofurantoin) and fluoroquinolones (including ciprofloxacin and enrofloxacin)
	Contaminant	Histamine
Fruit—fresh, chilled or frozen, or dried	Chemical and micro-organisms	Pesticides (including acephate benalaxyl, chlorfenvinphos and DDT) and <i>E. coli</i> .

Source: Department of Agriculture.

Food Import Compliance Agreements

1.14 Food Import Compliance Agreements (FICAs) are a co-regulatory assurance arrangement between food importers and Agriculture that allows importers to manage their own compliance with safety requirements and food standards as an alternative to IFIS inspection and testing. In order to qualify for a FICA, importers must demonstrate an ability to implement a quality assurance regime—through a food safety management system and meet other conditions, including mandatory reporting of non-compliant food. While FICA holders receive faster and more convenient clearance of their products without IFIS inspection and testing, the agreements are subject to periodic audits by Agriculture. As at March 2015, 14 importers had entered into a FICA covering a range of food types, including cheese, tuna, peanuts, sauces and condiments. Agriculture has undertaken over 30 audits of FICA holders since July 2012.

Selecting food for inspection

1.15 The Imported Food Control Regulations 1993 set the rate at which risk and surveillance food are to be inspected, as outlined in Table 1.4.

Table 1.4: Inspection rates for risk and surveillance food

	Risk	Surveillance
Initial rate	100 per cent of consignments ('tight')	Five per cent of consignments
Adjusted rate for history of compliance	Five consecutive passes, reduces inspection rate to 25 per cent ('normal') A further 20 consecutive passes, reduces inspection rate to five per cent ('reduced')	No reduction in inspection rate for compliance
Adjusted rate following non-compliance	Return to 100 per cent of consignments for that food	Increased inspection rate to 100 per cent (via a 'holding order' instrument) until five consecutive passes are achieved, then return to the initial rate of five per cent

Source: Imported Food Control Regulations 1993.

1.16 Customs refers imported food for inspection to Agriculture based on risk profiles linked to internationally agreed tariff codes in its Integrated Cargo System (ICS). Consignments of risk and surveillance food are targeted for inspection at rates prescribed in the Imported Food Control Regulations 1993. Agriculture may also take into consideration the compliance history of the importer or producer when selecting imported food for inspection.

1.17 For each category of testing, there is: a minimum number of sample units that must be examined for each consignment; a maximum allowable number of defective sample units; an acceptable microbiological level in a sample unit; and the level that, when exceeded in one or more samples, would result in the consignment being rejected.³³

Managing and enforcing compliance

1.18 Agriculture's *Biosecurity Compliance Strategy* provides guidance to stakeholders, the general community and staff on the management of compliance with both biosecurity and imported food regulation. The

33 These requirements are outlined in the Food Standards Code and Agriculture's procedural guidance.

department's approach to managing compliance is based on its 'responsive regulatory model' that rewards compliance with reduced regulation, provides advice and guidance in response in inadvertent non-compliance and targets enforcement effort towards deliberate and serious non-compliance.³⁴

Measuring and reporting performance

1.19 Agriculture's *Imported Food Inspection Data Report*, published biannually, contains summary data on inspection activity. Inspection data for the period January–June 2014 includes:

- 13 844 lines of imported food were inspected³⁵; and
- 44 648 tests were undertaken as part of the inspection process, including label and visual checks and laboratory testing for microbiological and chemical contamination.

1.20 The reported overall compliance rate was 98.5 per cent based on the tests completed, which is a similar rate to that reported in 2012. Non-compliant food labelling accounted for most findings of non-compliance, which, if removed from the test data, would increase the overall compliance rate to 99.5 per cent.

Scheme administration

1.21 The Scheme is managed in Canberra by Agriculture's Imported Food Section, which comprises 10 staff, within the department's Compliance Division. At January 2015, 147 Agriculture staff were authorised to undertake food safety inspections at ports and warehouses. Food inspections by departmental staff are to consist of a visual examination to determine if the food appears safe and suitable, and an assessment of food labelling against the requirements of the Code.³⁶ In addition, private laboratories are engaged by Agriculture as 'appointed analysts' under the Act to conduct analytical testing for microbial, chemical and other contamination.

34 Department of Agriculture, *Biosecurity Compliance Strategy Our plan for managing biosecurity compliance and enforcement in Australia*, 2012, p. 4.

35 Import entries (consignments) may consist of one or more lines of food product.

36 A series of procedural work instructions have been developed to guide staff on the requirements of visual and label inspections under the Act and the Code.

1.22 The Scheme is funded through cost-recovery arrangements from importers, including fees for inspections. Fees for these services are prescribed in the *Imported Food Control Regulations 1993*.³⁷

Stakeholders

1.23 Key IFIS stakeholders include Commonwealth, state and territory food authorities, importers, and laboratories engaged to conduct biological and contaminant testing. Primary stakeholders include FSANZ, which develops the Code and undertakes risk assessments of imported food, and an Imported Food Consultative Committee, with members representing Agriculture, FSANZ and industry.

Recent developments

1.24 Aspects of the regulatory framework for imported food have been subject to a number of reviews in recent years in response to food incidents and related concerns raised by consumers and industry. In October 2014, the House of Representatives Standing Committee on Agriculture and Industry tabled its report on its inquiry into country of origin labelling for food. The Committee made eight recommendations to clarify country of origin labelling for food products to better inform consumers.³⁸ In December 2014, the Senate Rural and Regional Affairs and Transport References Committee tabled its report on the requirements for labelling of seafood and seafood products. The Committee considered whether the current seafood labelling requirements provide consumers with sufficient information and recommended that cooked or pre-prepared seafood sold by the food services sector be made subject to country of origin labelling requirements.³⁹ In February 2015, a private Senator's Bill on country of origin labelling was also introduced into Parliament.⁴⁰ The Bill

37 The Regulations provide that the inspection of food, including time spent arranging for a person to analyse the food preparing an inspection report and assessing the results, is \$90 for the first half hour and \$45 for each quarter hour after the first half hour. These fees exclude the cost of any laboratory testing that is determined by arrangements made between individual importers and laboratories.

38 House of Representatives Standing Committee on Agriculture and Industry, *A clearer message for consumers: Report on the inquiry into country of origin labelling for food*, October 2014. The Government is yet to respond to this report.

39 Senate Rural and Regional Affairs and Transport References Committee, *Current requirements for labelling of seafood and seafood products*, December 2014, p. 28. The Government is yet to respond to this report.

40 The Competition and Consumer Amendment (Australian Country of Origin Food Labelling) Bill 2015 was introduced by Senator Milne on 12 February 2015.

mirrors a previous Bill introduced in 2013, which lapsed at the end of the 43rd Parliament.

1.25 In early 2015, the Australian Government Department of Health also detected a number of cases of Hepatitis A linked to the consumption of frozen imported berries which were sold in major supermarkets.⁴¹ Regulatory responses included national food recalls of relevant product lines, convening the National Health Incident Room to monitor the issue, and investigations into the issue by OzFoodNet and the Communicable Diseases Network of Australia.⁴² Agriculture's response included: establishing a holding order for relevant products; formally requesting a review of the risk status of frozen berries by FSANZ; engaging with foreign government authorities seeking assurance on further imports; developing new testing requirements; and engaging with co-regulators as part of the national response. The Minister for Agriculture noted that the Government was considering changes to country of origin labelling and foreshadowed a review of the testing of imported food.⁴³

Audit objective, criteria, scope and methodology

Objective

1.26 The audit objective is to assess the effectiveness of the Department of Agriculture's administration of the Imported Food Inspection Scheme.

Criteria

1.27 To form a conclusion against this objective, the ANAO adopted the following high level criteria:

- an appropriate governance framework to support effective regulation has been established;
- sound arrangements to collect regulatory intelligence and assess compliance risks have been established;

41 The frozen berries linked to Hepatitis A were from two particular producers in China, imported by Patties Foods Pty Ltd, under the brand 'Nannas'. In April 2015, Patties announced that it would recommence the importation of berries from different producers and increase product testing.

42 OzFoodNet works with states and territory health authorities to examine the causes and incidence of foodborne disease in Australia, and to provide an evidence base for policy formulation. The Communicable Diseases Network provides national public health co-ordination and leadership, and supports best practice for the prevention and control of communicable diseases.

43 Details of this review are yet to be announced.

- a compliance program to effectively monitor compliance with regulatory requirements has been implemented; and
- effective arrangements are in place to manage non-compliance.

Scope

1.28 The audit focuses on Agriculture's administration of regulatory requirements within the legislative framework in place for imported food to mid-2014. This includes Agriculture's development of its compliance strategy in accordance with statutory prescribed inspection rates, implementation of border inspections and laboratory testing, the investigation of serious non-compliance and management of remedial action. The audit does not examine import regulation by Customs, biosecurity regulation by Agriculture, the assessment of risk food by FSANZ, the regulation of food safety by state and territory authorities, or cost recovery arrangements.

Methodology

1.29 In undertaking the audit, the ANAO reviewed Agriculture's policies and procedures, analysed data and intelligence systems and interviewed inspectors and managers, key Commonwealth state and territory co-regulators, and industry representatives. The ANAO also conducted detailed analysis of a sample of regulatory activities undertaken in the two financial years 2012–13 to 2013–14.⁴⁴

1.30 The audit was conducted in accordance with the ANAO Auditing Standards at a cost to the ANAO of \$499 000.

44 The ANAO sampled 100 per cent of laboratory test results applied to risk food and 20 per cent of all action taken on food identified as non-compliant through inspections. The ANAO also examined all serious incidents reported, all investigations and all enforcement action, and all FICA audits with respect to the Act for the period July 2012 to June 2014.

Report structure

1.31 The structure of the report is outlined in Table 1.5.

Table 1.5: Structure of the report

Chapter	Overview
2. Compliance Intelligence and Risk Assessment	Examines Agriculture's compliance intelligence capability, its assessment of compliance risks and its approach to compliance monitoring.
3. Monitoring Compliance	Examines the implementation of key elements of Agriculture's compliance monitoring arrangements, including encouraging voluntary compliance, inspecting food and auditing compliance agreements.
4. Responding to Non-Compliance	Examines Agriculture's approach to addressing non-compliance with IFIS, including the conduct of investigations and implementation of enforcement action.
5. Governance Arrangements	Examines the governance arrangements in place to support Agriculture's administration of IFIS.

2. Compliance Intelligence and Risk Assessment

This chapter examines Agriculture's compliance intelligence capability, its assessment of compliance risks and its approach to compliance monitoring.

Introduction

2.1 Given the large and increasing volume of imported food entering Australia each year and the limited resources available to conduct assessments against safety requirements and food standards, the effectiveness of the department's regulation depends on a sound intelligence-based, risk-targeted compliance program. The ANAO examined Agriculture's:

- compliance intelligence capability;
- use of intelligence to assess risk(s) of non-compliance; and
- approach to targeting its compliance monitoring arrangements.

Compliance intelligence capability

2.2 The ability of Agriculture to receive and analyse regulatory intelligence depends on the effective collection and analysis of information, reliable internal and external sources of information and the development of appropriate systems to link and manage intelligence.

Planning for compliance intelligence collection and analysis

2.3 In November 2011, Agriculture developed a draft biosecurity intelligence operating strategy, which included coverage of food safety. The strategy outlined a proposed operating model to govern the collection and assessment of intelligence relating to biosecurity and food regulation. While the draft strategy was not finalised by the department, some initiatives foreshadowed in the draft strategy, such as the establishment of a biosecurity focused Compliance Policy Analysis and Intelligence (CPAI) function, have been implemented. The CPAI was established in 2012 to support decision-making in relation to compliance activity and the planning of targeted short-term compliance campaigns.

2.4 The establishment of a biosecurity intelligence function was also raised by the Interim Inspector-General of Biosecurity⁴⁵ in a 2013 review, with the new intelligence unit considered to be an area for further development. The Interim Inspector-General also recommended that the department 'improve its analytical and predictive functions by expanding its strategic operational intelligence capabilities, including the development of a complementary information management system'.⁴⁶ In response to this recommendation, Agriculture noted its plan to develop a whole of department intelligence strategy and review biosecurity intelligence collection. The department also informed the ANAO that it plans to improve the capture and linking of existing data, trial an electronic monitoring system and develop new intelligence products.⁴⁷ The completion of this work will position the department to integrate and make better use of the information it receives from a range of sources.

Compliance intelligence sources

2.5 Agriculture receives information on the importation of food into Australia through the direct transfer of import data from Customs ICS. The data transferred to Agriculture from the ICS includes information on importers, brokers, food and other goods imported into Australia and referred to the department for assessment and possible inspection for biosecurity and food safety purposes. The accuracy of ICS data is reliant on the import declarations provided by importers and customs brokers as well as other regulatory and quality assurance activities undertaken by Customs and Agriculture (this matter is examined further in Chapter 3). The data received from the ICS is transferred electronically into the department's Agriculture Import Management System (AIMS), which also includes additional information on importers and producers (discussed later in this chapter).

2.6 Intelligence on the activities of importers, including incidences of non-compliance, is obtained from the department's regionally-based operational staff (responsible for both biosecurity and food regulatory activities) and co-regulators, and, to a lesser extent, from information provided by members of

45 The role of the Interim Inspector-General of Biosecurity is to enhance the integrity of Australia's biosecurity systems through the independent evaluation and verification of the performance of these programs across the biosecurity continuum—pre-border, border and post-border.

46 Interim Inspector-General of Biosecurity, *Undeclared importation of food from the Republic of Korea detected in December 2010, Incident Review*, May 2013, p. 32.

47 These projects are in an early stage of development.

the public. Agriculture's regionally-based operational staff, including inspectors, use data from AIMS and additional information from importers to conduct inspection activities. The day-to-day interactions that operational staff have with importers provides 'on-the-ground' knowledge of the behaviour of importers within the regulatory system. This knowledge includes the general extent to which importers are aware of their regulatory obligations and importing practices that may have particular intelligence value, such as the importation of similar products under different names into a single warehouse. This accumulated operational knowledge is not, however, systematically collected by the department and linked with other information unless it is formally reported to the investigations unit as a suspected serious breach of regulation.

2.7 The activities of co-regulators in the food regulatory system⁴⁸, in particular cases of non-compliance identified by co-regulators, can be a useful source of intelligence to inform Agriculture's compliance activities and risk assessments under IFIS. The primary means by which the department currently obtains information from co-regulators is through membership of a number of multi-jurisdictional forums as part of the bi-national food regulatory system. The department also reviews publically available information released by co-regulators on food incidents, including national food recall notices and the published outcomes of compliance activities.⁴⁹ The department is, however, yet to establish agreed arrangements with co-regulators to share regulatory intelligence. The absence of agreed arrangements has been recognised by the department, with steps taken during the audit to initiate work on the strengthening of information sharing arrangements, such as the development of notification templates. While this early work is encouraging, further sustained work will be required to develop effective information sharing arrangements that usefully inform ongoing compliance work across jurisdictions.

2.8 While Agriculture has established arrangements to facilitate the reporting of suspected non-compliance with the requirements of the biosecurity and food regulatory systems from external sources such as

48 Such as the Victorian Department of Health and Human Services and the New South Wales Food Authority.

49 The information collected by Agriculture is generally recorded on the department's shared network drives. It is not, however, linked with other information sources, which ultimately limits its usefulness.

industry and members of the public⁵⁰, there are relatively few cases of suspected non-compliance under IFIS each year. Of the 526 cases reported to the department in 2014, five were imported food related matters.

Management of compliance intelligence

2.9 As outlined earlier, AIMS is the primary system used by Agriculture to support the delivery of IFIS. It is used by the department to refer food for inspection (based on data from ICS), allocate tests to be applied to food and manage the inspection process, including the recording of test results. AIMS is also used to store detailed compliance information, primarily related to the biosecurity and food regulatory systems. An overview of AIMS coverage of compliance intelligence is provided in Table 2.1.

Table 2.1: Summary of AIMS coverage of compliance intelligence

Information included in AIMS:	Information not included in AIMS:
<ul style="list-style-type: none"> • import records referred from Customs through ICS, including entry number, importer, broker, product description, tariff code, port of entry, date of entry¹; • directions applied to goods (for example, 'hold for inspection'); • tests applied to food and the outcomes of those tests; and • compliance history of goods and importers under IFIS and quarantine regulation. 	<ul style="list-style-type: none"> • consignment records not referred to AIMS, for example, the 95 per cent of surveillance food that is not selected for inspection and food imported through Food Import Compliance Agreements (FICAs); • non-compliance with regulations not related to IFIS operational sanctions², including evading inspection or the importation of non-compliant food through FICAs; and • non-compliance in relation to imported food regulation outside IFIS and quarantine, such as state and territory food regulation.

Source: ANAO analysis of Agriculture information.

Note 1: Agriculture plans to make the declaration of producer a mandatory requirement for all imported food in 2015. This was a business priority for 2011–12, which was delayed due to the requirement for technical changes in ICS.

Note 2: Operational sanctions, in the context of IFIS, include the supervised destruction or re-labelling of food that has failed inspection, and increased inspection rates for future consignments until a history of compliance is re-established.

2.10 While acknowledging that AIMS was designed as a processing system for the management of consignments through the quarantine and imported

50 Agriculture has established Redline which is a free call service for people to confidentially report information about suspected breaches of biosecurity, meat or food inspection laws. Redline can be accessed by telephone on 1800 803 006 or via the internet at: <http://www.agriculture.gov.au/biosecurity/legislation/compliance/redline>.

food regulatory systems, the system has been used by the department to record intelligence information. Agriculture also uses the Jade Investigator incident and investigation management system to record compliance information relating to the assessment of reports of suspected serious non-compliance with regulation, manage investigations and to prepare briefs of evidence for consideration by the Commonwealth Director of Public Prosecutions (Agriculture's management of incidents and investigations is examined in Chapter 4).⁵¹ The AIMS and Jade systems are, however, operated independently of each other, with no automated functionality to share compliance intelligence between the systems.

2.11 As outlined earlier, Agriculture established its intelligence function in 2012 to support decision-making in relation to its compliance activity. In undertaking this role, the intelligence unit produces reports based on the analysis of ICS and AIMS data, in addition to other internal data sources (such as the Quarantine Premises Register⁵²) and external sources (such as Dunn and Bradstreet company information). The department's use of its intelligence function to support imported food regulation has, however, been limited to the provision of reports on importers as part of the biennial review of FICA holders.

2.12 Overall, regulatory information collected and retained by Agriculture in AIMS is limited to the department's regulatory responsibilities for imported food and quarantine. Relevant information about incidents, recalls, and other information from ICS are not currently retained in an integrated intelligence system. Further, the department does not effectively capture and retain information on breaches of state and territory food regulation, where relevant, with new mechanisms for receiving information on compliance action taken by states and territories currently being explored. There is scope for Agriculture to better integrate its intelligence capability through the implementation of an appropriate intelligence strategy. Further, there would be merit in reviewing existing systems used to capture compliance intelligence and the further development of information sharing arrangements with co-regulators to strengthen the department's evidence base for the assessment of compliance risk.

51 Serious non-compliance in this context refers to breaches beyond operational sanctions, such as moving food to evade inspection or selling food that has failed inspection.

52 Agriculture is responsible for regulating Quarantine Approved Premises as places where post-entry biosecurity management may be carried out on a wide range of: plants; animals; and plant and animal products (section 46A of the *Quarantine Act 1908*).

