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Audit Report No.15 2010-11
Performance Audit

Food Standards Australia New Zealand

Australian National Audit Office

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Canberra ACT
18 November 2010

Dear Mr President
Dear Mr Speaker

The Australian National Audit Office has undertaken an independent performance audit in the *Food Standards Australia New Zealand* in accordance with the authority contained in the *Auditor-General Act 1997*. I present the report of this audit, and the accompanying brochure, to the Parliament. The report is titled *Food Standards Australia New Zealand*.

Following its tabling in Parliament, the report will be placed on the Australian National Audit Office's Homepage—<http://www.anao.gov.au>.

Yours sincerely

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

Ian McPhee
Auditor-General

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

AUDITING FOR AUSTRALIA

The Auditor-General is head of the Australian National Audit Office (ANAO). The ANAO assists the Auditor-General to carry out his duties under the *Auditor-General Act 1997* to undertake performance audits and financial statement audits of Commonwealth public sector bodies and to provide independent reports and advice for the Parliament, the Australian Government and the community. The aim is to improve Commonwealth public sector administration and accountability.

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Glossary and Abbreviations

ACCC	Australian Competition and Consumer Commission
ANAO	Australian National Audit Office
Application	An application to vary the Australia New Zealand Food Standards Code may be submitted to FSANZ by a person or body.
Application Handbook (Handbook)	The Handbook provides the essential information required to make an application.
APVMA	Australian Pesticides and Veterinary Medicines Authority
AQIS	Australian Quarantine and Inspection Service
CAC Act	<i>Commonwealth Authorities and Companies Act 1997</i>
COAG	Council of Australian Governments
Code	Australia New Zealand Food Standards Code
Codex	The Codex Alimentarius Commission—develops internationally recognised food standards, guidelines and related texts such as codes of practice under the Food Standards Program of the Joint Food and Agriculture Organisation and the World Health Organisation.
DoHA	Department of Health and Ageing
Food Standards Development Work Plan (Work Plan)	The Work Plan lists all applications and proposals, both current and future, their categories and timeframes for assessment
FRSC	The Food Regulation Standing Committee provides policy advice to the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council).

FSANZ	Food Standards Australia New Zealand
FSANZ Act	<i>Food Standards Australia New Zealand Act 1991 (amended 2002, 2007)</i>
Incident	A food incident may present a public health and safety risks and can arise from issues such as a food containing contaminants or food being subjected to inappropriate hygiene practices.
ISC	FRSC's Implementation Sub Committee which coordinates the activities of the States and Territories to implement and enforce the Code.
Jurisdictions	The State and Territory governments and local councils in Australia; and New Zealand through the New Zealand Food Safety Authority.
Ministerial Council	The Australia and New Zealand Food Regulation Ministerial Council which comprises Health Ministers from all Australian states and territories, the Australian and New Zealand Governments, as well as other Ministers from related portfolios where these have been nominated by their jurisdictions.
NZFSA	New Zealand Food Safety Authority
OBPR	Office of Best Practice Regulation
Parliamentary Secretary	Prior to 14 September 2010, the Parliamentary Secretary for Health Since 14 September, 2010 the Parliamentary Secretary for Health and Ageing
Proposal	FSANZ may prepare its own proposals to consider changes to the Code. Proposals are also used by FSANZ to adopt changes to Maximum Residue Limits in the Code.

Recall	A recall is an action taken to remove from distribution, sale or consumption, food which may pose a health and safety risk to consumers.
Sanitary and Phytopsanitary	sanitary – food health; phytopsanitary – animal and plant health

Summary and Recommendations

Summary

Introduction

1. Australia's international and domestic reputation for producing high quality food is supported by a 2008 international study that ranked Australia fourth in the world for food safety performance.¹ Australian consumers expect that governments, producers and suppliers will maintain the safety of food and ensure its quality and availability whether it is domestically produced or imported.

2. Food regulation is an important public function for the primary purpose of avoiding food-borne illnesses, and the associated costs for individuals and the community. These costs include medical costs, lost productivity, business disruptions resulting from food recalls, decreased sales and possible legal costs. A Department of Health and Ageing (DoHA) report in March 2006 estimated that the total annual cost, in 2004 prices, of food-borne illnesses was \$1.2 billion.

3. Food regulation in Australia and New Zealand is designed to provide: an effective, transparent and accountable regulatory framework within which the food industry can work efficiently; the provision of adequate information relating to food to enable consumers to make informed choices; and the establishment of common rules and harmonisation between domestic and international food regulatory measures while maintaining public health and protecting consumers.²

Australia and New Zealand: a bi-national approach

4. Australia and New Zealand harmonised food standards in 1983 as part of the *Australia New Zealand Closer Economic Relations Trade Agreement*. In 1995 the *Joint Food Standards Treaty* between Australia and New Zealand committed both countries to a single set of food standards and a bi-national agency, then the Australia New Zealand Food Authority, to develop those standards.

5. In November 2000, the Council of Australian Governments (COAG) agreed to a new food regulatory system in response to the recommendations of

¹ *Food Safety Performance World Ranking May 2008*, Dr. Sylvain Charlebois, Dr. Chris Yost, p.15.

² These are the objects of the FSANZ Act.

the Food Regulation Review (the Blair Report). The *Food Standards Australia New Zealand Act, 1991* (FSANZ Act) was consequently amended in 2001 to reflect the new co-operative bi-national system for food regulation. The amendments also established Food Standards Australia New Zealand (FSANZ) as the new statutory authority to develop and maintain food standards for the production, processing and sale of food in, or from, Australia and New Zealand.

Food Standards Australia New Zealand

6. FSANZ is an Australian Commonwealth statutory authority established under the FSANZ Act. It is part of the Australian Government's Health and Ageing portfolio with the Parliamentary Secretary to the Minister for Health and Ageing having portfolio responsibility.

7. FSANZ has offices in Canberra and Wellington, New Zealand and employs 145 staff in multi-disciplinary teams. FSANZ's total revenue for 2009-10 was \$22.5 million.

8. FSANZ's role is to provide expert advice on food based on the best available science. It develops and varies food standards to be included in the Australia New Zealand Food Standards Code (Code) which are approved by the FSANZ Board and subject to review by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council). When it develops or amends food standards, FSANZ must have regard to Ministerial Council policy.

9. The Ministerial Council comprises Health Ministers from all Australian States and Territories, the Australian and New Zealand Governments, as well as other Ministers from related portfolios where these have been nominated by their jurisdictions. Once the Ministerial Council process is finalised, the variations to the Standards are gazetted and then automatically adopted by reference under food legislation of the Commonwealth of Australia, the Australian States and Territories and New Zealand.

10. Although FSANZ develops food standards, responsibility for ensuring compliance with these standards for domestically produced or imported food rests with local government and State and Territory Governments in Australia and the New Zealand Government.

11. FSANZ may conduct scientific research in support of its own proposals but it does not conduct scientific research for paid or unpaid applications.

Consequently, it requires applicants to provide data to support their applications. The quality of this data is important to FSANZ to support its risk assessments and for accountability purposes because stakeholders need to know the extent to which they can rely on the data that underpins FSANZ's food regulations.

12. FSANZ has a range of other functions under the FSANZ Act including facilitating harmonisation of State and Territory laws relating to food, and national coordination of food surveillance, incidents and recalls.

Developing and amending food standards

13. Section 18 of the FSANZ Act sets out FSANZ's objectives (in descending priority order) in developing food regulatory measures and variations of food regulatory measures as:

- the protection of public health and safety; and
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.³

14. When FSANZ develops or amends a standard it must meet these legislated objectives.

15. Food standards are developed or amended in response to applications by a body or person, and proposals developed by FSANZ.

16. Applications are subject to a two-part assessment process to determine whether: the application is accepted⁴; and a standard should be developed or amended⁵, both of which have legislated timeframes.⁶ FSANZ must commence consideration for paid applications as soon as a fee is paid which, in practice, results in compression of the timeframe between the two parts of the assessment process.

17. FSANZ develops its own proposals to address: major clarification, corrections or reviews of the Code; changes to COAG or Government policy

³ *Food Standards Australia New Zealand Act 1991*, section 18 (1).

⁴ FSANZ refers to this process as the administrative assessment.

⁵ FSANZ refers to this process as the consideration period.

⁶ The time to develop any consequential standard is included in the timeframe.

(for example, removing trade restrictions); a policy guideline from the Ministerial Council or Food Regulation Standing Committee; and public submissions.⁷

18. The FSANZ Act provides that FSANZ must develop a three year forward plan including all applications and proposals, and that paid applications 'must not' displace unpaid applications or proposals listed on that plan.