Assessing compliance risk

2.13 Once collected and analysed, compliance intelligence relating to the food regulatory system provides an important basis on which to assess the risk of non-compliance.⁵³ The assessment of compliance risk may be based on, for example: the type of food; health hazards; the compliance history of importers, brokers and producers; compliance margin⁵⁴; food production processes, and country of origin. The primary approach of assessing compliance risk under IFIS is the categorisation of food, based on a consideration of potential safety hazards, which is to be inspected at prescribed rates. The Imported Food Control Regulations 1993 provides that the rates of inspection are to vary in accordance with categories of food classified as risk, surveillance and compliance agreement food.

2.14 Agriculture's classification of risk food is guided by FSANZ's assessments of food that present a medium to high risk to public health⁵⁵, which is to be referred to the department at a rate of 100 per cent. Food that is not classified as risk or compliance agreement food is to be classified as surveillance food, which is to be inspected at the lower rate of five per cent. While food imported under a FICA is not subject to the IFIS inspection regime, companies operating under the arrangements are subject to periodic audits. In addition, Agriculture is to issue holding orders following the identification of unsafe or non-compliant food at inspections, which compels the inspection of future entries of the food at a rate of 100 per cent until a history of compliance is re-established. Holding orders may also be issued where there are 'reasonable grounds' for believing that food of a particular type would fail inspection.⁵⁶

53 Agriculture also undertakes periodic biosecurity risk analysis to determine the conditions under which certain goods, including food, may be imported into Australia. If food does not meet biosecurity requirements, such as quarantine permits, treatments or pass inspection, it will not be allowed entry. Food is not to be subject to clearance under IFIS unless it is permitted under quarantine conditions. Agriculture's biosecurity risk assessments and policy advice are designed to protect the economy, the environment, social amenity, and human, animal and plant health from the risk of foreign pests and diseases.

54 Compliance margin refers to the gap between the identified level of particular contaminants and the standards against which it is measured.

55 Examples of imported food classified as risk food include cheese (soft, semi-soft and fresh), peanuts and peanut products, tuna, mackerel and bivalve molluscs (clams, mussels, and oysters).

56 Advice obtained by Agriculture in early 2015 clarified for the department that, under the Act, the Secretary (or delegate) must be satisfied that there are reasonable grounds for believing that food of a particular kind would be identified as a 'failing food' before issuing a holding order—that is the food poses a risk to human health or is not compliant with relevant Australian food standards. In practice, the department relies on advice from FSANZ and the Department of Health in forming a view as to whether a food poses a risk to human health.

Food risk assessment and advice

2.15 As the bi-national food standards authority, FSANZ is responsible for assessing food risks taking into account new and emerging food safety issues both domestically and internationally. FSANZ's advice to Agriculture under IFIS is issued in the form of imported food risk statements, designed to be science-based food safety assessments that outline the risks posed by a specific food item to public health. FSANZ is to develop imported food risk statements on request from Agriculture, in response to trigger events, such as imported food incidents, or a scheduled review of previously issued risk statements.

2.16 FSANZ risk statements cover a range of matters, including: the rationale for the decision to assess the food as medium to high risk, descriptions of adverse health effects; consumption patterns; risk factors; compliance history; relevant standards; and the approach taken overseas.⁵⁷ In August 2014, the risk statements for six food items were reviewed and re-issued.

2.17 In addition to scheduled reviews by FSANZ, Agriculture can use its compliance intelligence and compliance risk assessments to request a food risk assessment by the Authority. Since July 2010, Agriculture has made eight requests for imported food risk statements from FSANZ, including two in February 2015. Five of those requests were triggered by external sources, such as the notification of Hepatitis A cases linked to imported frozen berries, rather than departmental risk management activities.⁵⁸

2.18 Agriculture's process for documenting and approving the actions taken to respond to the risk statements issued by FSANZ were largely informal until September 2014.⁵⁹ Agriculture is now required to formally respond to risk statements in accordance with new inter-agency cooperation arrangements established in 2014. The department's response to the six risk food assessments issued by FSANZ in 2014, discussed earlier, included the development of risk management strategies based on classifying the food as risk food and mandating laboratory testing for the hazards identified by FSANZ. Any

57 Since the implementation of IFIS in 1993, the risk list has been reviewed five times—in 1994, 1997, 2001, 2007 and in 2014. The 2014–15 review covers a total of 62 risk statements for 27 food types.

58 Agriculture's request to FSANZ to review the risk status of imported frozen berries was initially triggered by a notification of the Hepatitis A link with the food from the Victorian Department of Health to members of the bi-national food safety network of agencies.

59 Previously, the approval to publish Agriculture's response to risk statements on the department's website was considered as approval of the approach to managing the risk foods.

changes to the testing regime adopted by Agriculture for risk food are to be published on the department's website.

Surveillance food

2.19 As surveillance food generally presents a low risk to public health, Agriculture's monitoring of surveillance food is focused on compliance with the Australia New Zealand Food Standards Code developed by FSANZ. The department's approach is to select specific standards from the Code based on risk, to provide an indication of the overall compliance of a food rather than assessing compliance against the entire Code. Agriculture's policy for determining surveillance food tests is designed to target food based on the most relevant areas of risk. This approach, while generally sound, needs to be supported by systematic and regular review to appropriately target risks and maintain public confidence in the system.

Reviewing surveillance foods

2.20 The tests that Agriculture applied to surveillance foods, which remained largely unchanged between 2007 and 2013, generally included label, visual and food-specific tests for agriculture and veterinary chemical residues, natural contaminants (such as histamine and cadmium), and microorganisms (such as *Salmonella* and *E. coli*).⁶⁰ The department amended the requirements for laboratory tests in March 2013 following recommendations from a commissioned review undertaken by an external consultant. In reviewing surveillance category food tests for Agriculture, the consultant considered:

- the compliance history of the food in Australia and overseas, as well as the compliance margin;
- the nature of the food, or a production or manufacturing issue in exporting countries;
- whether the food is a significant component of the diet; and
- the need for, and availability of alternative monitoring strategies.

2.21 As part of its response to the review, Agriculture developed a draft procedure for a rolling review of surveillance food monitoring arrangements in February 2013. The procedure, which is yet to be formally endorsed,

60 Prior to a link being made to Hepatitis A and imported berries in February 2015, Agriculture had not considered testing for foodborne viruses in surveillance food.

includes decision-making processes for the review of existing surveillance tests and the consideration of new tests, consistent with the approach proposed by the consultant. According to the draft procedure, reviews are to be undertaken by food group and conducted biennially. Agriculture informed the ANAO in April 2015 that it intends to revise the draft procedure and establish a schedule for reviews.

2.22 In September 2014, the department finalised surveillance test reviews for: fruit and vegetables; cereal and grains; and edible fats and oils. The new testing arrangements for fruit and vegetables, implemented in April 2015, replaced the previous requirement for a 49 pesticide screen test with a 108 chemical test.⁶¹ The changes to cereal and grains and edible fats and oils testing were implemented by Agriculture in November 2014. A summary of the revised testing strategy is outlined in Table 2.2.

61 Agriculture informed the ANAO that the implementation of the new chemical screen for fruit and vegetables was delayed due to electronic reporting system issues with laboratories.

Table 2.2: Changes to surveillance food testing (November 2014–April 2015)

Food	Test Applied	Test Removed	Reason
Cereal grains, flours, processed cereals	Arsenic (total) Lead	Pesticide screen 49 residues	Heavy metals not previously tested under IFIS.
Edible oils – plants	Erucic acid	Pesticide screen 49 residues	Residues not relevant. Low consumption. Standard for erucic in Code. Only tested previously in mustard and canola oil.
Highly processed, refined fats and oils (for example, margarine, glycerol)	No analytical test	Pesticide screen 49 residues	Not relevant, low consumption.
Ready to eat frozen berries	E. coli	None	Process hygiene indicator (response to information on process contamination following outbreak of Hepatitis A linked to imported frozen berries)
Preserved and canned fruit	Lead	None	Response to information about levels of lead in preserved fruit. Maximum level for lead in fruit in Standard 1.4.1
Canned fruit	Tin	None	Response to information about levels of tin in canned fruit. Maximum level for tin in canned food in Standard 1.4.1

Source: Agriculture.

2.23 The three reviews undertaken were generally consistent with the draft procedural framework for the rolling review of surveillance tests, although they were not conducted in accordance with the planned timeline.⁶² The surveillance testing reviews contained references to external sources, such as the National Residue Survey Proficient Tests Handbook, the broad rationale for the decisions, laboratory testing and reporting requirements, and methods of implementation. While the reviews noted that Agriculture had consulted

62 According to the planned timeframe for reviewing surveillance food tests as outlined in the draft procedural framework, the final decision on tests to be amended was to take place in March 2014 for implementation in April 2014.

with FSANZ, co-regulators, Imported Food Consultative Committee and laboratories, the reviews did not contain information on the basis on which the new chemicals were selected and details of the consultations with co-regulators and industry. Further, unlike FSANZ risk assessments, Agriculture's reviews of surveillance food tests did not include detailed information on the previous compliance history of the food.

2.24 In general, comments provided to the ANAO by stakeholders indicated a general acceptance of the testing regime applied by Agriculture, particularly in relation to risk foods. There were, however, concerns expressed regarding the limitations of current pesticide tests and a general lack of understanding of the need for certain surveillance food tests.

Additional approaches to assessing compliance risk

2.25 A primary focus on food and its assessed risk by FSANZ, while prescribed by the Act, is one approach to the assessment of compliance risk under IFIS. Alternative approaches include the assessment of information on specific incidents, and importer, broker and producer compliance risks. In addition to routine reviews of risk and surveillance food testing arrangements, Agriculture has worked with other agencies and used compliance intelligence to implement additional testing in response to specific incidents as outlined in Table 2.3.

Table 2.3: Increased monitoring in response to specific incidents

Time Period	Trigger	Action
September 2012 to January 2014	Advice from the Australian Radiation Protection and Nuclear Safety Agency relating to the additional risk of nuclear contaminants from food imported from Japan following damage to Japan's Fukushima nuclear facility.	Agriculture implemented additional testing for radionuclides in prescribed food from Japan.
February 2014 to November 2014	State government notification of a consumer fatality arising from an undeclared allergen in an imported drink. ¹	Agriculture issued a holding order targeting all importers of the drink.
October 2014	Australian Competition and Consumer Commission action under Australian consumer law on artificial honey (based on corn sugar syrup) labelled as honey.	Agriculture issued a holding order targeting the importation of artificial honey and established additional testing arrangements.
February 2015	Australian Government Department of Health OZ Food NET detected cases of Hepatitis A linked to the consumption of imported frozen berries from China.	Agriculture issued a holding order targeting the importation of frozen berries from two manufacturers and: <ul style="list-style-type: none"> • requested a formal review of the risk status of frozen berries from FSANZ; • developed new testing requirements of E. coli as an indicator of process hygiene; • engaged with Chinese Government authorities through the Australian embassy in Beijing, seeking assurances on safety of further entireties of frozen berries; and • contacted other potential importers the frozen berries.
February 2015	A NSW Food Authority investigation scombroid food poisoning identified links with tuna and mackerel products from a particular manufacturer in Thailand.	Agriculture increased the inspection rate for tuna from a Thailand factory to 100 per cent. ² Agriculture also contacted the Thailand Department of Fisheries to inform it of the incident, that border inspection was raised to 100 per cent of consignments and request that it investigate.

Source: ANAO analysis of Agriculture information.

Note 1: The label on the drink was found to be in breach of the Code by failing to declare dairy content.

Note 2: Tuna is classified as risk food and is subject to 100 per cent referral for inspection. When inspected, samples are taken to test for histamine, which is linked to scombroid food poisoning. The factory in Thailand that produced the product linked to this food incident had an established history of compliance and was on the reduced rate of inspection prior to the incident.

2.26 Apart from responding to individual incidents referred to the department, Agriculture has not used its compliance intelligence to develop targeted campaigns or compliance information gathering activities due to legislative constraints.⁶³ Of the 149 reports produced by the department's intelligence unit over the period from 2012–13 to 2013–14, six related to the regulation of imported food. In all six cases, the reports were requested as part of the process of biennial review of FICA holders (this matter is discussed further in Chapter 3).

2.27 By contrast, planning for biosecurity focused compliance activities has involved greater use of compliance intelligence, enabled by more flexible provisions under the *Quarantine Act 1908*. Since 2010, Agriculture has implemented targeted cargo campaigns that comprise short-term compliance activities focused on known or potential biosecurity risks. The campaigns are informed by compliance intelligence and overseen by a National Profiling and Targeting Committee.⁶⁴ While some targeted campaigns have included imported food, the primary focus has been on biosecurity regulation.⁶⁵ There would be merit in Agriculture exploring options for the greater use of intelligence capabilities to inform the development of short-term targeted compliance plans.

Compliance monitoring arrangements

2.28 The delivery of compliance monitoring activities informed by an assessment of compliance risk can direct limited regulatory resources towards those areas of highest risk. Agriculture's approach to compliance monitoring includes a high level strategy to align regulatory action with risk, program-specific operating arrangements and regionally-based implementation of compliance activity.

Compliance strategy

2.29 Agriculture's *Biosecurity Compliance Strategy* outlines the department's approach to the management of compliance with biosecurity and imported food regulation. The Strategy is based on the premise that most stakeholders

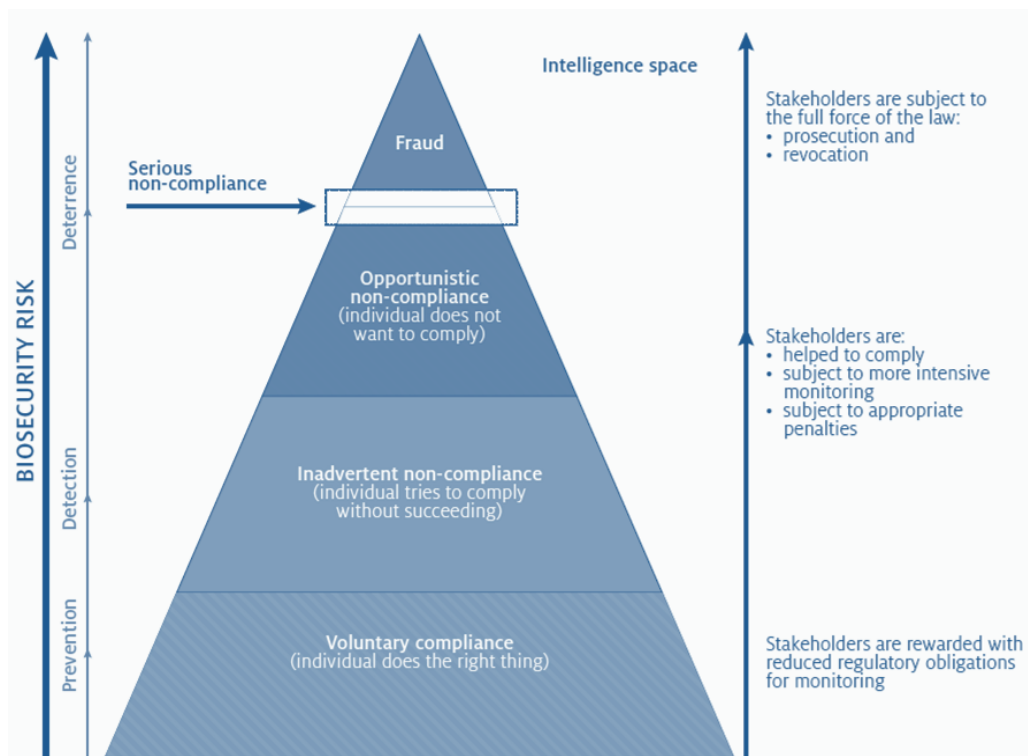
63 The Act currently restricts compliance activities to the inspection of risk and surveillance food. In 2015, Agriculture received advice that holding orders may only be issued where there exists reasonable grounds to believe the food would fail inspection.

64 The role of the National Profiling and Targeting Committee is to provide national direction, prioritisation and oversight of cargo profile intervention and target campaign activity.

65 Operation Hayride (2011) focused on the importation of meat from Korea. Operation Balmain (2012) focused on the importation of bananas from a range of countries.

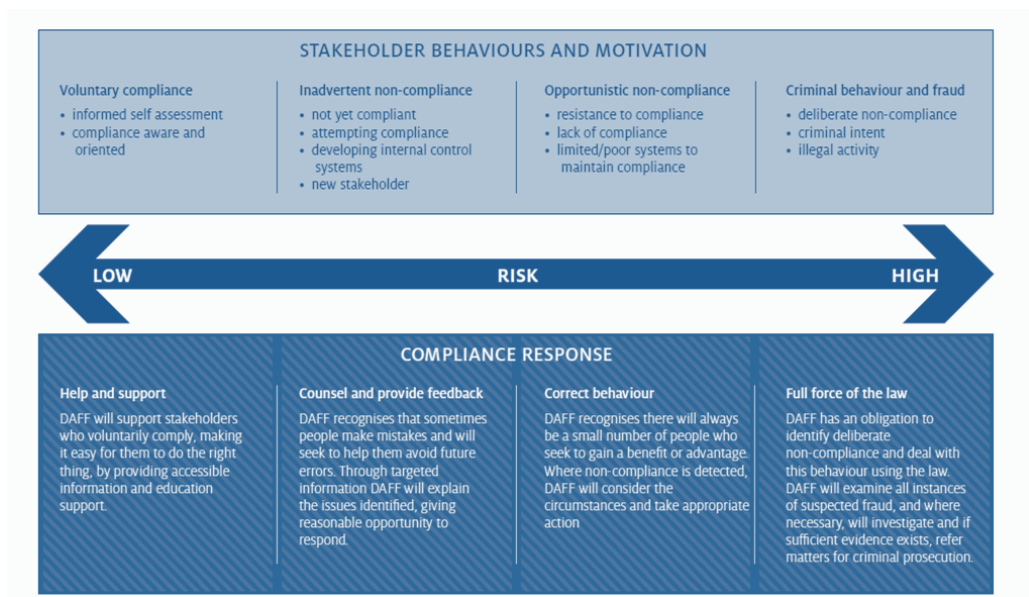
will comply or attempt to comply with their regulatory obligations and outlines a regulatory model of graduated responses to non-compliance proportionate to the level of risk presented, as illustrated in Figure 2.1.

Figure 2.1: Responsive regulatory model



Source: Agriculture (reproduced by the ANAO).

2.30 Agriculture’s compliance response continuum (outlined in Figure 2.2 on the following page) indicates that guidance and support is to be offered to encourage voluntary compliance and feedback is to be used in response to inadvertent non-compliance. Corrective sanctions are to be implemented in response to opportunistic non-compliance and the full force of the law is to be applied to criminal behaviour and fraud.

Figure 2.2: Agriculture’s compliance response continuum

Source: Agriculture (reproduced by the ANAO).

2.31 Agriculture’s compliance response continuum reflects a graduated response to non-compliance with enforcement action weighted towards the most serious and deliberate breaches of regulation. This general model for addressing non-compliance is to apply across the department’s regulatory responsibilities.

2.32 The department has established a range of IFIS-specific operating arrangements, policies and procedures to support the implementation of compliance activities undertaken through its regional offices. These arrangements include:

- the requirement that all inspections (including risk, surveillance and holding order food) include label and visual checks of the food products;
- competency accreditation and verification systems for inspectors and entry processors;
- procedures for the engagement of laboratories to undertake biological and chemical contaminant testing on behalf of the department; and
- separate regime to audit the performance of importers under FICAs.