Regulated timeframes

19. The FSANZ Act specifies the objectives FSANZ must meet when it develops and amends food standards. While the focus is on satisfying consumer protection matters, FSANZ must also have regard to 'the desirability of an efficient and internationally competitive food industry'.⁸

20. The main aim of the 2007 legislative reforms was to streamline FSANZ's application procedures and enhance the efficiency of the regulatory process. Under the previous legislation, all applications received by FSANZ were subject to the same processing requirements, regardless of their complexity. The 2007 legislative amendments introduced processes which reduced legislated timeframes for most applications.

21. Previous legislative changes were to allow an applicant to pay a fee for FSANZ to develop or amend a standard that could give the applicant a competitive advantage. An applicant may also pay a fee to expedite the consideration of an application. The legislative changes that have been introduced since 2000 are designed to enable industry to have its applications dealt with more rapidly and to overcome what was seen as an impediment to an efficient and competitive food industry.

Cost-model

22. FSANZ charges fees for applications based on the expected consideration period⁹ at the determined level of complexity. For the three years from 2007-08 to 2009-10, FSANZ received \$1.669 million in fees for paid

⁷ FSANZ has publicly advised it considers proposals in similar timeframes to applications although proposals are not bound by a legislated timeframe.

⁸ *Food Standards Australia New Zealand Act 1991*, section 18.

⁹ The consideration period commences when a fee is paid and ends when the FSANZ Board approves or rejects the new or amended standard.

applications which comprised 2.8 per cent, 1.8 per cent, and 3 per cent respectively of FSANZ's revenue. In the same period, paid applications accounted for 94 per cent of the food standards that had been incorporated into the Code.

23. As well as processing applications, FSANZ staff regularly spends additional time providing pre-application guidance and ongoing advice to assist in the preparation of applications with further advice provided if the application is initially incomplete or rejected. Although this contributes to a successful relationship with the applicant and applications meeting FSANZ's requirements, the additional time is not included in the fee, so is not recoverable.

Audit objectives and scope

Objective

24. The objective of the audit was to assess FSANZ's administration of its food standard functions, as specified in the *Food Standards Australia New Zealand Act, 1991 (last amended 2007)*.

25. Particular emphasis was given to whether:

- FSANZ's performance management and reporting provided effective support and ensures accountability;
- FSANZ effectively administered its food standard development and variation function, including its stakeholder management; and
- FSANZ effectively monitored the implementation of its standards and coordinates relevant jurisdictions to address market failures.

Scope

26. The scope of the audit included FSANZ's: development and amendment of food standards; coordination and surveillance activities; coordination of food incidents and recalls; provision of information to consumers; and supporting corporate processes. The scope of this audit did not include the bodies primarily involved in food regulation policy or the bodies responsible for the implementation, compliance and enforcement of the standards.

Methodology

27. In order to form an opinion against the audit objective the ANAO: examined policy documents, guidelines, procedures, operational documents and reports; stakeholder surveys, files, records, systems and publications; and interviewed FSANZ staff and the Board Chair.

28. To determine whether regulated timeframes had been met the ANAO also reviewed and analysed: 16 proposals (the oldest had commenced in 2002) included on the February 2010 Food Standards Development Work Plan; and all of the 47 applications that had undergone an initial assessment, received by FSANZ between 1 October 2007 and 30 June 2010.

29. To determine whether applications had met FSANZ's mandatory requirements, the ANAO also reviewed the information provided by applicants to support 15 applications, and the relevant assessment reports produced by FSANZ. Ten of these applications were accepted and five were rejected after completion of the first part of FSANZ's two-part assessment process.

30. The audit forms part of the ANAO's strategic focus on regulators within the Health and Ageing portfolio.

Overall conclusion

31. Over time, Australian and New Zealand Governments have committed to reducing the regulatory burden on businesses within the food industry, without compromising public health and safety. Recent amendments to food legislation have focused on maximising the efficiency of processing applications to change or amend the joint Australia New Zealand Food Standards Code (the Code) and avoiding unnecessary compliance costs, while protecting consumers. In this environment, the role of Food Standards Australia New Zealand (FSANZ) is to develop food standards (regulations) based on the best available scientific evidence which FSANZ requires applicants to provide for paid and unpaid applications. FSANZ has advised that it researches and collates available evidence when it develops a proposal.