2.33 Agriculture’s implementation of these arrangements is based on its practice statement system, which includes procedural guidance, work instructions, business rules and operating procedures. The delivery of nationally consistent compliance activities requires the development and regular review of procedural guidance and processes to ensure that regionally-based operational staff are acting in accordance with established requirements.⁶⁶

2.34 Agriculture’s regional offices are tasked with delivering on the department’s compliance strategy and program-specific operating arrangements. As areas within each region have different operational conditions (goods imported and exported, the frequency, volume, and transportation methods), each region is largely responsible for determining its staffing requirements to address inspection workloads within a staffing limit established by the national office. The department is, however, seeking to achieve greater consistency in practices across regions and modernise its service delivery through the development of a National Service Delivery Model (which is examined further in Chapter 5).

Conclusion

2.35 While Agriculture’s compliance intelligence capability has improved in recent years, for example with the introduction of an intelligence unit in 2012, its management of intelligence related to imported food is hindered by a lack of integration between its primary inspection system, AIMS, and other relevant information on incidents, recalls, and breaches of co-regulator legislation. Further work on linking information based on an intelligence strategy, and arrangements to share intelligence with state and territory authorities, would better position the department to support compliance planning and decision-making with a sound evidence-base.

2.36 Agriculture’s classification of risk food is appropriately based on FSANZ risk assessments, in accordance with the legislative framework for the regulation of imported food. However, the department has made limited use of its compliance intelligence and assessments of compliance risk to inform its requests of FSANZ for food risk assessments and more often relies on external triggers. There is scope for the department to make greater use of its

⁶⁶ Agriculture’s quality assurance and verification activities are examined in Chapter 3.

compliance intelligence to help ensure that food is appropriately classified as risk or surveillance, and that the tests that are applied over time are appropriate.

2.37 Agriculture's arrangements for determining surveillance food tests have evolved since 2013 and are maturing. To help ensure that surveillance food tests are appropriately aligned to changing risks over time, there would be benefit in Agriculture finalising its procedural framework for the rolling review of surveillance food tests. There is also scope for the department to explore options to use its regulatory intelligence to inform imported food compliance activities. Targeted short-term campaigns specific to imported food compliance risks, would be a useful addition to Agriculture's graduated actions in response to non-compliance directed towards opportunistic and deliberate breaches of regulation.

3. Monitoring Compliance

This chapter examines the implementation of key elements of Agriculture's compliance monitoring arrangements, including encouraging voluntary compliance, inspecting food and auditing compliance agreements.

Introduction

3.1 The importation of safe and compliant food depends on importers appropriately managing the risks associated with their goods and Agriculture effectively monitoring compliance with regulatory requirements. The ANAO examined Agriculture's implementation of primary regulatory activities under its graduated approach to monitoring compliance:

- encouraging voluntary compliance by communicating regulatory expectations;
- sampling, inspecting and applying laboratory test results to risk and surveillance food; and
- auditing Food Import Compliance Agreements (FICAs).

Encouraging voluntary compliance

3.2 Agriculture encourages voluntary compliance primarily through the provision of general guidance and advice, direct engagement with importers, and the promotion of FICAs. These activities are linked with the department's Compliance Division Stakeholder Engagement Strategy, which is discussed further in Chapter 5.

General guidance and advice

3.3 Agriculture maintains a dedicated webpage for IFIS, which provides general information on the scheme.⁶⁷ The webpage includes information on tests applied to food, FICAs, fees, tailored information for consumers, importers and laboratories, and minimum documentary requirements. The information available from the website is supported by information made available to subscribers through an imported food electronic distribution list,

67 Available from: <<http://www.agriculture.gov.au/biosecurity/import/food/inspection-scheme>>.

which is used to convey news such as changes to testing requirements for particular food products.

3.4 Stakeholders are also able to contact Agriculture directly via telephone, the internet or in person to obtain information on the regulation of imported food. In 2014, the department established a new system for monitoring general enquiries, with initial data reports on general enquiries suggesting that imported food is not a major stream of interest from stakeholders contacting the department. This is consistent with the department's monitoring of client feedback. In the period from July 2012 to April 2015, Agriculture received 887 complaints of which nine related to imported food. In the same period, 387 compliments were received of which one related to imported food.

Direct engagement with importers

3.5 Direct engagement with importers may be initiated by Agriculture as part of its processing of entry documentation prior to an inspection, or by importers providing documentation or scheduling an inspection. Often the initial contact is made between Agriculture and brokers, who subsequently provide information and documents to their client importer to facilitate an inspection. As brokers are required to be licenced under the *Customs Act 1901* and tend to work with more than one importer, they are generally more familiar with the biosecurity and imported food regulatory systems.

3.6 As there are minimal industry barriers, a large number of businesses import a small number of food consignments each year.⁶⁸ These small scale importers, in particular, have fewer opportunities to interact with Agriculture and build an understanding of the regulatory system. In 2013–14, 586 brokers facilitated 510 828 quarantine and food consignments for 91 277 importers. Of these, 74 257 (81 per cent) had only one or two consignments for the financial year referred by Customs to Agriculture for assessment and inspection. Of the 3599 importers of food over the same period, 2180 (or 61 per cent) had only one or two entries referred under IFIS. In contrast, the top 10 food importers had an average of over 500 referrals.

3.7 Certain small-scale importers, such as those catering for niche cultural markets, are at risk of inadvertent non-compliance if they are not adequately

68 There are no licencing or fit and proper person requirements to import food.

informed of regulatory requirements.⁶⁹ Agriculture is yet to develop information, such as pamphlets in English and in other languages, to communicate imported food regulatory requirements to importers. By contrast, information on biosecurity, animal and plant health and use of farm chemicals is available on the department's website in 23 languages and pamphlets are produced for biosecurity regulation.⁷⁰ The absence of targeted information for new importers highlights the important educative role of inspectors in encouraging voluntary compliance, in addition to their primary role of monitoring compliance.

Promotion of compliance agreements

3.8 Importers may apply to Agriculture to enter into a FICA to manage their compliance with food standards as an alternative to routine inspections under IFIS. The 'trusted' arrangement offers industry a faster, more convenient and cost effective clearance of food. In order to qualify for a FICA, importers must meet certain conditions, assessed by Agriculture, including having a food safety management system in place that is periodically audited by the department.⁷¹

3.9 As at February 2015, 14 importers have entered into FICAs since the agreements were introduced in 2010—considerably lower than Agriculture's initial expectation of 30–50. The department's initial activity to promote FICAs was undertaken through the Imported Food Consultative Committee, workshops for importers and the recruitment of FICA trial participants. To encourage further take up of FICAs, Agriculture reviewed import data to identify importers most likely to be interested in the arrangement. In the period from 2012 to 2014, the department directly approached 66 importers, four of which undertook a FICA gap audit for a detailed assessment of suitability, while a further nine expressed interest in the arrangement. Agriculture also published a pamphlet in July 2013 to further promote the availability of FICAs.

69 Large volume importers are generally subjected to greater levels of inspection activity and are more likely to be compliant if they have in place a food safety management system, recognised by major retailers, to assist in managing imported food risks.

70 As part of Agriculture's Portfolio Multicultural Plan 2013–15, the department has undertaken to develop a language and communication plan for its culturally and linguistically diverse clients.

71 FICA holders have commented to the ANAO that they were satisfied with the arrangement, noting that their food safety management systems, recognised by major retailers, require a broader range of food testing than that required by Agriculture.

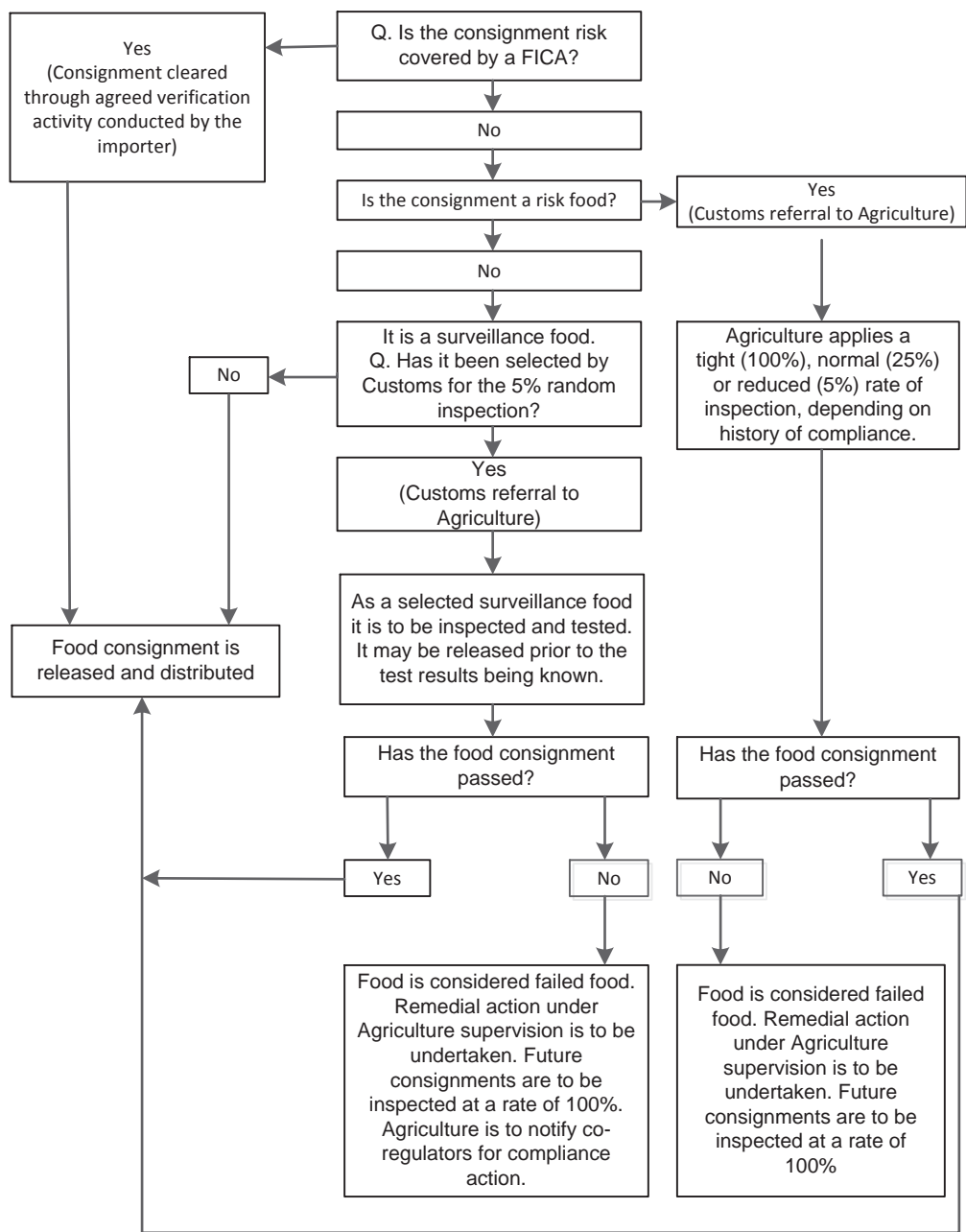
3.10 The ANAO sought comments from stakeholders regarding the take-up of FICAs, with importers advising that there may be a reluctance to enter into the arrangement because the agreements exclude quarantine obligations, must cover all food imported by the agreement holder, and may require the restructure of internal business processes to fit the FICA model. Large-scale importers that supply major retailers with a wide range of products have well-established supply chain management processes, controlled by different operating divisions, that may not easily be integrated into a single FICA.

3.11 Given the key role that education and awareness activities play in managing compliance with regulatory requirements, it is important for Agriculture to effectively communicate with both small and large-scale importers. There would be merit in Agriculture continuing to encourage FICAs for the high-volume importers with food safety management systems and to consider possible changes to the arrangements to make the agreements more accessible (while ensuring that relevant risks are managed). As more high-volume importers take up FICAs, small-scale importers will potentially be subject to more routine IFIS inspections. As such, there is scope for the department to consider the development of specialised communication products for small-scale importers.

Inspecting risk and surveillance food

3.12 As outlined earlier, imported food must first pass through customs and quarantine clearance before it may be subject to inspection under IFIS. The process for selecting food for inspection (once it is cleared for customs and quarantine purposes) involves the following stages: the referral of food for inspection by Customs' ICS; pre-inspection entry processing; label and visual inspections; and laboratory testing, if applicable (the process is summarised in Figure 3.1).

Figure 3.1: Summary flowchart of imported food regulation under IFIS



Source: ANAO from Agriculture information.

Referral of food for inspection

3.13 Importers (or their brokers) are required to register their details on ICS and provide Customs with a declaration when arranging for the importation of goods.⁷² The required entry information to be provided includes the type of goods, country of origin and applicable tariff code. Agriculture uses risk profiles within ICS to identify food subject to IFIS coverage based on the entry information provided by the importer. As at February 2015, there were 1500 ICS imported food profiles managed by the department containing a range of parameters, such as:

- tariff code;
- importer, supplier or country of origin codes;
- exceptions to IFIS referral (for example, food imported under FICAs); and
- the importers' answers to additional 'community protection' questions about the food.⁷³

3.14 The imported food profiles currently in place do not, however, target imports on the basis of brokers, producers of surveillance food or importers who had previously imported failing food under a different name.⁷⁴

3.15 Once consignment information matches a profile in ICS, the record is to be electronically referred to the Agriculture Import Management System (AIMS) for possible inspection under IFIS. A consignment may match multiple profiles (for example, risk and surveillance profiles) and be referred under more than one category, in which case it would be referred as risk food. However, if the food is not declared correctly then it may not match a profile and may not be referred. To monitor compliance with import requirements, Customs undertakes a range of assurance activities, including cargo control

72 There are two types of Customs declarations: Full Import Declarations; and Self Assessed Clearance Declarations for consignments with a value of less than \$1000.

73 The additional questions are designed to assist the selection of food for inspection by providing a level of detail that is not generally covered under tariff codes. An example of a community protection question is: 'are the goods poultry pate or poultry livers that have been cooked?' (answer 'no' to this question if the product is canned and shelf stable)'.

74 If the previous failure was due to chemical or microbiological contamination, the profile is to target the food, regardless of the importer, whereas future inspections of particular food triggered by previous label and visual failures are to target the importer.

and compliance checks, general monitoring and targeted declaration assessments.⁷⁵

3.16 As outlined earlier, the rate of referral to Agriculture is specified in the Imported Food Control Regulations 1993 as 100 per cent for risk and holding order food and five per cent for surveillance food. Once the food is referred, it is subject to Agriculture's compliance verification processes. Agriculture has procedures in place to help ensure that its profiles are matching the goods as intended, including initial system checks when amending profiles and quarterly reporting of profile matches for commercial quarantine and imported food entries. The department does not, however, have monitoring arrangements in place to determine whether entries of imported food are being referred from Customs at the prescribed rate. Moreover, profile effectiveness reviews of imported food profiles are not undertaken, limiting the ability of the department to determine the extent to which referred imports matched the intended profile.

3.17 In the absence of routine monitoring of the performance of imported food profiles, Agriculture undertakes annual verifications of a sample of food to assess the level of food referred for inspection against ICS data on relevant tariff codes. For example, the department's July 2014 verification focused on five profiles covering beef and seaweed tariff codes (less than one per cent of all profiles). The aim of the verification was to gain assurance that the selected profiles had referred entries to Agriculture at a rate of 100 per cent. The verification compared import data referred at 100 per cent from ICS with AIMS imported food data for the calendar year 2013. No major issues were identified by Agriculture as part of the verification process.

3.18 Notwithstanding the insights gained from the verification process, the selection of food subject to the assessment was not representative of the total population of profiles. Further, the conduct of the verification process six months after the period of assessment also creates an increased risk of a profile not operating correctly for over one year before it may be identified and corrected. As the verification process did not assess actual referrals against total imports into Australia for each food category, there is insufficient assurance that risk profiles are operating effectively. As a result, Agriculture

75 Customs' assurance activities are designed to support Customs' regulatory responsibilities rather than the specific regulation of imported food.

has limited assurance that it is appropriately targeting imported food at the prescribed rates.

3.19 In the absence of a routine monitoring arrangement to determine whether the rate of Customs referral of food to Agriculture was in accordance with prescribed rates, the ANAO reviewed the performance of a random sample of 152 profiles, stratified in proportion to the total population in operation between July 2012 and June 2014 (27 risk, 80 holding order and 45 surveillance). The sampled risk profiles matched 13 961 consignments of which all were received in AIMS by Agriculture. Similarly, the holding order profiles matched 235 consignments in ICS, all of which were received in AIMS. In relation to the 192 284 consignments that matched the sampled surveillance profiles, 11 169 (5.8 per cent) were received in AIMS (see Table 3.1).

Table 3.1: Summary referrals from selected profiles (July 2012–June 2014)

	Risk	Holding Order	Surveillance
Prescribed referral rate (per cent)	100	100	5
Profiles sampled	27	80	45
Profile matches in ICS ¹	13 961	235	192 284
Matches referred from ICS ²	13 961	235	11 169
Average rate of referral from ICS (per cent) ³	100	100	5.8
Received by Agriculture ⁴	13 961	235	11 169 ⁵
Average rate of referral received (per cent)	100	100	5.8

Source: ANAO analysis of Agriculture and Customs information.

Note 1: Profile matches and referral data based on entry number from Customs ICS data extract.

Note 2: Based on Customs ICS data extract.

Note 3: Based on Customs ICS data extract.

Note 4: Based on entries in AIMS relevant to the categories of risk, holding order or surveillance.

Note 5: The 11 169 referrals received by Agriculture includes the following surveillance profile entry matches: 10 346 entries received as surveillance referrals; 50 entries received as holding order referrals; 684 received as risk referrals; 72 entries received as risk and holding order referrals, 17 entries that were subsequently amended by brokers.

3.20 The ANAO also reviewed Agriculture's list of surveillance food profiles to assess the risk that food subject to IFIS may not be identified for referral due to its tariff code. Of the 194 general and specific tariff codes covered by surveillance food profiles intended to cover all food, two food

commodities were not covered.⁷⁶ The ANAO also identified nine further technical amendments required to update the surveillance food list and profiles. Overall, in the absence of a systematic review of the effective operation of profiles, Agriculture is not well positioned to demonstrate that inspection levels are in accordance with prescribed rates.

3.21 The implementation of a systematic approach to monitoring the referral of food to the department under the Scheme would provide greater assurance that its risk profiles are operating effectively and that inspections are conducted in accordance with prescribed rates. This approach could include analysis of existing data to determine whether: profiles correctly apply the relevant criteria (including the tariff code); the criteria appropriately target the intended food; that profile matches are referred at the prescribed rate; and that matches referred are received into departmental systems as intended.

Recommendation No.1

3.22 To gain appropriate assurance that imported food is referred for inspection in accordance with prescribed rates, the ANAO recommends that the Department of Agriculture implement a systematic approach for monitoring the operation of risk profiles and the referral of imported food for inspection under the Imported Food Inspection Scheme.

Agriculture's response: *Agreed*

3.23 *The department notes that there is already a considerable body of evidence providing assurance that, on the whole, referrals are being transferred appropriately into its systems. This includes testing processes that are conducted when a new profile is created or amended and some internal auditing, done by the Imported Food section, to verify that legislated referral rates for specific foods are being met.*

3.24 *The department will develop and implement a process to provide additional assurance that import consignments profiled in the Australian Customs and Border Protection Service's Integrated Cargo System are referred correctly into the Agriculture Import Management System.*

76 Tariff codes 201 (beef, fat component only, fresh or chilled) and 202 (beef, fat component only, frozen) were not covered by existing surveillance profiles.

Pre-inspection entry processing

3.25 When a consignment of imported food is referred to Agriculture, Customs is required to notify the importer of its conditional release subject to quarantine approval and/or a food control certificate.⁷⁷ The notification also advises the importer to provide additional import documentation to Agriculture to enable the department to assess the entry. Mandatory import documentation includes a lot code list, a laboratory nomination form, importer information, including inspection location and an invoice or packing list that links each food to each line of the referral.⁷⁸

3.26 When entry information on risk food is received by Agriculture, a system generated check is performed by AIMS on the compliance history of the food. The entries may then be randomly sampled for inspection (at the prescribed rate) and allocated tests. Tests are initially allocated to food by AIMS based on the tariff code declared by the importer. As some tariff codes may not sufficiently represent the particular type of food being imported, Agriculture is also required to assess the documentation provided by the importer against the information about the consignment in AIMS to confirm that:

- the food is not exempt from IFIS (for example, food for private consumption);
- the tariff code, country of origin, producer and any foreign government certificates have been declared correctly;
- AIMS has correctly applied tests to the food; and
- any community protection lodgement questions have been answered correctly.

3.27 On the basis of the outcome of the assessment, Agriculture may issue a food control certificate to authorise the release of the food without inspection (if the risk food was not selected for inspection⁷⁹), request further documentation or

77 A food control certificate is issued under the *Imported Food Control Act 1992* (s.12)

78 A 'lot' is a quantity of food of a particular kind prepared under the same general conditions from a particular packing or preparation unit during a particular period (usually indicating a 24-hour period of production). A lot may be identified by marks or codes devised by the manufacturer. Examples are expiry dates, use by dates, best before dates, production dates, date of manufacture, or packing dates. Where the code is not clear, importers may provide an explanation.

79 The three sampling rates for risk food are 100 per cent for 'tight', 25 per cent for 'normal' and five per cent for 'reduced'.

permit the movement of the food to premises where an inspection can be undertaken.⁸⁰ The department may change the tests to be applied to the food where it is considered that the AIMS applied tests are not appropriate.⁸¹ In cases where entry processing staff determine, on consideration of the importer's documentation, that lines referred as risk food are not risk food, it is the department's policy that all tests including any surveillance tests applied to the food are removed and the product is not inspected.⁸²

3.28 In 2013–14, 88 414 lines of food were referred to Agriculture of which around half (44 782) had tests removed at the entry processing stage. The most common tests removed were labelling and visual (mandatory tests for any food to be inspected) and salmonella, listeria, aflatoxin and E coli. In general, the removal of tests was on the basis that the test was not considered appropriate for the food, with other reasons including administrative change, sampling plan applied, personal consignment and trade sample.

3.29 To undertake entry processing of imported food without supervision, Agriculture staff are required to complete competency-based training and job card requirements (examined further in Chapter 5). Procedural guidance for the assessment of documentation and allocating tests has also been established to underpin consistent decision-making. In addition, Regional Food Safety Managers (FSMs) are required to verify samples of entry processing each month and address any identified procedural non-compliance. The outcomes from this verification work are to be reported to the national office, which is responsible for monitoring subsequent action.⁸³

3.30 In 2013, Agriculture conducted five audits to assess a sample of FSM verifications in each region, re-examining entry processing and assessing the implementation of further action in response to issues identified.⁸⁴ The audits found that regional offices had effectively implemented national verification

80 Where information, such as tariff code appears to have been declared incorrectly, the department is to request the importer to amend its entry in ICS.

81 Decisions to amend tests are recorded in AIMS.

82 The removal of tests is undertaken so that the re-classification of food as surveillance food does not result in the legislated five per cent inspection rate being exceeded.

83 In addition to the imported food-specific assurance processes, biosecurity targeted campaign and cargo compliance verification system arrangements have been established to support quarantine and imported food processes.

84 An audit was undertaken in each region and involved: observing a monthly entry verification exercise; examining six previously completed monthly entry verifications; reviewing officer training records; reviewing records management for entry processing; and reviewing actions following previous audits.

procedures while noting variable processes in place to manage entry inspection workflow. In particular, each region had established different processes for the storage of documentation and allocation of entry processing work. To help ensure that entry-processing decisions are soundly-based and nationally consistent, it will be important for Agriculture to maintain its program of procedural verification and progressively address inconsistent regionally-based processing practices.⁸⁵

Label and visual inspections

3.31 Importers are requested to contact Agriculture to arrange an inspection within three weeks of receiving a food control certificate. Generally, inspections occur at premises (such as a warehouse) nominated by the importer. Surveillance food may be released after inspection prior to the finalisation of test results whereas risk/holding order food may only be released after testing is finalised and the food is found to be safe and compliant. Inspectors are required to manually complete a one page inspection report.⁸⁶

Inspection process

3.32 Under the established inspection policy, all inspections must include visual and label tests in addition to any microbiological and chemical tests that may be deemed necessary. The application of tests is guided by work instructions on sampling, with the aim of ensuring that the portion selected for testing is representative of the consignment.⁸⁷

85 The impact of Agriculture's regionally-based practices on the consistency of regulatory activity is examined later in this chapter and in Chapter 4.

86 As part of the Agriculture's Service Delivery Modernisation Program, the department plans to introduce tablet devices to enable inspectors to electronically complete inspection reports. The Service Delivery Modernisation Program is discussed further in Chapter 5.

87 The approach to sampling may vary depending on whether the food is surveillance or risk/holding order, and how the consignment is declared. The number of lines under the same tariff or the number of food commodities referred under different tariffs within the same line, will determine the number of lines, lots and batches to be inspected. For example, where there are two–eight lines in an entry under the same tariff, two lines are to be subject to inspection and/or laboratory testing.

3.33 Once the sample is selected, visual and label tests are to be undertaken. The purpose of visual tests is to identify unsafe and unsuitable food, guided by the Code as follows:

Food is not safe if it would be likely to cause physical harm to a person who might later consume it ...

Food is not suitable if it –

(a) is damaged, deteriorated or perished to an extent that affects its reasonable intended use;

(b) contains any damaged, deteriorated or perished substance that affects its reasonable intended use ...⁸⁸

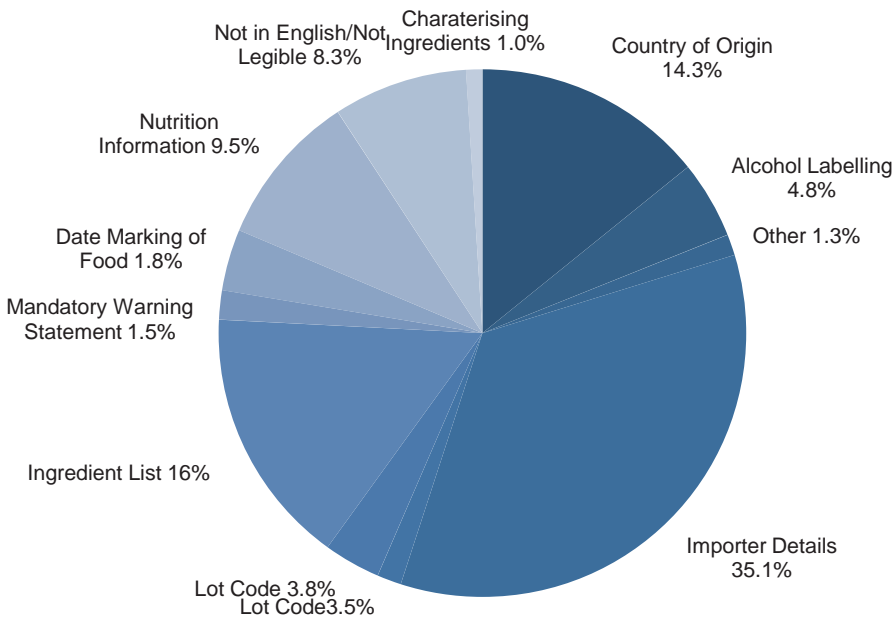
3.34 Labelling tests are based on the Australia New Zealand Food Standards Code, requirements assessed during a label inspection including whether the label:

- is legible and in English;
- states the product name;
- includes the lot code or production / packing date;
- provides directions for use and storage;
- includes mandatory warning and advisory statements;
- discloses the country of origin; and
- contains a list of ingredients.

3.35 Agriculture has reported that, of the 682 food failures under the Scheme (in the period January to June 2014), 537 (79 per cent) were due to breaches of labelling requirements (as outlined in Figure 3.2).⁸⁹

88 Standard 3.1.1 2(1) and 3.1.1 2(4) of the Australia New Zealand Food Standards Code.

89 Department of Agriculture, *Imported Food Inspection Data Report January–June 2014*, p. 3. This is the most recent inspection data published.

Figure 3.2: Sources of non-compliant labelling

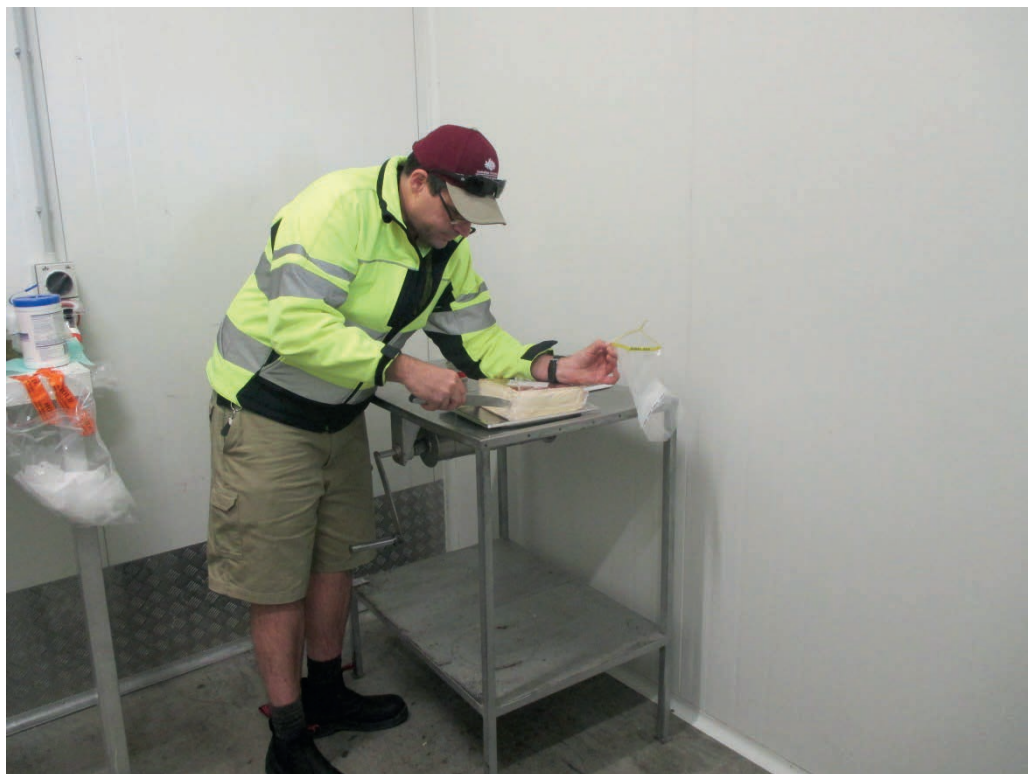
Source: Agriculture.

Extraction of samples for laboratory testing

3.36 It is critical that any samples taken by the inspector for laboratory testing are extracted in a manner that retains the integrity of the product. This means using sterile knives/spoons, clean sealable containers, tamper evident bags and portable fridge/freezers. To support appropriate food sampling techniques, Agriculture has established procedures for the selection and extraction of samples for laboratory testing, including aseptic and non-aseptic sampling techniques. The general requirement outlined in Agriculture's procedures for sample sizes for laboratory testing is five 100 gram sub-samples per sample.

3.37 The ease of extracting samples for testing varies across food types. For example, the risk of contaminating a sample is low for certain food products, such as canned tuna, which can be sampled across five cans, without compromising the integrity of the product. Other food, such as a large wheel of cheese or a barrel of concentrated frozen orange juice, can be more challenging to extract a suitable sample, particularly in a refrigerated warehouse with limited facilities (Figure 3.3 shows an imported food inspector extracting samples of cheese for laboratory testing at an importer's warehouse).

Figure 3.3: Agriculture inspector extracting samples for laboratory inspection



Source: ANAO attendance at Agriculture inspections 2014.

3.38 Once extracted, samples are to be secured in a tamper evident bag and taken to an Agriculture regional office, registered and stored for collection by the importer’s nominated laboratory. It is the responsibility of the importer to contact their nominated laboratory to advise that an inspection has been undertaken and that samples are to be collected from Agriculture for testing. In relation to this aspect of the inspection regime, laboratories advised the ANAO that importers are not always prompt in informing its laboratories that samples are available for collection. These delays have the potential to impact on the timeliness of laboratories’ registration of samples, which is monitored by the department (examined later in this chapter). Notwithstanding this issue, Agriculture has appropriate procedures in place for the extraction and management of samples for laboratory testing.

Managing inspection workload

3.39 In the period from July 2012 to June 2014, Agriculture conducted over 33 000 inspections under IFIS. While the department has not established target

timeframes for the conduct of inspections or the notification of final outcomes, on average, food is inspected 11.9 days after arrival and final notification of the outcome, including processing time for laboratory test results, is 19.1 days.

3.40 Regions with significant food imports generally conduct inspections in accordance with the average national time from the arrival of the consignment in Australia and the final notification of the inspection outcome. There is variability across regions in the time taken to process laboratory test results following inspections. The national average time to assess a laboratory test result and allocate a pass/fail outcome is 2.2 days, ranging from 1.5 days in the Central East Region to 3.4 days in the South East Region.⁹⁰ These variances primarily relate to the different procedures established to manage inspection workflow across regions.

3.41 The three east coast regions, which were visited by the ANAO during the audit, have established different processes designed to ensure that importers provide additional documentation where required, that importers book inspections, that inspections are undertaken and pre-inspection processing is completed. For example, the North East Region informed the ANAO that it extracts information from AIMS on a daily basis to review outstanding entries, while the Central East Region extracts a much broader range of AIMS data on a monthly basis.

3.42 The procedures for follow-up action with importers also vary across regions. Of the three east coast regions, the South East Region is more likely to request a letter of explanation when an inspection is not arranged, whereas the Central East Region has a procedure in place to issue reminder emails to importers that do not arrange inspections within three weeks of the food control certificate being issued.⁹¹ The adoption of different workflow monitoring process across regions presents an increased risk of inconsistent decision-making on significant issues, such as when to report a missed inspection as an incident.⁹²

90 Post-inspection processing of laboratory test results is measured from the time the result is received by Agriculture to the time of the notification of the outcome to the importer. The department's approach to assessing laboratory test results is examined later in this chapter.

91 Procedural guidance has not been established for staff on the use of letters of explanation.

92 The reporting of incidents is examined in Chapter 4.

Microbiological and chemical testing

3.43 Agriculture has appointed laboratories to undertake testing of imported food samples⁹³, with these laboratories responsible for a range of activities, including:

- transporting food samples from Agriculture’s regional offices to their facilities;
- handling, processing, and storing samples;
- reporting test results through the department’s e-Results system;
- destruction and disposal of unused and partially processed samples; and
- documenting the movement of samples (from receipt to destruction).

3.44 As at December 2014, 10 laboratories were appointed under the Act, servicing importers across the country. The level of work undertaken by each laboratory depends on its nomination by importers, which is influenced by the range of tests it provides and the cost to the importer for undertaking the tests. Some importers have established ongoing arrangements whereby all testing of imported food samples are undertaken by the one laboratory.

3.45 Once all required tests have been completed, laboratories are required to report on the level of microbiological or chemical detected in each sample for the required test. Procedural guidance is in place to assist laboratories report on test results, with results conveyed electronically to Agriculture on the eResults system. On receipt, Agriculture staff are to individually review each test result and assign a pass or fail with reference to the acceptable limits for the test as prescribed in the Code.

3.46 In the period from January to June 2014, Agriculture reported that a total of 10 009 laboratory tests had been undertaken with an overall compliance rate of 98.6 per cent—ranging from 98.3 per cent for chemical tests and 98.8 for microbiological tests.⁹⁴

3.47 The ANAO reviewed laboratory results for risk food tested from July 2012 to June 2014 to assess the extent to which Agriculture had applied the

93 The *Imported Food Control Act 1992* (s. 34) provides Agriculture with the authority to appoint laboratories.

94 Department of Agriculture, *Imported Food Inspection Data Report January–June 2014*, pp. 9-10.

Code in making decisions to pass or fail food. During this period, laboratories provided Agriculture with 29 430 test results for risk food across 24 tests. The ANAO's analysis of reported results identified variability in approaches across laboratories, with laboratories reporting results in a variety of formats. This variability hinders the ability of the department (and the ANAO) to electronically verify the department's application of the Code. As a consequence, the ANAO was unable to analyse Agriculture's assessments for four tests.⁹⁵ Of the 27 828 laboratory test results that were analysed by the ANAO, Agriculture's assessment was consistent with the Code in 27 791 (or 99.9 per cent) cases.⁹⁶

3.48 While acknowledging that any incorrect application of the Code may have serious consequences for consumers and costs to industry, given the very large number of laboratory tests undertaken, overall Agriculture's decision-making on test results is largely in accordance with the requirements of the Code. However, the variation in the reporting of results provided by laboratories increases the risk that results may be misinterpreted and hinders electronic verification and quality assurance. While Agriculture has taken steps to improve the consistency in the reporting of test results by laboratories⁹⁷, it will be important for the department to continue working with laboratories on this issue to support accountable decision-making and minimise the cost to industry and risk to consumers of incorrect decisions.

Monitoring the work of laboratories

3.49 Agriculture undertakes a range of activities to monitor the performance of laboratories, including: biennial audits of compliance against the department's conditions of appointment; an annual review of timeliness in reporting test results to the department; and routine monitoring of issues as they arise.

Biennial audits

3.50 In August 2013, Agriculture undertook 12 audits of laboratories that included verifying laboratories' testing capabilities and accreditations with the National Association of Testing Authorities, Australia. While the audits

95 These four tests were for staphylococci, standard plate count, pesticides and cadmium tests that had been undertaken on 1602 occasions.

96 A small number of inconsistencies (nine) were identified in Agriculture's application of outcomes for five tests: listeria; E coli; histamine; aflatoxins and colour screen.

97 Agriculture has worked with laboratories to improve the consistency of test reports through the facilitation of workshops, reviewing and updating procedural guidance and engaging with laboratories on an individual basis.

identified overall compliance with the department's conditions of appointment, they did identify several issues including analysts reporting a small number of tests outside their testing capability.⁹⁸

Review of laboratory timeliness or reporting

3.51 Agriculture monitors the timeliness of laboratories' processing of samples from the date of inspection to the registration of the sample (conditions of appointment specify three business days) and the date of registration to the date that the result is reported (10 business days). The department reported that the average processing time across all laboratories from the date of inspection to the date that the sample was registered was two days. The ANAO's analysis of AIMS data confirms these figures. Performance information against reporting measures is provided to laboratories and the Imported Food Consultative Committee. The average processing times across all laboratories for reporting of results by type of test range from 12 days for chemical tests to six days for microbiological tests.