32. FSANZ is a relatively small agency operating in a complex multi-jurisdictional environment and has used the resources available to it to meet most of its key responsibilities and, over time, complete a large component of its annual work program. Although FSANZ actively engages stakeholders, there is a broad range of views held by FSANZ's stakeholders as to the direction and appropriateness of food standards. Against this

background, an important consideration for FSANZ is being able to report more fully on its effectiveness in developing food standards including:

- developing performance indicators to identify: FSANZ's contribution to its single Outcome: *a safe food supply and well-informed consumers in Australia and New Zealand*;
- documenting how FSANZ takes into consideration its legislative objectives when it develops or amends food standards; and
- the approach being taken by FSANZ to manage a recognised non-compliance issue, that is, the processing of paid versus unpaid applications and proposals using FSANZ's current resources.

33. FSANZ also has a role in monitoring food standards across Australia and, given that this function is undertaken in consultation with the Australian jurisdictions, FSANZ has successfully managed its coordination role including: coordinating the collection of data on monitoring and surveillance activities; coordinating responses to major food incidents; and developing stakeholder education activities.

Performance indicators

34. In planning to meet its overall Outcome, FSANZ operates in an environment where consumer and industry groups hold different views on the degree of regulation required in the food industry. In addition, the multi-jurisdictional nature of FSANZ's operating environment requires it to work with a range of entities, including State and Territory food regulation enforcement agencies.

35. In order to progress the achievement of its intended Outcome, a priority for FSANZ is to manage these strategic relationships and associated risks. Currently, FSANZ's effectiveness measures for its Outcome focus on one of its three Major Activities: *Effective evidence-based food standards*. For FSANZ to be in a position to determine its contribution to *a safe food supply and well-informed consumers*, it should develop and make use of appropriate effectiveness indicators for its other two Major Activities: *Protect health and safety*, and *Citizen and stakeholder engagement*. The resulting measures would assist in conveying FSANZ's role more effectively to stakeholders and provide a basis for a better understanding of the progress being made in achieving its Outcome.

Setting food standards: FSANZ's consideration of legislative objectives

36. To progress its overall Outcome, FSANZ must meet its legislated objectives when it develops or amends food standards. These are set out in section 18 of the FSANZ Act: 'the protection of public health and safety; and the provision of adequate information relating to food to enable consumers to make informed choices; and the prevention of misleading or deceptive conduct'. While FSANZ advised that it does take into account its legislated objectives when it considers applications and proposals, information on how the objectives were considered is not included in FSANZ's assessment reports.

37. An approach for FSANZ to demonstrate how it meets its legislated objectives when it develops food regulatory measures would be to include more explicit information in its assessment reports for all applications and proposals that explains how the three objectives were considered. Monitoring and reporting how FSANZ's three objectives were considered at the application and proposal level could then be consolidated to enable broader reporting against FSANZ's Outcome, and be an effective way of communicating to stakeholders the breadth of work that is involved in setting food standards.

Setting food standards: FSANZ's approach to prioritisation

38. Over time, the Australian Government has committed to reducing the regulatory burden on Australian businesses and not-for-profit organisations within the food industry, without compromising public health and safety. Changes to the *Food Standards Australia New Zealand Act, 1991* (FSANZ Act) in 2007 reflected this approach and made provision for applicants to pay a fee if they wished to expedite the consideration of an application. These changes to the FSANZ Act were designed to enable industry to have its applications dealt with more rapidly and to promote an efficient and internationally competitive food industry.

39. However, the FSANZ Act also requires that assessment of paid applications must not displace the development of, or variation to, any other food regulatory measure in a three year plan (Work Plan). This requirement means that FSANZ must respond in a timely way to paid applications, while not compromising its ability to respond to unpaid applications or to generate its own proposals to develop or amend food standards.

40. Of the 48¹⁰ applications received between 1 October 2007 and 30 June 2010, FSANZ met the timeframe to assess whether to accept or reject the application. The timeframe for FSANZ to subsequently consider an application was met for nine paid applications, with five of these being completed one month or more ahead of schedule. Of the 12 paid applications that were not finalised, three were already exceeding the planned timeframe. Over the same period, FSANZ delayed the commencement of two unpaid applications and three proposals, and had commenced consideration for only one of the 14 unpaid applications received.

41. This trend highlights that FSANZ manages its Work Plan by prioritising paid applications, followed by unpaid applications and proposals.

42. FSANZ has advised that although resource constraints have limited its ability to meet the legislated requirement that paid applications must not displace other food regulatory measures in its three year Work Plan, it now identifies in each Work Plan any applications or proposals that have been displaced by paid applications. FSANZ also advised that it intends to report in future annual reports its compliance against this requirement which will improve the transparency associated with FSANZ's prioritisation of its Work Plan.