Monitoring of issues

3.52 Agriculture maintains an issues register to record and address operational issues raised by laboratories and departmental staff, such as testing timeframes, the reporting of results and the collection of samples. The register details actions taken by the department and the outcomes of that action, and is maintained by staff within the Imported Food Section in Canberra.

3.53 In the period from July 2012 to June 2014, there were 82 issues recorded, of which the majority (55 per cent), related to laboratories not reporting results in accordance with program guidelines. Of the 82 recorded issues, 55 (67 per cent) were raised by departmental staff, 20 (24 per cent) by laboratories and the remaining seven (9 per cent) raised through verification forms. Of the recorded issues, 61 were recorded as resolved. The average time taken by Agriculture to resolve the issues was 6.2 days ranging from zero (resolved on the day reporting) to around 10 weeks.

98 The department informed the ANAO that it had responded to issues identified through the audits, for example, the laboratories conducting tests outside their testing capability were found to be using accredited subcontracted laboratories, records had been updated to identify these arrangements and corrective action taken to prevent recurrence.

Auditing compliance agreements

3.54 As outlined earlier, importers may apply to Agriculture to establish a FICA to self-manage their compliance with regulatory requirements as an alternative to departmental inspections. A key obligation of an importer under a FICA is to implement a food safety management system, which includes the following elements:

- clear allocation of responsibilities and authority for the FICA;
- education and training in food safety of personnel;
- requirements for premises and equipment;
- food risk assessment procedures;
- manufacturer assurance;
- must be fully documented and reviewed at least once every 12 months⁹⁹; and
- procedures to inform Agriculture of food failures.

3.55 Agriculture has established procedures for the assessment of food safety management systems for FICA applications and auditing the performance of importers under the arrangements.

3.56 Agriculture relies on the assurances provided by third parties in assessing FICA applications and conducting audits. The department requires FICA holders to maintain manufacturer assurance for imported food products from a recognised certifier, such as the United Kingdom Assurance Service, in accordance with an internationally recognised standard such as the Hazard Analysis Critical Control Point, the British Retail Consortium Standard and Quality Management Systems. Given this requirement, it is generally more likely that unsafe food would be identified and addressed through a food safety management system than routine IFIS testing due to the much broader scope of system testing required under recognised food quality assurance systems.

3.57 Agriculture accepted the manufacturer's assurance provided by a third party in its assessment of the FICA application for the company responsible for the importation of frozen berries linked to an outbreak of Hepatitis A in

99 Reviews of food safety management systems may include internal management reviews and external reviews commissioned by management in accordance with a recognised food quality assurance standard.

February 2015.¹⁰⁰ While the manufacturer’s assurance on food safety controls did not prevent the release of contaminated food in this instance, it would have been more likely to have been identified through certified process hygiene controls under a food safety management system than through routine IFIS tests, which does not require manufacturer assurance and specific testing for what was, at that time, considered to be a low risk food.

FICA audit regime

3.58 Once approved, all importers that enter a FICA are to be audited by the department approximately eight weeks after commencement and future audits are to be determined by the classification of the food imported under the agreement and previous audit performance. The FICA compliance regime, updated in 2013, is outlined in Table 3.2.

Table 3.2: Food Import Compliance Agreement audit regime

Import Type	‘A’ rating at Previous Audit	‘B’ rating at Previous Audit	One or More Critical Non-compliance Recorded at Previous Audit
Where only surveillance food is imported	9 months	4 months	2 months
When risk food is imported	6 months	3 months	Monthly

Source: Agriculture.

3.59 Audits of FICAs are to have regard to the following criteria:

- Manufacturer assurance—the auditor is to randomly select five entries from ICS to assess whether the imports are covered under the FICA holder’s approved supplier list and that the food safety assurance of production processes remains current.
- Food safety management system assessment and verification of testing—the auditor is to review FICA control procedures and supporting documentation, including the product testing records for the five selected imports.

100 Agriculture had most recently audited the importer on 1 December 2014. The audit identified that the producer of the frozen berries was compliant with an internationally recognised food processing safety standard (British Retail Consortium), with certification provided by the United Kingdom Assurance Service on 21 August 2014.

- Process controls and traceability—the auditor is to review the FICA holder’s inventory management system that is used to manage and control stock to ensure that non-compliant product is not released.

3.60 While the audits are scheduled at the convenience of the FICA holder, the food entries that are to be sampled by the departmental auditors are not disclosed prior to the audit commencing. The department’s examination of selected food entries during audits is reliant on the FICA holder’s retention of complete and accurate records, including laboratory test results. There is, however, a risk of food entries being re-tested by a FICA holder until they meet requirements, with records of earlier failed results being discarded or not recorded.¹⁰¹ As such, there would be merit in Agriculture reviewing options to mitigate the risk of deliberate non-compliance when reviewing its FICA audit methodology.

Agriculture’s conduct of audits

3.61 In the period from July 2012 to June 2014, 34 FICA audits were conducted for the 10 active FICA holders. Nine of the FICA holders during this time imported either risk or both risk and surveillance food and were subject to the risk food testing regime. On average, risk audits were undertaken every six months in accordance with the requirements of the FICA audit regime. In one instance the first audit was undertaken 17 weeks after the FICA commenced (nine weeks late).¹⁰² In relation to the 34 completed audits, 33 either resulted in a ‘pass’ or ‘A’ rating with no more than four advisory findings and no more than two advisory findings issued as a result of a single audit.¹⁰³

3.62 Agriculture made a total of 15 corrective action requests arising from the 34 audits (see Table 3.3 for an overview of corrective action requests). On average, the department set the deadline to implement the action 30 days from the date of issue, ranging from 14 to 44 days. These requests were closed on average one day after the deadline (or one day late)—ranging from 25 days early to 39 days late.

101 It is a breach of FICA conditions to re-test food that has failed laboratory testing.

102 An eight week initial compliance audit was delayed to enable the audit to be undertaken at the same time as another audit and, thereby, reduce departmental travel expenses.

103 In one instance an audit was rated ‘A-B’, which was not in accordance with the audit rating procedures for a risk food compliance audit.

Table 3.3: Categories of corrective action requests issued

Category of Corrective Action Request	Number Issued
Failure to update FICA documentation	3
Non-compliance with testing requirements	2
Expired or missing food certification documents	6
Non-compliance with food importation requirements	3
Other	1
TOTAL	15

Source: ANAO analysis of Agriculture information.

3.63 Agriculture’s FICA audit regime is appropriate for importers with sound compliance histories, established food safety management systems in operation and who seek to voluntarily comply. There have been no FICA audits that have identified instances where importers have distributed food that poses a risk to human health.

3.64 Agriculture’s implementation of its FICA arrangements are, however, less effective for importers that present risks of opportunistic non-compliance, as demonstrated by the following case study.

FICA Case Study

An importer submitted an application for a FICA in 2012, with Agriculture initially advising the importer that it was unwilling to enter into the arrangement due to the importer's history of non-compliance with imported food and quarantine regulation.

In 2013, the importer contacted Agriculture seeking reconsideration of its FICA application. In its reconsideration of the application, the department produced an intelligence report, indicating that the company directors had been charged with offences under the *Quarantine Act 1908* and *Criminal Code Act 1904* in 2010 and 2011. It was also noted that the importer's 'performance and compliance history since the offences had been good, with no other critical non-conformities' recorded. The intelligence report recommended that Agriculture not enter into further agreements with the company while the company directors remained in positions of authority.

In April 2013, Agriculture agreed to continue with the assessment of the suitability of the importer as a FICA holder, with its recent compliance history taken into consideration. An initial audit was undertaken of the importer's premises to ascertain its suitability to enter into a FICA in June 2013. The importer officially re-applied for a FICA in July 2013 and, in August 2013, the department approved the application.

The eight week initial compliance audit was delayed to enable the audit to be undertaken at the same time as another audit, and thereby reduce departmental travel expenses. At that audit, two corrective action requests were lodged. One was issued for food safety assessments for two products, and two certification records for another supplier expired (five months prior and one month before they commenced the FICA). A further corrective action request was issued at the following compliance audit in June 2014, relating to the lack of a food safety assessment for one company. All corrective action requests were closed out in accordance with established timeframes.

In May 2014, anonymous information was provided to Agriculture alleging that the company had provided falsified analysis certificates to facilitate the release of goods for sale. An investigation into this allegation is currently underway.

3.65 In assessing applications for trusted arrangements, such as FICAs, it is prudent to seek additional advice, particularly where intelligence reports raise doubt about the suitability of an applicant. Where a decision is made to enter into an arrangement with an importer presenting a higher risk of non-compliance, the audit regime to be applied should be adjusted to account for that higher risk with greater compliance measures. As noted earlier, the methodology for routine audits should include measures to identify and respond to deliberate non-compliance. Suspension of the arrangement should be formally considered where a company is under investigation for breaches of that arrangement.

Conclusion

3.66 Agriculture monitors compliance with imported food regulation in accordance with its *Biosecurity Compliance Strategy* by encouraging voluntary compliance through the provision of information and assessing compliance through inspections, tests and audits. The department's encouragement of voluntary compliance has focused on providing general information on its website and promoting FICAs. There is, however, scope for the department to develop targeted communication products for small-scale importers at risk of inadvertent non-compliance. Further, with industry take up of FICAs considerably lower than expected since their introduction in 2010, there would be merit in the department continuing to promote the arrangements to high volume importers with established food safety management systems.

3.67 The management of the imported food inspection process is subject to potential leakage points involving the referral of food for inspection, pre-inspection entry processing, the inspection process and post-inspection processing. The department is, however, yet to establish a sufficiently robust approach to monitoring the operation of risk profiles that would provide greater assurance that inspection levels are in accordance with prescribed rates.

3.68 Agriculture has appropriate arrangements in place to manage pre-inspection processing of entries referred to the Scheme and the conduct of inspections including, competency requirements for staff, procedural guidance on key activities and regular management verifications. However, the department's adoption of regionally-based processing practices presents an increased risk of nationally inconsistent regulation. Further, as noted in Chapter 2, the department's use of inspection and testing data to inform the development of its compliance strategy is limited. There would be merit in the department making greater use of its compliance intelligence to help ensure the effective targeting of its regulatory activities.

3.69 The arrangements established by the department for the management of the work of laboratories engaged under IFIS are generally sound and include performance monitoring and audit processes. Agriculture's allocation of final outcomes to laboratory test results in accordance with the Food Standards Code is generally sound, acknowledging that the inconsistent reporting formats presents an increased risk of misinterpretation of testing results. The results for certain tests, such as listeria and aflatoxin, are at particular risk of misinterpretation due to the variance in laboratory reporting.

The standardisation of the reporting of test results is an area for specific attention.

3.70 The procedures for monitoring compliance of importers who hold FICAs have been established by the department and have been refined over the five years since the arrangements have been in operation. The agreements offer streamlined clearance processes for FICA holders with a reasonable level of assurance on the safety and compliance of food being demonstrated. While Agriculture has implemented generally appropriate arrangements to manage FICAs, there is scope to better align its compliance approach with the risk posed by individual importers.

4. Responding to Non-Compliance

This chapter examines Agriculture’s approach to addressing non-compliance with IFIS, including the conduct of investigations and implementation of enforcement action.

Introduction

4.1 The importation of food that is not safe for human consumption or does not meet food standards can have potentially serious consequences for consumers. Effective responses to non-compliance, once identified, should be, applied consistently, fully documented, meet core requirements of the Australian Government Investigation Standards (AGIS)¹⁰⁴ and graduated in proportion to the level of risk. The ANAO examined Agriculture’s management of:

- food failures;
- reported incidents;
- investigations of incidents; and
- enforcement action.

Food failures

4.2 When imported food is determined by Agriculture to be unsafe or non-compliant following inspection, it is to be deemed ‘failing food’ under the Act.¹⁰⁵ Food failures are generally classified as visual, label, composition, chemical, microbial or contaminant, with the department issuing the relevant importer with an Imported Food Inspection Advice setting out the details of the food failure. As an operational sanction, the Act requires future consignments of the food to be subject to a 100 per cent inspection rate until a compliance history is re-established. To prevent failed food from reaching consumers, importers are also required to take one of the following forms of remedial action:

104 The AGIS establish the minimum standards for entities conducting investigations relating to the programs and legislation they administer. The AGIS apply to all entities required to comply with the Public Governance, Performance and Accountability Act 2013 (which includes Agriculture).

105 Section 14(1)(c) of the Act.

- treat the food to bring it into compliance with the Act (for example re-labelling);
- destroy the food;
- re-export the food; or
- downgrade the food to stock-feed.

4.3 The Imported Food Inspection Advice provided to the importer of the failed food contains a declaration to be completed by the importer setting out its intended remedial action with respect to the food. The department's policies specify a period of seven days for importers to advise of their intended action, which is to be carried out under the department's supervision at an additional inspection.

4.4 In the period from July 2012 to June 2014, a total of 1890 lines of imported food failed out of 126 000 lines inspected during 33 000 inspections. Of these failed food lines, the ANAO examined 378 (20 per cent) including 136 risk, 191 surveillance, 47 holding order and four Food Import Compliance Agreement (FICA) foods, to assess Agriculture's responses to the failures, including its completeness, timeliness and compliance with procedures. A breakdown of the characteristics of the sampled failed food is provided in Table 4.1.

Table 4.1: Sampled failed food characteristics (2012–14)

Food Category	Risk	Surveillance	Holding Order	FICA	Total
Label	44	150	25		219
Micro-biological	67	3	1	4	75
Composition		21	14		35
Chemical	4	15	7		26
Contaminant	19	2			21
No BSE certificate ¹	1				1
Visual	1				1
Total	136	191	47	4	378

Source: ANAO analysis of Agriculture information.

Note 1: Bovine Spongiform Encephalopathy (BSE) is a transmissible and fatal neurodegenerative disease that affects cattle (commonly known as mad cow disease). Agriculture requires all imports of beef and beef products to be accompanied by a compliant BSE certificate.

4.5 According to Agriculture's procedures, decisions on failed food are to be reviewed by both the regional FSM and the national office through a Failed Food Notification (FFN) form. Surveillance food failures also require authorisation to raise a holding order to refer all future imports for inspection under IFIS until a history of compliance is established.

4.6 The department's documentation on failed food was generally complete with 353 (93 per cent) of sampled cases having a completed FFN appropriately reviewed, signed and dated. However, nine FFNs could not be located, five had evidence of a review, but were not signed and dated, six were not signed and five were not dated. Of the 191 surveillance food failures, all had holding orders in place, although a holding order authorisation was not able to be located for seven cases (four per cent).

4.7 As most food failures occurred due to labelling issues, remedial action taken by importers generally related to the re-labelling of products. Agriculture's monitoring of remedial action taken by importers in relation to food failures, is reliant, to an extent, on the cooperation of the importer, such as arranging additional appointments and providing further documents in a timely manner. Of the five cases where failed food had been sold, one case, relating to risk food, triggered an incident report in accordance with procedures. The other four cases related to surveillance food, which may be released after inspection prior to Agriculture's assessment of laboratory test results. While the sale of failed surveillance food is not prohibited under the Act, Agriculture's procedures require the matter to be reported to the relevant state or territory food authority. Of the four surveillance food failures, the department had retained one notification to a state food authority.

4.8 Agriculture's procedures require departmental staff to supervise the destruction of failed food where an importer has selected this form of remedial action. Of the 142 cases of destroyed failed food, three consignments were destroyed without Agriculture's supervision. In response to the importer's failure to ensure departmental supervision, the department sought a letter of explanation from each importer. Two letters of explanation were received by the department. In the remaining case, the importer was no longer contactable by the department.

4.9 Of the two cases where remedial action was yet to be completed (as at March 2015), one related to surveillance food and one related to risk food. In each case, action to refer future entries for inspection at a rate of 100 per cent

had been undertaken. However supervised remedial action on the failed food had not been completed. Details of these cases are provided in Table 4.2.

Table 4.2: Failed food remedial action to be completed

Date of Failure	Product Description	Reason for Failure	Agriculture's Additional Comments
15 November 2013	Atlantic mackerel	Histamine detected in excess of level permitted.	This incident is being actively followed up under the region's outstanding entries process. The broker has advised that the importer is difficult to contact by phone. A follow up email has been sent to the broker to forward to the importer.
3 December 2013	Frozen crab legs in brine	No importer details; no country of origin.	The importer did not advise if it would re-label, export or destroy. Multiple calls to the importer were not answered or returned. An officer attended the premises in August 2014 to verify the goods were there and not all the goods were available. Despite returning to the importer's premises, to date, no one has been in attendance. A further verification inspection was booked in March 2015.
10 January 2013	Frozen goby fish (retail)	Enrofloxacin Ciprofloxacin Leuco-Malachite Green detected in excess of level permitted.	Information recorded in AIMS indicates that some or all of the goods were distributed before failed test results were reported. This was permitted as the goods were surveillance foods and New South Wales Food Authority was contacted about distributed product.

Source: ANAO analysis of Agriculture information.

4.10 Once failed food is identified at the regional level, an FFN is, on average, provided to the national office in around six days (ranging from 0–71 days). In the case of surveillance food failures, where the food may be released prior to the results of laboratory tests being finalised, the average days between failure and a holding order being implemented was 12 days (ranging from 1–44). As Agriculture does not have the ability to monitor the further entry of surveillance food between the time of its failure and the

implementation of a holding order¹⁰⁶, there is a risk that failed food will be inadvertently or deliberately sold.

4.11 While finalising remedial action with low-volume importers that may not understand their regulatory requirements can be particularly time consuming and follow up activities can present challenges (as outlined in Table 4.2), overall, Agriculture's follow up actions in relation to the identification of failed food is appropriate. There is, however, scope to improve the timeliness of remedial action, which will reduce the risk of inadvertent or deliberate sale of failed food. In particular, further work will be required to improve the timeliness of implementing holding orders following the failure of surveillance food to reduce the risk that further entries of the same food is released without inspection.

Reported incidents

4.12 Certain forms of non-compliance that are not addressed through operational sanctions also have the potential to expose consumers to direct risk of food borne illness. Serious non-compliance includes importers evading inspections, the sale of failed food and undertaking remedial action on failed food without Agriculture's supervision. Suspected incidents of serious non-compliance should be considered promptly to address any immediate threat posed by the incident and facilitate investigation and enforcement action where necessary.

4.13 Agriculture has established procedures for staff to report all suspected incidents through an electronic incident report, phone or fax. Members of the public can also anonymously report incidents via Agriculture's reporting hotline 'Redline' (as outlined in Chapter 2). In the period from July 2012 to June 2014, Agriculture received a total of 1721 reports of suspected breaches, with 78 reports relating to IFIS.¹⁰⁷ The ANAO examined all 78 cases in its analysis of Agriculture's responses to non-compliance, with an additional three cases examined relating to investigations that were finalised during the period under review.

106 Surveillance food entry data is only transferred from Customs if it selected as part of the five per cent sampling rate.

107 Of the 1721 incident reports made in the period July 2012 to June 2014, 1652 (96 per cent) related to the *Quarantine Act 1908*; the *Export Control Act 1982*; and the *Imported Food Control Act 1992*. Of the 78 reports relating to IFIS, two were reported via Redline from external sources.

4.14 The most common IFIS related reports involved food sold prior to inspection, the sale of failed food and the unauthorised treatment of failed food. A breakdown of incident type by region compared with imported food referred to IFIS is presented in Table 4.3.

Table 4.3: Imported food incidents reported by region (2012–2014)

Incident	Central East	South East	North East	Northern	South West	National Total
Food sold prior to IFIS inspection	5	7	7	0	19	38
Sale of failed food	2	2	2	0	2	8
Unauthorised treatment/movement of failed food	3	0	0	0	4	7
Undeclared goods	3	1	0	0	2	6
Other ¹	10	3	4	0	5	22
Totals	23	13	13	0	32	81
Imported food entries ²	73 116	52 592	20 156	107	30 068	176 039
Share of entries (per cent)	41.5	29.9	11.4	0.1	17.1	100
Share of incidents reported (per cent)	28.4	16.0	16.0	0	39.5	100
Rate of incidents reported (per thousand entries)	0.3	0.3	0.6	0	1	0.5

Source: ANAO analysis of Agriculture information.

Note 1: Includes failure to move goods to a Quarantine Approved Premises, goods stolen while on hold, goods not re-conditioned prior to destruction, fraudulent paperwork, illegal labelling, and movement of goods without Agriculture's permission.

Note 2: Entries referred to each region under IFIS, including inspections and entries processed but not inspected.

4.15 The reporting of incidents by departmental staff can vary due to a number of factors, including staff awareness of reporting requirements, the risk profile of the goods being imported at particular locations, and regionally-based inspection workflow management procedures. While incidents have been reported in most categories for all regions except the Northern Region, the level of reporting in the South West Region, at a rate of one incident per thousand entries, is twice the national rate of 0.5.

4.16 The sale of food prior to inspection is a contravention of regulations and constitutes a reportable incident under procedural guidance material. To assess Agriculture's consistency in the reporting of incidents across regions, the ANAO compared AIMS data on food sold prior to inspection with records of incidents

recorded in the department’s case management system (Jade Investigator). The South East Region had almost double the number of inspections that did not proceed because the food had been sold when compared with the Central East Region (120 compared to 66 cases), as outlined in Table 4.4.

Table 4.4: Entries sold prior to inspection by region (2012–2014)

Region	Entries Sold Prior to Inspection	Incidents Reported
South East	120	7
Central East	66	5
North East	23	7
South West	22	19
Total	231	38

Source: ANAO analysis of Agriculture information.

4.17 Apart from the South West Region, data retained in AIMS for food sold prior to inspection do not align with the number of incidents reported in Jade Investigator, with only 17 per cent of incidents reported. The low number of reported incidents may, in part, be related to supplementary processes established by the department. Agriculture informed the ANAO that when a food is found to have been sold prior to an inspection, regional staff are to initially request a letter of explanation from the importer. The department is, however, yet to establish procedural guidance for staff in relation to the letter of explanation process, particularly in the context of reportable incidents.

4.18 As outlined in Chapter 3, the differing workflow management practices adopted across regions can influence the extent to which a potential issue is anticipated and managed at the operational level and when it is formally reported as an incident for review and investigation. Agriculture’s partial and inconsistent reporting of incidents coupled with differing operational oversight practices across regions adversely impacts on the integrity of its regulatory activities. As such, there is scope for greater standardisation of workflow management procedures to deliver nationally consistent regulation and reduce the risk that unsafe food is released into the community.

Preliminary reviews

4.19 Agriculture’s procedures require regional investigation managers to conduct a preliminary review of each reported incident to determine whether an investigation is warranted.¹⁰⁸ The guidance material established by the department covering preliminary reviews includes that the following matters should be considered when determining whether to conduct an investigation:

- impact on human health (in and outside of Australia);
- maintaining public confidence in the criminal justice system;
- the availability of information to identify a suspect against relevant legislation; or
- whether the incident indicates significant weakness in operational procedures.¹⁰⁹

4.20 A robust review process for preliminary reviews, underpinned by the appropriate documentation of decisions, is required to substantiate investigation and enforcement action. While most preliminary reviews were documented, a significant proportion were documented inconsistently, as outlined in Table 4.5.

Table 4.5: Documentation of preliminary reviews of reported incidents

Level of Documentation	Number	%
The outcome of the preliminary review and rationale for the assessment was fully documented	50	62
Outcome of the preliminary review and limited rationale for the assessment was documented	24	30
Outcome of the preliminary review was documented	4	5
Documentation of the preliminary review was not retained	3	4
Total¹	81	100

Source: ANAO analysis of Agriculture information.

Note 1: There were no significant differences in the documentation of preliminary reviews between regions. Numbers do not add to 100 due to rounding.

108 The AGIS provides that: entities must ensure that any instructions, comments, observations or views relating to decisions or actions resulting in an investigation being accepted by the entity, are communicated to the assigned investigations team. This would include detailing the intended scope of the investigation, expected outcomes, available resources, reporting arrangements and relevant stakeholders. All relevant documentation should be provided to the investigations team in a timely manner.

109 The level of detail required in documenting a preliminary review is not outlined in procedural guidance and there is no established template for use by departmental staff. During the course of the audit, Agriculture did, however, inform the ANAO that it was developing further procedural guidance to assist in the documentation of preliminary reviews of incidents.

4.21 Of the 81 reported incidents, investigations were not commenced for 40 (49 per cent). The reasons for not proceeding to an investigation included: insufficient evidence; no offence detected; and resolved through discussion with management (see Table 4.6 for further detail).

Table 4.6: Reasons for not proceeding to investigation

Reason	Number	%
Insufficient evidence	2	5
No offence detected	5	12.5
Resolved through discussion with management	1	2.5
Referred to program	16	40
Minor non-conformance matter recorded, but not pursued	16	40
Total	40	100

Source: ANAO analysis of Agriculture information.

4.22 The documentation retained by Agriculture relating to the conduct of preliminary reviews of reported incidents generally indicates that assessments were undertaken relevant to the circumstances of the incident and in accordance with established procedures. There is, however, scope for staff undertaking preliminary reviews to enhance the transparency of decision-making by improving the documentation of the rationale for decisions.

Investigations of incidents

4.23 The primary purpose of an investigation is to gather evidence to assess the veracity of the alleged or prima-facie incident to support any subsequent action, whether through routine management, administrative sanction or court action. The ANAO examined all investigations undertaken by Agriculture between July 2012 and June 2014 for the incidents reported in relation to the Act.

Conduct of investigation

4.24 The AGIS establish minimum standards for entities conducting investigations and outline that entities should commence each investigation with a written investigation plan, incorporate risk management in decision-making throughout the investigation process and that supervisors review investigations at appropriate intervals to ensure adherence with the AGIS and investigation plans. Agriculture’s investigation procedures are based on the AGIS and include guidance material relating to key investigation activities (interviews, activity recording, brief preparation and adjudication)

and planning, reviewing and prioritising of the investigation workload.¹¹⁰ Of the 41 IFIS-related investigations conducted, one case was classified as high priority, six cases medium priority, and 34 cases low priority. Nine cases had an investigation plan developed, incorporating a risk assessment, including the three medium priority cases. However, the high priority case, relating to the sale of failed peanuts, was conducted without an investigation plan.

4.25 In the period under review, Agriculture's investigation procedures required quarterly reviews (at a minimum) to be undertaken by regional investigation managers, to assess the progress of each case and determine whether the investigation should continue. The conduct of quarterly reviews was not, however, undertaken consistently. Of the 27 investigations that exceeded three months in duration:

- three investigations were subject to timely quarterly reviews;
- there was no documentation of a review retained for six investigations (the duration of these investigations ranged from 135 to 359 days); and
- 18 investigations were subject to irregular reviews, including:
 - one investigation, which involved 8200 kg of surveillance food (fish) that was sold prior to testing, was inactive for over 18 months and was closed due to the lapse of time since the offence;
 - one investigation of bottled water sold prior to inspection was inactive for over one year and closed as it was a low risk commodity and considered unlikely to progress to prosecution; and
 - one investigation was inactive for 11 months where an importer re-tested peanuts that failed for aflatoxin contaminant without Agriculture's permission.¹¹¹

110 High priority investigations are to be commenced for incidents that should be acted on as soon as possible, for example: suspected quarantine disease or pest risk; strong evidence of criminality; or significant illegal import detected. Medium (routine) priority investigations to be commenced for incidents where the initial risk has been mitigated and other incidents of a more urgent nature require action. Low priority investigations are to be commenced for matters where no particular offence is clearly evident or matters relating to a relatively minor nature that may not progress to prosecution.

111 It is a breach of the Act to re-test a product that has failed testing without Agriculture's permission. This investigation resulted in a letter of advice being issued to the importer.

4.26 In recognition of the importance of taking a structured approach to the management of investigations, in January 2015, the department introduced a new requirement for monthly reviews of active cases, supported by a template investigation progress report. The implementation of systematic reviews of all ongoing cases will better position the department to direct its limited investigation resources to the areas that pose the greatest risk.

Discontinued investigations

4.27 Of the 41 IFIS-related investigations examined, 24 (59 per cent) were discontinued for a range of reasons, including no offence detected, resolved through discussion with management and insufficient evidence. Of the 24 discontinued cases, 13 related to preliminary reviews of incidents that were not fully documented. For these cases, there was no documentation retained by Agriculture to substantiate whether there were sufficient grounds for the cases to be referred for investigation when the preliminary review was undertaken. This suggests that a more robust preliminary review process would assist in targeting investigation resources more effectively.¹¹² Of note, among the discontinued cases:

- four cases that were deemed ‘resolved through discussion with management’ resulted from a breach of the broker rather than the importer. The closing of the investigation involved the broker updating its procedures to prevent similar incidents occurring;
- one incident relating to the issuing of a Food Control Certificate six months after the goods had arrived, as such Agriculture did not comply with its requirement to issue the advice as soon as practicable. The regional FSM was briefed on this issue and procedures were amended to help identify entries that were not actioned in a timely manner; and
- one incident was referred to investigation without evidence of a preliminary review, was inactive for four months, and then closed as it related to a minor labelling issue that was managed at the operational level.

112 Agriculture informed the ANAO that it is in the process of re-drafting procedural guidance to assist in improving the allocation of investigation resources.

4.28 Investigations should be undertaken in a timely manner to ensure that any immediate risk to the public is managed appropriately and the risk of future non-compliance is minimised through enforcement action. The timeframes for the completion of investigations can, however, vary according to the complexity of the case and the availability of evidence. Of the 41 IFIS-related investigations examined, the duration of the high priority investigation was 357 days, with medium priority investigations averaging 227 days (ranging from 31 to 751 days), and low priority investigations averaging 213 days (ranging from zero to 757 days). While target timeframes for completing investigations are difficult to determine, the establishment of targets and regular monitoring of the progress of investigations against those targets would better position the department to manage and improve its investigation practices.

4.29 In relation to the 41 investigations reviewed, 22 per cent had investigation plans, 20 per cent were not subject to quarterly reviews and 56 per cent were discontinued, more than half of which related to poorly documented preliminary reviews. Further, the level of planning and oversight of these cases did not accord with the level of priority assigned to them.¹¹³ There is scope for Agriculture to improve the management of investigation activity by ensuring that fit-for-purpose investigation plans are developed and by implementing systematic and regular reviews of all cases, to better target resources and support subsequent enforcement action, including the preparation of briefs of evidence.

Enforcement management

4.30 As outlined in Chapter 2, Agriculture's compliance strategy includes responses to non-compliance that are graduated in proportion to the level of risks posed by the non-compliant activity. The ANAO examined the department's management of enforcement action to assess whether its approach is proportionate, timely, lawful and fully documented.

Enforcement measures

4.31 The Act and Regulations provide Agriculture with a limited range of enforcement measures to address non-compliance. These include prosecution, operational sanctions (for example, increasing inspection rates) and

¹¹³ Of the one high and six medium, priority cases, only three investigation plans were prepared and one quarterly review was undertaken for the four investigations that exceeded three months.

administrative notices, letters of advice and letters of warning. Agriculture may issue letters of advice and warning to finalise a matter by informing and educating an individual or company in response to non-compliant behaviour. The letters are not penalties or sanctions and have no legal effect other than to provide factual information for the benefit of the recipient, and serving as a record of non-compliance for consideration in any future investigations.

4.32 Agriculture's procedures require the consideration of a similar range of matters for issuing letters of warning and advice, including sufficiency of evidence to establish a prima facie case, whether the person of interest acknowledged their role in the incident and use of department's resources. The following enforcement action has been taken in relation to the 17 completed imported food investigations examined by the ANAO:

- six letters of advice were issued;
- five letters of warning were issued (including one letter of warning sent by the Commonwealth Director of Public Prosecutions (CDPP) after a brief of evidence was prepared);
- three convictions were recorded;
- one case proceeded to prosecution, with no conviction recorded; and
- two cases are awaiting a final court outcome.

4.33 Of the six letters of advice issued: four were sent to the importer; one was sent to the broker; and one was sent to both the importer and broker. The reasons provided for the decision to issue a letter of advice included 'risk mitigated by program', 'no proof of deliberate intent', 'minor offence/low risk commodity', 'inexperienced importer or broker'. The five letters of warning were sent to importers, with reasons for issuing these letters including 'limited resources to pursue prosecution', 'inexperienced importer', and 'no proof of deliberate intent'. Regional investigation managers are required to review the decision to issue letters of advice and warning. There was evidence retained of this review for five of the six letters of advice and for three of four letters of warning issued by Agriculture.

4.34 The average timeframe from the date of the reported incident report to the issuing of letters of advice was 211 days (ranging from 54 to 379 days) and 209 days for letters of warning (ranging from 35 to 324 days). While there is no formal requirement for recipients of these letters to respond, they are nonetheless requested to acknowledge receipt. A receipt of acknowledgement

from letters of advice was retained in two of the five cases and two of the three cases from letters of warning.

4.35 The justifications for the decision to issue the letters of advice and warning were aligned with Agriculture's procedural guidance and its graduated enforcement approach. However, limited documentation was retained to confirm receipt of those administrative sanctions.

Briefs of Evidence

4.36 In circumstances where it is suspected that an offence has been committed and prosecution is determined as the appropriate means of enforcement, a brief of evidence is to be prepared by Agriculture for consideration by the CDPP.

4.37 The CDPP and Agriculture have established procedures to guide the development of briefs of evidence to support any proposed prosecutions. When considering whether to proceed with prosecutions, the CDPP takes into account a number of factors, including sufficiency of the evidence, resourcing constraints, the seriousness of the alleged offence and the expected penalties to be imposed by the court. Briefs of evidence based on appropriately scoped and rigorous investigations that target viable offence provisions support timely and efficient criminal litigation.

Cases referred to the CDPP

4.38 The ANAO reviewed the seven imported food cases referred to the CDPP between July 2012 and June 2014, against internal guidance material and CDPP guidelines.¹¹⁴ The ANAO found that all briefs of evidence provided the information that is required under the CDPP guidelines for preparing a brief and each brief was reviewed internally prior to submission to the CDPP.¹¹⁵ For the cases that were subject to court proceedings, two had final charges consistent with those outlined in the briefs of evidence and two did not

114 While breaches of the *Imported Food Control Act 1992* are Commonwealth offences, the matters are heard in state courts. Agriculture informed the ANAO that courts do not have a significant body of sentencing precedents on which to rely on given limited prosecutions for offences against the Act.

115 The ANAO assessed whether the briefs of evidence included: a letter of referral; witness contact details; disclosure certificate; brief cover sheet; proposed defendant's name, address, criminal history and role in the offence; charges laid or proposed; statement of facts, witness list, exhibit list; statements; exhibits (exhibit list). Agriculture's investigation procedures require an internal brief adjudicator to be allocated to each brief of evidence, to review the briefs of evidence prior to submission to the CDPP. The brief adjudicator is the Principal Investigator's manager or another Principal Investigator.

(one with no conviction recorded, one with charges under Regulation 25(3) discontinued¹¹⁶). In one case, the charges were dismissed by the court.¹¹⁷

4.39 Three briefs of evidence resulted in convictions—two under section 9(1A)¹¹⁸ and one under section 20(8)¹¹⁹ of the Act resulting in fines of \$2641.60, \$4000 and \$7500 (increased to \$20 000 on appeal). An overview of the outcomes of briefs of evidence relating to imported food investigations is provided in Table 4.7.

Table 4.7: Outcomes of imported food briefs of evidence

Outcome	Number
Accepted by CDPP and concluded in court with convictions established	1
Issues raised by CDPP and concluded in court with convictions established ¹	2
Accepted by the CDPP and yet to go before the court	2
Accepted by the CDPP and dismissed in court	1
Prosecution declined by the CDPP ²	1
Total briefs of evidence submitted to the CDPP	7

Source: ANAO analysis of Agriculture information

Note 1: In two cases, the CDPP requested changes to the briefs of evidence prepared, one required additional evidence, while the other related to the downgrading of the charges due to lack of evidence.

Note 2: The CDPP issued a letter of warning to the importer in relation to this case.

4.40 Agriculture’s seven briefs of evidence to support prosecutions on imported food met core investigative standards although matters were raised by the CDPP in relation to two of those briefs. The development of briefs of evidence that provide an appropriate level of material to support prosecutions is reliant on the implementation of sound procedures for the planning, conduct and oversight of investigations. Improvements in the management of investigations, including the recently introduced procedures for monthly review of cases, will better position the department to prepare briefs of evidence that effectively meet the requirements for prosecution.

116 Imported Food control Regulation 25(3) relates to interfering with the markings on a batch of food held for inspection.

117 The Brief Preparation Guidelines require the recommendation of charges by the entity conducting the investigation (Agriculture). The laying of charges is, however, at the discretion of the CDPP after assessing the brief of evidence.

118 Section 9(1A) of the Act relates to dealing with imported food, to which a food control certificate has been issued, in a manner that has not been authorised by Agriculture or Customs. For example an importer who intentionally does not arrange for an IFIS inspection.

119 Section 20(8) of the Act relates to when an owner of failed food that is to be destroyed or re-exported intentionally refuses or fails to comply with the requirement to destroy or re-export the food.

Conclusion

4.41 Overall, Agriculture's completion of action following the identification of failed food, through physical inspection and laboratory testing, is appropriate. However, there is scope to improve the timeliness of implementing holding orders to reduce the risk that further entries of failed surveillance food is released without inspection.

4.42 The different inspection workflow monitoring processes that are currently in place across regions increases the risk of inconsistent regulatory decision-making. In particular, the department's reporting of suspected serious non-compliance with importer obligations, including evading inspections and the sale of food prior to inspection, is not well supported by regional work practices, leading to partial and inconsistent reporting of incidents.

4.43 Agriculture's preliminary reviews of reported incidents were largely relevant to the circumstances of the incident and in accordance with procedures where documentation of the review was retained. However, appropriate documentation was not retained for 40 per cent of preliminary reviews, limiting the level of transparency in decision-making and hindering the efficient allocation of investigation resources (13 of the 24 discontinued investigations related to insufficiently documented preliminary reviews). Further, the level of planning and oversight of investigations was not consistent with the department's procedures and not reflective of the level of priority assigned to cases.

4.44 While briefs of evidence met core investigation standards, the CDPP's use of those briefs suggest that further improvements are needed to meet the requirements for prosecution. The improved management of investigations would better support the preparation of briefs of evidence.

Recommendation No.2

4.45 To improve the management of inspection-related activities and responses to non-compliance under the Imported Food Inspection Scheme, the ANAO recommends that the Department of Agriculture:

- (a) implement nationally standardised procedures for the management of inspection workflow;
- (b) reinforce to staff the importance of consistently applying existing procedures for the reporting of incidents of serious non-compliance;
- (c) appropriately document its preliminary reviews of reported serious incidents; and
- (d) develop plans for each investigation into reported incidents.

Agriculture's response: *Agreed*

4.46 *Since the initial field work was completed by ANAO, the department has implemented some changes to its procedures that are relevant to aspects of this recommendation. The department does note there are gaps in nationally standardised service delivery procedures which will be addressed to improve national consistency.*

4.47 *The department notes recommendation 2(b) and will reinforce procedures for the requirement to report incidents of serious non-compliance.*

4.48 *The department notes recommendations 2(c) and 2(d) and has procedures in place to conduct preliminary reviews and develop plans for conducting investigations. Improvements to the management of investigations have been implemented, focusing on case management practices including the introduction of monthly case reporting on all open investigations*

5. Governance Arrangements

This chapter examines the governance arrangements in place to support Agriculture's administration of IFIS.

Introduction

5.1 Sound governance arrangements and practices are required to support the effective delivery of regulatory activities and build stakeholder and public confidence in the regulation of imported food. The ANAO examined the appropriateness of Agriculture's governance arrangements for IFIS, including:

- administrative arrangements;
- business planning and risk management;
- stakeholder engagement;
- information management; and
- performance monitoring and reporting.

Administrative arrangements

5.2 Effective administrative arrangements are underpinned by clear roles and responsibilities, sound mechanisms to coordinate activities and share information, and appropriately qualified and supported staff. The delivery of regulatory activities under IFIS is shared across Agriculture's national office and regional office network.

National and regional office network

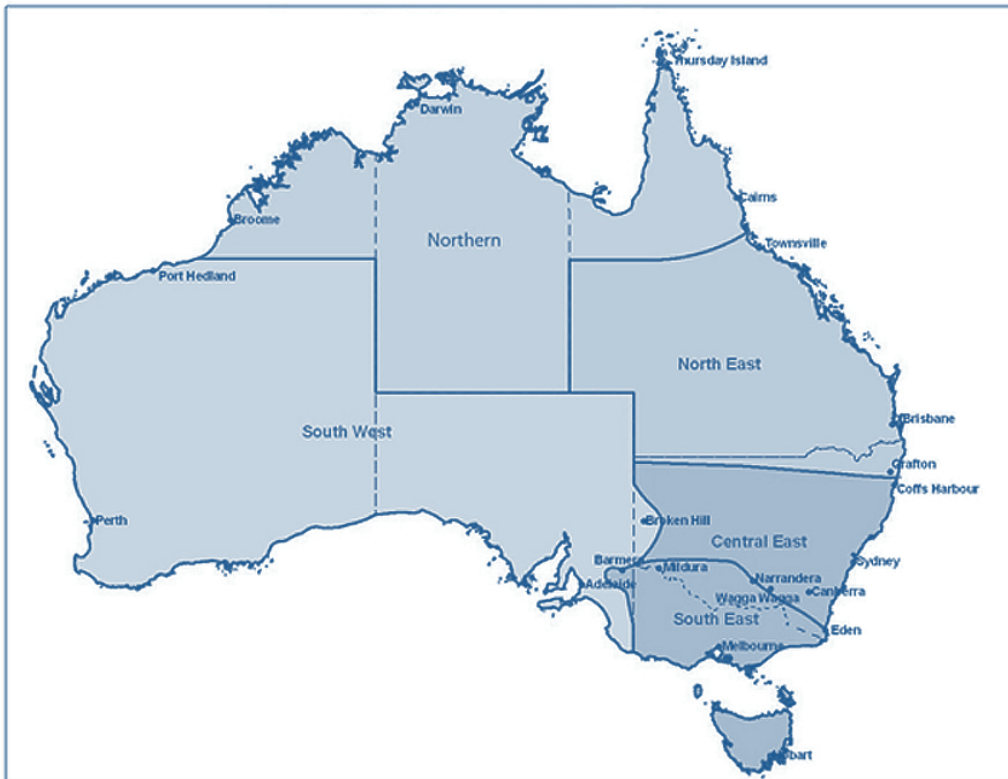
5.3 The Imported Food Section comprises 10 staff located within the Compliance Arrangements Branch, which is one of three branches in the Compliance Division within Agriculture's national office in Canberra.¹²⁰ The Imported Food Section has been assigned responsibility for the regulation of imported food into Australia, including overseeing and coordinating the implementation of IFIS by:

120 The two other branches within the Compliance Division are the Pathway Compliance Branch and the Targeting and Enforcement Branch.

- engaging with co-regulators (as part of the bi-national food safety regulatory system), importers and laboratories on an ad hoc basis and through the Imported Food Consultative Committee;
- reviewing food failures and other food safety related incidents of relevance to the Scheme;
- developing and updating procedural guidance to promote nationally consistent regulation;
- providing training for regionally-based food safety staff;
- monitoring and reporting IFIS performance at a national level; and
- maintaining key IT systems used to administer the Scheme, including the Agriculture Import Management System (AIMS).

5.4 National office staff engage with regional office staff on a day-to-day basis to inform the delivery of compliance activities (for example, by reviewing decisions on failed food) and through a structured series of meetings, workshops and teleconferences. These activities provide an opportunity to review emerging issues, develop procedural guidance and identify lessons arising from verification activities coordinated by the national office.

5.5 The delivery of compliance activities under IFIS is primarily managed by five administrative regions across Australia outlined in Figure 5.1.

Figure 5.1: Administrative regional boundaries

Source: Agriculture.

5.6 The operational activities undertaken at the regional level include:

- receiving records of food referred for inspection and reviewing those records to confirm the tests to be applied;
- ensuring that inspections are undertaken;
- processing the results of inspections and tests; and
- undertaking follow-up inspections for failed food.

5.7 To deliver these operational activities, regional offices have established Compliance Assessment and Management Services work units that process information on imports referred under IFIS, a Client Contact Group that schedules inspection appointments with importers, and an Inspectorate

comprising inspectors and their supervisors.¹²¹ Imported food inspectors (APS Level 4 staff) are supervised by regionally-based Inspectorate Managers. Food Safety Managers (FSMs–APS Level 6 staff), also located within each Inspectorate, are responsible for providing technical guidance to Compliance Assessment and Management Services, liaising with the national office on imported food issues, conducting imported food verification activities and engaging with importers and brokers at the local level.¹²²

5.8 Overall, the roles and responsibilities of the national office, regional offices and work units have been clearly defined, with mature arrangements in place to coordinate IFIS activities and share information.

Staff capability

5.9 To help ensure that a sufficient number of skilled staff are available to undertake the breadth of its regulatory activities for both quarantine and food functions, Agriculture has developed a People Strategy and Action Plan 2014–17. This plan is linked to a Workforce Action Plan and an Annual Learning and Development Program. The planning framework establishes a mandatory requirement for all departmental staff to undertake specific training, including work health and safety, fraud and corruption awareness, privacy principles and security awareness. The completion of mandatory training is recorded in a central IT system and is monitored, along with a range of other human resources performance information, by the department’s Executive Management Committee (EMC).

5.10 In relation to the delivery of IFIS, Agriculture has established a Scheme-specific Imported Food National Curriculum, which includes additional role-based training and job card competency accreditation. These competency requirements are mandatory for all staff undertaking entry processing and inspection duties, without direct supervision. IFIS-specific accreditations include training modules on:

- the Agriculture Imports Management System (AIMS);

¹²¹ The work units established by Agriculture to deliver IFIS compliance activities also deliver quarantine compliance activities, with some staff specialising in a particular function, while others work across both functions.

¹²² Investigations into serious non-compliance are conducted by regionally-based investigators, with coordination provided by the Enforcement Section in the national office. Both the regional and national investigation teams cover quarantine and food safety incidents.

- entry management;
- the Integrated Cargo System; and
- imported food fundamentals.

5.11 While the national curriculum provides coverage of the core competency requirements for inspection and processing officers, there are some gaps in the curriculum, including in relation to assessing information and processing entries in AIMS, assessing laboratory results and managing failed food. Agriculture has informed the ANAO that it plans to develop new procedural guidance and roll out additional training on these IFIS-specific duties.

Verification of competency

5.12 The department's IFIS Program Supervisory Verification Policy requires annual verifications of inspector and processing officer competency to be conducted by FSMs. The verification includes an assessment of the officer's knowledge of work instructions on taking samples of imported food, interpreting laboratory test results and failing food processes. The outcomes of the competency verification process are recorded in spreadsheets and monitored by national office.

Allocation of staff

5.13 Given the broad range of responsibilities of regional office staff, Agriculture has indicated that most, if not all, imported food inspectors have competencies in other areas, particularly in quarantine inspections. These additional competencies assist the department to manage variable workloads over time and across regions. The number of quarantine and imported food qualified inspectors operating from regional locations can vary, as each location within regions has a different operating environment (goods imported and exported, the frequency, volume, and transportation methods). As a result, each region is responsible for determining its own staffing requirements to cover projected activities within overall limits set by national office.

5.14 The deployment of an appropriately skilled workforce in each region facilitates the delivery of seamless inspection services to importers. However, at present, importers subject to quarantine and imported food inspections are

required to make separate bookings, often at different times and different places.¹²³

5.15 Overall, Agriculture has established appropriate administrative arrangements to manage staff capability under IFIS. Exploring options to optimise the skill mix in regional locations to minimise the need for importers to arrange separate inspections for quarantine and imported food regulatory requirements has the potential to deliver efficiencies to the department and reduce the regulatory burden on importers.

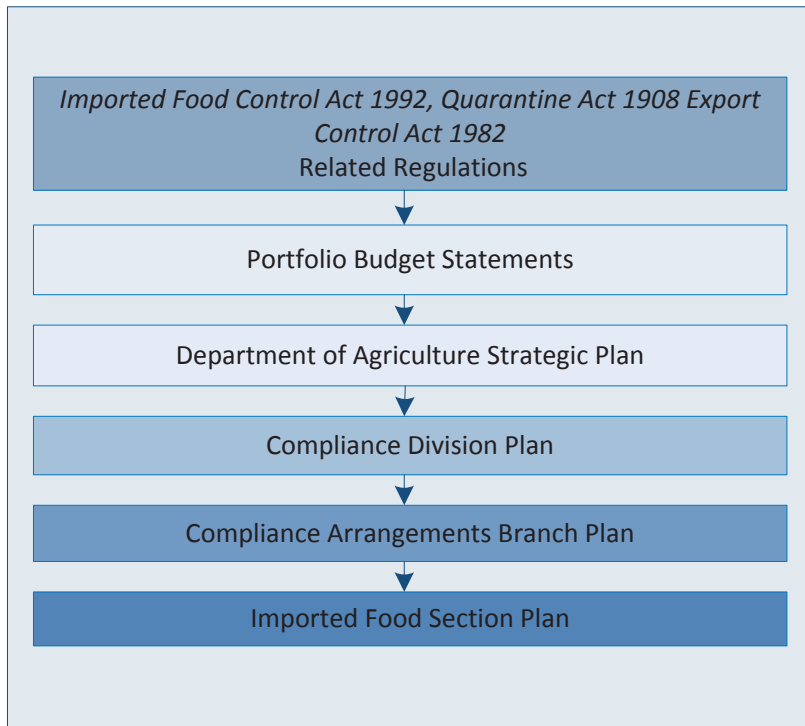
Business planning and risk management

5.16 A structured, systematic and integrated approach to strategic planning and risk management enables regulators to appropriately respond to opportunities and threats to achieving regulatory objectives.

Business planning

5.17 To support the achievement of its strategic objectives, Agriculture has established a framework for developing business plans within a structured hierarchy, as outlined in Figure 5.2.

123 The *Quarantine Act 1908* and the *Imported Food Control Act 1992* provide differing requirements for the movement of goods and location of inspections. For example, quarantine inspections for food may take place at a port or a Quarantine Approved Premises (QAP). Under the *Imported Food Control Act 1992*, food may be moved to any warehouse or other location for inspection.

Figure 5.2: Agriculture’s corporate planning framework

Source: ANAO from Agriculture information.

5.18 Within the broader strategic objectives established in Agriculture’s Strategic Plan, the Compliance Division’s 2014–15 Business Plan outlines five key business objectives for the division, including the primary objective of the ‘development of effective and efficient risk management policies for operational surveillance, monitoring, inspection and verification—across biosecurity pathways and beyond—including the setting of regulatory standards’. The plan links with PBS outcomes (discussed later in this chapter) and outlines a range of deliverables, identifies a number of risks and establishes performance indicators that broadly cover regulatory activities for which the division is responsible. The plan does not, however, establish deliverables or performance measures that specifically relate to IFIS.

5.19 Agriculture has established formal mechanisms to monitor the implementation of divisional business plans, including monthly monitoring by divisional management and biannual reviews conducted by the division and monitored by the EMC. The biannual reviews of the Compliance Division Plan that have been conducted since July 2012 have primarily focused on biosecurity activities and did not include specific coverage of IFIS initiatives.

These reviews have included coverage of IFIS-specific work priorities such as responses to imported food risk statements. In relation to branch and section plans, a formal mechanism of regular review has not been established.

Planning for service delivery and regulatory reform

5.20 In 2012, Agriculture commenced the implementation of a range of initiatives to modernise and improve the consistency of service delivery under a National Service Delivery Model. Under the model, there is a focus on reforming administrative structures and workflows to make the department more client-focused, cohesive and nationally consistent across its functions.¹²⁴ Agriculture's Service Delivery Modernisation Program, which has been established to implement the new model, is designed to make it easier for clients to access services and comply with their regulatory obligations. The projects to be delivered over the five year program include improved online self-service facilities for clients and the implementation of new mobile workforce tools.¹²⁵ The roll-out of initiatives under these programs is in the early stages of implementation.

5.21 In line with the Government's deregulation agenda, Agriculture also established a Deregulation Unit in 2013 to coordinate the department's deregulation initiatives. The department has reported that its initial review of portfolio regulations has led to reductions in the regulatory burden on industry in six key areas of regulatory activity, all of which were outside of IFIS.¹²⁶

Risk management

5.22 Agriculture has established a risk management framework based on the relevant international standard (ISO 31000:2009 *Risk Management* and the related Risk Management Guide). The framework defines the department's tolerance for risk, sets out procedures for reporting risks, and describes the approach to measuring risk management performance.

124 In April 2014, staff performing quarantine and imported food document assessments in each region, were brought together to form a national 'virtual team' reporting to a single National Service Manager.

125 In July 2014, Agriculture commenced a 12 month pilot to test the use of tablet devices for its mobile workforce. The pilot involved the development of specific tools and redesign of business processes to support the new technology. The adoption of such mobile devices over time offers the potential to reduce paperwork, provide real time clearances at inspections and avoid current delays due to back office processing.

126 These areas included simplifying export arrangements for plants and plant products and reducing the regulatory burden for importers of new agricultural machinery. See Agriculture, *Annual Report 2013–14*, p. 110.

5.23 Agriculture's EMC, chaired by the departmental Secretary, is responsible for the oversight and monitoring of the framework, including reviewing monthly dashboard reports on key business objectives and directions. The EMC is also responsible for determining the strategic risks facing the department. In August 2013, the EMC agreed on seven high level strategic risks for the department, five of which are relevant to the implementation of IFIS. These include the failure to:

- identify, engage and maintain stakeholder relationships;
- comply with legislative and/or regulatory requirements;
- deliver government priorities, including regulatory reductions;
- plan for and respond to future challenges; and
- deliver timely, high quality and influential advice to government.

5.24 Departmental divisions are also required to prepare risk assessments, which are to be incorporated into divisional business plans. The risks identified in the Compliance Division's 2014 Business Plan were not, however, developed as part of the process to identify the department's strategic risks and do not directly align with those risks. Of the seven risks identified, the only one IFIS-specific business risk included was the 'failure to provide effective training resources and adequately support the training and knowledge required for staff administering IFIS'. The other broad business risks identified were relevant to the administration of the Scheme.

5.25 The remaining risks identified in the business plan were more general in nature and included 'poor outcomes despite risk-based methodologies', 'significant biosecurity breaches' and 'industry failure to provide assistance in delivering good biosecurity outcomes'. These risks are reviewed on a biannual basis as part of the department's business planning review process, which is primarily focused on biosecurity regulation.

5.26 As outlined earlier, the risks contained in the Imported Food Section's 2014–15 Business Plan were reproduced from the divisional business plan with limited program-specific content to effectively guide the day-to-day activities of the section to mitigate the more significant threats to the achievement of regulatory objectives under IFIS.

5.27 Business planning and risk management for IFIS represents a small, but generally integrated component within Agriculture's biosecurity planning processes. While processes for the oversight and review of higher level

business plans and risks have been established, the inclusion of appropriate performance measures in business plans at all levels would better position the department to monitor the extent to which the objectives established in each plan are being achieved. The department's management of business risks would also be strengthened by integrating high-level risk planning with program-level risks and developing and regularly monitoring IFIS-specific business risks.

Stakeholder engagement

5.28 The effective regulation of imported food requires the maintenance of stakeholder relationships that facilitate constructive engagement on strategic and operational issues with co-regulators and importers. The ANAO examined Agriculture's relationships with state and territory food regulatory authorities, FSANZ and imported food industry stakeholders.

State and territory food regulatory authorities

5.29 Agriculture is engaged with other Commonwealth, New Zealand, and state and territory food safety authorities as a member of the bi-national food regulation system. At the strategic level, this engagement includes supporting the Minister for Agriculture as a member of the Council of Australian Governments Legislative and Governance Forum on Food Regulation, which is the peak national food policy development forum. At the operational level, Agriculture is a member of the Food Regulation Standing Committee Implementation Sub-Committee for Food Regulation to help promote a nationally consistent regulatory approach across jurisdictions.

5.30 The matters discussed at cross-jurisdictional forums and working groups have included imported food risk statements, retail presentation of food, health claims on food products, incident response arrangements and labelling compliance issues associated with imported food. While these forums provide a useful mechanism to raise and discuss a range of matters there is scope for the department to further explore information sharing opportunities with state and territory co-regulators, as outlined in Chapter 2.

Food Standards Australia New Zealand

5.31 As FSANZ is responsible for developing and administering the Australia New Zealand Food Standards Code, Agriculture is required to engage with the authority to share information on food risk, obtain risk

assessments on imported food and to monitor the operation of the regulatory framework. The arrangements between Agriculture and FSANZ in relation to imported food is formalised through a memorandum of understanding (MoU), which was established in 2007. Following a joint Agriculture-FSANZ review finalised in July 2011, a revised MoU was agreed July 2014, which is supported by inter-agency operating procedures outlining the respective roles and responsibilities of each entity. The role of Agriculture and FSANZ in regulating imported food is outlined in Table 5.1.

Table 5.1: Role of Agriculture and FSANZ

FSANZ	Agriculture
Developing and maintaining a risk assessment framework for imported food. Providing advice to assist the determination of possible action under IFIS. Publishing the risk statements provided to Agriculture on the FSANZ website. Reviewing the advice previously submitted to Agriculture and used by the Imported Food Section as the evidence base to categorise food as 'risk'.	Administering IFIS and classifying food based on the level of risk it poses to human health and safety as advised by FSANZ. Considering the advice provided by FSANZ to determine appropriate action in accordance with internal guidance. Determination of the appropriate actions in response to risk statements under the Act. Notifying FSANZ of any proposed actions.

Source: ANAO analysis of Agriculture information.

5.32 Routine operational meetings between Agriculture and FSANZ are conducted on a monthly basis in accordance with inter-agency arrangements. The matters discussed at these meetings have included testing requirements for imported food, emerging food risks and responses to food incidents.

Importers

5.33 Agriculture developed an internal Compliance Division Stakeholder Engagement Approach in 2012 to guide its interactions with industry. While it was intended that the Engagement Approach would be reviewed and modified, where necessary, on an annual basis, it has not been updated since its initial development in September 2012. The approach outlined key messages for industry stakeholders and described regional and national program management roles in coordinating stakeholder engagement activities. The approach is focused on biosecurity regulation, and is consistent with the department's Biosecurity Compliance Strategy, discussed in Chapter 2.

5.34 On a day-to-day basis, Agriculture engages directly with importers, brokers and freight forwarders in each of its five regions, primarily in relation

to inspection activity. The department also engages strategically with industry representatives through the Imported Food Consultative Committee (IFCC), which meets biannually and includes representatives from the department, FSANZ, and industry representatives (including the Food and Beverage Importers Association, Seafood Importers Association and a representative from laboratories).¹²⁷ Meetings of the IFCC have considered a broad range of matters relating to the regulation of imported food, including the administration of the Act, proposed developments in regulation and operational matters. In particular, meetings have reviewed program activities, laboratory data and proposed new laboratory tests. Comments provided to the ANAO by IFCC members indicate that the forum functions as an effective mechanism for discussing important strategic and operational issues.

5.35 While Agriculture's engagement with state and territory food authorities and FSANZ is based on structured arrangements agreed between entities, the department's engagement with industry is guided by its own internal procedures, operational requirements and established industry consultation arrangements. To better coordinate and target its external engagements, there would be benefit in the department giving further consideration to the development of a stakeholder engagement strategy for IFIS. Such a strategy would better place the department to develop an appropriate range of communication materials, for example awareness materials directed at small volume importers and to organisations that may be suitable to participate in a FICA, and to monitor the ongoing effectiveness of education and awareness activities.

Information management

5.36 Sound information management systems form the basis of effective regulatory administration, performance monitoring and reporting. A number of national and regional databases and other systems are used to support the management of IFIS, including shared drives, an electronic document and records management system, internal team collaboration software (SharePoint), a national appointments system and an entry workflow management system (AIMS) and a laboratory test reporting system (eResults).

¹²⁷ Agriculture also facilitates a National Cargo Consultative Committee although this forum is primarily focused on biosecurity related matters.

The ANAO reviewed the two primary support systems (AIMS and eResults) to assess the extent to which they support effective regulation of imported food.

Agriculture Import Management System

5.37 AIMS is a bespoke database that was initially developed in 1995 and is used to receive referrals for inspection and manage inspection related information for the quarantine and imported food functions. AIMS primarily relies on import data received from Customs' ICS. In addition, Agriculture staff also record inspection related information in AIMS and laboratories exchange testing information with AIMS through eResults.

5.38 The ANAO examined AIMS to determine the extent to which it facilitates:

- inspection workflow business requirements, including receiving records of entries from ICS, allocating tests to entries and managing other inspection related processes; and
- management oversight and monitoring of operational activities.

5.39 As discussed in Chapter 3, the ANAO's analysis of a sample of imported food profiles found that all entries referred to Agriculture by Customs were recorded in AIMS. Once import data is received into AIMS, the ANAO found that the system appropriately applied business rules governing the allocation of tests to imported food. Further, the automatically applied tests for food are not undertaken unless they are reviewed and confirmed or amended by an Agriculture entry processor. The system will not allow an entry to be finalised unless relevant lines are allocated a pass or fail and an Inspection Advice to the importer has been created.

5.40 Notwithstanding the general functionality of AIMS, the lack of functionality for exception reporting (such as reporting on entries yet to be scheduled for inspection) limits the extent to which the system supports operational oversight and management decision-making. To work around this limitation, national and regional offices maintain a range of supplementary workflow management tracking spreadsheets.¹²⁸ While limited reporting functionality is not uncommon in legacy IT systems, the adoption of a variety of workflow tracking spreadsheets in each region has resulted in nationally

¹²⁸ The tracking sheets are based on a reporting application that extracts data from AIMS and operational information is manually entered into spreadsheets.

inconsistent administrative practices that increase the risks to the integrity of regulatory decision-making, as outlined earlier in Chapter 4. A further issue relates to system administration, with limited documentation retained on system changes and maintenance, and a heavy reliance on the working knowledge of a limited number of staff. As a result, the department is exposed to business continuity risks in the event of unplanned staff absences or movement.

eResults

5.41 Laboratories engaged to conduct testing on behalf of Agriculture are to use the eResults system to receive and transmit data with AIMS. The ANAO reviewed Agriculture's controls over the data capture process for AIMS and eResults, the guidelines and procedures for each system and business transaction record maintenance. Overall, the interface between AIMS and eResults is sound, with appropriate controls in place to ensure that the data that is sent is confirmed with the data received. Further, the system is sufficiently integrated with laboratories that use the Laboratory Information Management System as their internal testing management system, which facilitates laboratory quality assurance.

5.42 However, as discussed in Chapter 3, test results are reported to Agriculture in inconsistent formats across laboratories and tests, increasing the risk that results are misinterpreted by departmental staff and food is incorrectly passed or failed. As such, there would be merit in the department working with laboratories to establish consistent formats for data fields and providing additional guidance to improve the consistency of reported test results.

Performance monitoring and reporting

5.43 The safety and compliance of imported food is of continuing interest to consumers, industry, the media and Parliament, particularly in light of recent events relating to the consumption of contaminated imported food in Australia. Accurate performance monitoring and reporting informs internal management decision-making and external accountability on the extent to which regulatory objectives are being achieved.

Internal performance monitoring and reporting

5.44 Agriculture's internal monitoring of performance is primarily based on measures contained in the Compliance Division and Imported Food Section business plans.¹²⁹ While both the division and section plans are aligned in terms of regulatory objectives, the performance measures contained in the plans do not directly correspond with the objectives or deliverables outlined in those plans. In relation to the Compliance Division Plan, there are no IFIS-specific performance indicators or targets established and, as a consequence, the biannual reviews of the plan do not involve specific consideration of performance under the Scheme.

5.45 The 2014–15 Imported Food Section Plan includes the following four performance indicators that are related to the delivery of IFIS:

- provide input to and support development of the divisional work programmes which are signed off by the Deputy Secretary;
- improvement in overall compliance with biosecurity requirements for imported food;
- improvement in the efficiency of detecting non-compliant imported food; and
- positive feedback from National Service Delivery leads and Service Delivery Modernisation project managers on Compliance Division support.

5.46 As noted earlier, the department is yet to establish requirements for the structured review of performance under branch and section plans and, as such, the performance of the Imported Food Section against established indicators is not formally monitored.

5.47 Agriculture's Compliance Division Management Committee, established in 2014, is the primary forum of national oversight of biosecurity and imported food regulation, including setting strategic direction and monitoring performance.¹³⁰ However, apart from biannual reports on incidents and the review of program-specific projects, the Committee's monitoring of financial, cargo compliance, passenger, and stakeholder interactions is primarily focused on biosecurity matters. The Committee does not receive

129 As noted earlier, the Compliance Arrangements Branch Plan does not include performance measures.

130 As noted earlier, issues relating to the day-to-day implementation of IFIS are monitored by the Imported Food Section and regional offices, including through regular regional forums.

routine reports against performance measures or dashboard-style information in relation to the delivery of imported food inspection activities, or workflow management effectiveness indicators. In the absence of regular internal monitoring of performance indicators, the operational and strategic oversight of IFIS at the national level is limited. The development of appropriate performance indicators and the establishment of regular monitoring arrangements would better position the department to identify and respond to emerging trends, and to determine the extent to which it is achieving its regulatory objectives.

External performance monitoring and reporting

5.48 The public reporting of the performance of IFIS assists the Government, the Parliament and stakeholders to assess the effectiveness of Agriculture in regulating imported food. Public sector entities are required to set out their outcome(s), programs, expenses, deliverables, and key performance indicators in their Portfolio Budget Statements (PBS) and subsequently report their performance against these measures in their annual report. In addition to the annual report, Agriculture provides supplementary reporting on its regulatory performance under IFIS in Imported Food Inspection Data Reports and Failing Food Reports.

Portfolio Budget Statements and annual reporting

5.49 Agriculture's 2014–15 PBS established two outcomes for the department, with the regulation of imported food covered by Outcome 2:

Safeguard Australia's animal and plant health status to maintain overseas markets and protect the economy and environment from the impact of exotic pests and diseases, through risk assessment, inspection and certification, and the implementation of emergency response arrangements for Australian agricultural, food and fibre industries.¹³¹

5.50 Agriculture has used the outcomes established in the PBS as a basis for strategic planning, with the department's 2013–14 Strategic Statement identifying 14 strategic priorities, including biosecurity reform, improving service delivery, consolidating and stabilising ICT systems and enhancing strategic capacity. As IFIS is a relatively small component of the department's regulatory activities, it is not specifically referred to in the Strategic Statement.

131 Department of Agriculture, *Portfolio Budget Statements 2013–14*, p. 4.

5.51 As is the case for the Strategic Statement, Agriculture’s PBS does not include specific performance indicators for IFIS and the performance of the department’s regulatory responsibilities under IFIS is not directly addressed in the department’s annual report.¹³²

Supplementary reporting

5.52 The department’s biannual Imported Food Inspection Data Reports are the most comprehensive form of public reporting on IFIS inspection activities. These reports, published six months after the period subject to review, detail tests applied to food, lines inspected by country, and the nature of non-compliant test results.¹³³ The Imported Food Inspection Data Reports do not, however:

- present inspection data in the context of total volume of food imports arriving in Australia that are subject to IFIS compliance activities;
- identify tests and results applied to risk, surveillance and holding order categories of food; or
- contain data on the volume of food imported through Food Import Compliance Agreements (FICA).

5.53 The monthly Failing Food Reports are also published on Agriculture’s website, detailing food descriptions (such as ‘cooked prawns’ and ‘spicy vinegar’), country of origin, date of failure, test applied, result and standard. However, relevant product brand and Australian importer details are not disclosed. The reports are usually published within two months of the month to which they relate.

5.54 The feedback from industry to the ANAO indicates that the Imported Food Inspection Data Reports and the Failing Food Reports are valued because the publications can be used in the consideration of import risks and decision-making. Notwithstanding the value of the reports to stakeholders, one co-regulator commented to the ANAO that the delay in publishing the reports detracts from their usefulness in assisting retail regulation and that the

132 The department’s *Annual Report 2013–14* contained one reference to IFIS in relation to its attendance at two meetings of the Imported Food Consultative Committee. Department of Agriculture, *Annual Report 2013–14*, p. 90. The department’s *Annual Report 2012–13* contained one reference to an imported food related biosecurity targeted compliance campaign. Department of Agriculture, *Annual Report 2012–13*, p. 96.

133 The Imported Food Inspection Data report for January to June 2014 was published in February 2015.

availability of real-time data would be of greater assistance (arrangements for the sharing of information with co-regulators is discussed in Chapter 2).

5.55 Agriculture's performance monitoring of IFIS is largely limited to the tracking of operational activities and processes as part of the broader management of biosecurity regulation. Given the level of community and Parliamentary interest in the quality and safety of imported food, there is scope for the department to develop an appropriate set of performance measures and targets to inform its response to emerging trends and demonstrate the extent to which it is achieving its regulatory objectives.

Recommendation No.3

5.56 To inform management and stakeholders of the effectiveness of the regulatory activities under the Imported Food Inspection Scheme, the ANAO recommends that the Department of Agriculture:

- (a) develop appropriate performance measures for the Scheme; and
- (b) report against these measures on the extent to which objectives are being achieved.

Agriculture's response: *Agreed*

5.57 *The department notes the development of appropriate performance measures can present challenges but acknowledges the importance to report on the effectiveness of the regulatory activities under the IFIS to management and stakeholders.*

Conclusion

5.58 Agriculture has established generally appropriate administrative arrangements to support the delivery of imported food regulatory activities, with mature processes in place for the department's national office to oversee and coordinate the operational activities delivered through regional offices. The department has also established arrangements to support staff competency, although continued effort will be required to deploy targeted staff capability in regional locations to efficiently meet the demand for quarantine and imported food inspection services. Business planning for IFIS represents a small, but generally integrated component of biosecurity regulatory planning, with links established to departmental-wide plans for service delivery reform and modernisation. However, departmental strategic risks are not directly integrated with program-level risk planning and IFIS-specific risks have not

been assessed and monitored, potentially exposing the department to adverse events in relation to imported food.

5.59 The primary IT systems used to support the delivery of regulatory activities under IFIS are sufficient to perform the workflow functions of receiving referrals for inspection, allocating tests to food and managing inspection related information. There are, however, areas for further attention, to better support the Scheme, including the development of system documentation, implementation of consistent workflow tracking mechanisms and the standardisation of laboratory reporting formats. Addressing these areas would strengthen quality assurance and support performance monitoring and reporting activities.

5.60 Current performance monitoring in relation to imported food is indirect and primarily limited to the tracking of operational activities and processes as part of the broader management of biosecurity regulation. The establishment of IFIS-specific performance indicators and targets would better position Agriculture to identify and respond to trends and measure the effectiveness of its regulatory performance. Further, from 1 July 2015, Agriculture will be required to prepare annual performance statements in accordance with requirements established under the *Public Governance, Performance and Accountability Act 2013*. The enhancement of performance measures for its programs, including IFIS, will assist the department to meet revised reporting requirements.



Ian McPhee

Canberra ACT

10 June 2015

Appendices

Appendix 1 Entity Response



Australian Government
Department of Agriculture

ACTING SECRETARY

Ref: EC15-000367

Ms Barbara Cass
Group Executive Director
Australian National Audit Office
19 National Circuit
BARTON ACT 2600

Dear Ms Cass

Thank you for your letter of 13 May 2015 regarding the proposed audit report on the Administration of the Imported Food Inspection Scheme (IFIS) and for the opportunity to respond to the report.

The Department of Agriculture (the department) agrees with the recommendations in the report. The report recognises the context within which the IFIS operates. This includes being an integral part of the Australian food regulatory system and the reliance on strategic partnerships with Food Standards Australia New Zealand and the Australian Customs and Border Protection Service to support the administration of the IFIS.

The report also acknowledged the department's administration of its responsibilities under the IFIS as being generally effective.

Specific responses to each of the Recommendations are provided below.

Recommendation 1

To gain appropriate assurance that imported food is referred for inspection in accordance with prescribed rates, the ANAO recommends that the Department of Agriculture implement a systematic approach for monitoring the operation of risk profiles and the referral of imported food for inspection under the Imported Food Inspection Scheme.

Department of Agriculture response

Agreed

- The department notes that there is already a considerable body of evidence providing assurance that, on the whole, referrals are being transferred appropriately into its systems. This includes testing processes that are conducted when a new profile is created or amended and some internal auditing, done by the Imported Food section, to verify that legislated referral rates for specific foods are being met.
- The department will develop and implement a process to provide additional assurance that import consignments profiled in the Australian Customs and

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Border Protection Service's Integrated Cargo System are referred correctly into the Agriculture Import Management System.

Recommendation 2

To improve the management of inspection-related activities and responses to non-compliance under the Imported Food Inspection Scheme, the ANAO recommends that the Department of Agriculture:

- a) implement nationally standardised procedures for the management of inspection workflow;
- b) reinforce to staff the importance of consistently applying existing procedures for the reporting of incidents of serious non-compliance; and
- c) appropriately document its preliminary reviews of reported serious incidents; and
- d) develop plans for investigation into reported incidents.

Department of Agriculture response

Agreed

- Since the initial field work was completed by ANAO, the department has implemented some changes to its procedures that are relevant to aspects of this recommendation. The department does note there are gaps in nationally standardised service delivery procedures which will be addressed to improve national consistency.
- The department notes recommendation 2(b) and will reinforce procedures for the requirement to report incidents of serious non-compliance.
- The department notes recommendations 2(c) and 2(d) and has procedures in place to conduct preliminary reviews and develop plans for conducting investigations. Improvements to the management of investigations have been implemented, focusing on case management practices including the introduction of monthly case reporting on all open investigations.

Recommendation 3

To inform management and stakeholders of the effectiveness of the regulatory activities under the Imported Food Inspection Scheme, the ANAO recommends that the Department of Agriculture:

- a) develop appropriate performance measures for the Scheme; and
- b) report against these measures on the extent to which objectives are being achieved.

Department of Agriculture response

Agreed

- The department notes the development of appropriate performance measures can present challenges but acknowledges the importance to report on the effectiveness of the regulatory activities under the IFIS to management and stakeholders.

Finally, I would like to acknowledge the cooperation and assistance provided by members of your audit team.

If you require further clarification on our comments, please contact Greg Healy, Director Internal Audit, Business Assurance and IIGB on 6272 5543 or greg.healy@agriculture.gov.au.

I trust that you will find these comments useful in preparing your final report.

Yours sincerely



Phillip Glyde

03 June 2015

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Australian Securities and Investments Commission

ANAO Report No.39 2014–15

Promoting Compliance with Superannuation Guarantee Obligations

Australian Taxation Office

ANAO Report No.40 2014–15

Transport Services for Veterans

Department of Veterans' Affairs

ANAO Report No.41 2014–15

The Award of Funding under the Safer Streets Programme

Attorney-General's Department

ANAO Report No.42 2014–15

Administration of Travel Entitlements Provided to Parliamentarians

Department of Finance

ANAO Report No.43 2014–15

Managing Australian Aid to Vanuatu

Department of Foreign Affairs and Trade

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Interim Phase of the Audits of the Financial Statements of Major General Government Sector Entities for the year ending 30 June 2015

Across Entities

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Central Administration of Security Vetting

Department of Defence

ANAO Report No.49 2014–15

Administration of the Imported Food Inspection Scheme

ANAO Report No.46 2014–15

Administration of the Australian Childhood Immunisation Register

Department of Human Services

ANAO Report No.47 2014–15

Verifying Identity in the Citizenship Program

Department of Immigration and Border Protection

ANAO Report No.48 2014–15

Limited Tender Procurement

Australian Customs and Border Protection Service

Department of Foreign Affairs and Trade

Department of Human Services

ANAO Report No.49 2014–15

Administration of the Imported Food Inspection Scheme

Department of Agriculture

Better Practice Guides

The following Better Practice Guides are available on the ANAO website:

Public Sector Financial Statements: High-quality reporting through good governance and processes	Mar. 2015
Public Sector Audit Committees: Independent assurance and advice for Accountable Authorities	Mar. 2015
Successful Implementation of Policy Initiatives	Oct. 2014
Public Sector Governance: Strengthening performance through good governance	June 2014
Administering Regulation: Achieving the right balance	June 2014
Implementing Better Practice Grants Administration	Dec. 2013
Human Resource Management Information Systems: Risks and Controls	June 2013
Public Sector Internal Audit: An Investment in Assurance and Business Improvement	Sept. 2012
Public Sector Environmental Management: Reducing the Environmental Impacts of Public Sector Operations	Apr. 2012
Developing and Managing Contracts: Getting the Right Outcome, Achieving Value for Money	Feb. 2012
Fraud Control in Australian Government Entities	Mar. 2011
Strategic and Operational Management of Assets by Public Sector Entities: Delivering Agreed Outcomes through an Efficient and Optimal Asset Base	Sept. 2010
Planning and Approving Projects – an Executive Perspective: Setting the Foundation for Results	June 2010
Innovation in the Public Sector: Enabling Better Performance, Driving New Directions	Dec. 2009
SAP ECC 6.0: Security and Control	June 2009
Business Continuity Management: Building Resilience in Public Sector Entities	June 2009
Developing and Managing Internal Budgets	June 2008