43. As indicated above, the capacity for FSANZ to suitably balance competing priorities is influenced by its resourcing and approach to prioritisation. Whereas FSANZ receives very little of its income from paid applications, the bulk of its standards setting between 2007-08 and 2009-10, resulted from paid applications.¹¹ While all government agencies need to balance their priorities with respect to available resources, any underlying reasons for not being able to consistently comply with legislative requirements should be examined. Many factors can influence an agency's performance, including workload, how resources are allocated to different functions and the productivity achieved. Understanding these factors would better position FSANZ to assess its current approach and, as necessary, discuss its resourcing with government and stakeholders.

¹⁰ One of these applications was withdrawn by the applicant before the timeframe expired.

¹¹ Although standard setting constitutes FSANZ's major responsibility it also carries out a number of other activities such as coordinating: food incidents; recalls; monitoring and surveillance; and education and providing information to stakeholders.

44. FSANZ has stated that owing to resource constraints, it has also considerably reduced its evaluation capability in terms of staff and activity. FSANZ uses reviews and evaluations to identify gaps in the Code and assess the effectiveness of existing standards. Generally, proposals were developed to address these gaps and also allow FSANZ to set standards that may better address their legislated objectives rather than relying on the particular interests of each applicant. FSANZ has not yet assessed whether this reduction in evaluation capability at the individual standard level will affect its evidence base and risk assessments when introducing new food standards.

Monitoring food standards: FSANZ's approach to addressing market failures

45. As well as its role in setting food standards, FSANZ has a number of additional functions including: coordinating the collection of data on monitoring and surveillance activities; coordinating responses to major food incidents; coordinating food recalls; and developing stakeholder education activities. While FSANZ is generally effective when it carries out these additional functions, there are some matters outside of FSANZ's control that impact on the success of these activities.

46. An important role of FSANZ is to coordinate and monitor food recalls within Australia in consultation with health authorities from the affected State/s and Territory/s and the relevant sponsor (usually the product's manufacturer or importer). Two trade recalls conducted by the affected States and coordinated by FSANZ in 2009 raised concerns. In these two instances sponsors reported that 55 per cent and 70 per cent of the potentially infected products were not recovered from retail outlets because they could not be traced, so may have been available to consumers.

47. FSANZ is working through food incident and recall protocols to address traceability issues to prevent further products entering the market in similar circumstances. In the interim, FSANZ could consider how it would address recalls of a similar nature should they arise. This is particularly important because the information that FSANZ provides to the Australian Competition and Consumer Commission (ACCC) was used to satisfy the Minister for Competition Policy and Consumer Affairs¹² that recalls have been conducted satisfactorily and that consumers are protected.

¹² On 14 September 2010, the Treasurer became the responsible Minister.

Key findings

Planning, risk management and performance information (Chapter 2)

48. FSANZ's stakeholder surveys have identified a number of strategic risks including differing views on FSANZ's role and responsibilities. FSANZ has recognised that a key risk is meeting the diverse and sometimes divergent expectations of consumers, food businesses and public health groups. Accordingly it has identified stakeholder relationships as a strategic imperative, including developing appropriate performance measures, in its 2009-12 Corporate Plan. Such measures will assist FSANZ to place a greater emphasis on managing risks at the strategic level.

49. FSANZ's program and major activities are intended to produce a stated Outcome including a *safe food supply and well-informed consumers in Australia and New Zealand*. An effective program is one that makes a difference in meeting this Outcome. Currently, FSANZ's effectiveness measures for its outcome focus on one major activity: *Effective evidence-based food standards*. However, FSANZ has not developed effectiveness measures for its two other major activities: *Protect health and safety* and *Citizen and stakeholder engagement*.

50. In seeking to measure the performance of its program, FSANZ faces the challenge of determining the specific contribution that its program makes towards the achievement of broader government outcomes. Given that a range of factors affect public health and safety, only some of which are under the control of, or subject to the influence of, FSANZ, it is appropriate for FSANZ to consider a range of supplementary measures to help explain its contribution to broader government outcomes. Such measures include the use of contextual trends and, although not as timely, information obtained through evaluations.

51. Historically, FSANZ has used reviews and evaluations to identify gaps in the Code and assess the effectiveness of existing standards. Generally, proposals were developed to address these gaps. Proposals also allow FSANZ to set standards that may better address its legislated objectives rather than relying on the particular interests of each applicant. However, owing to limited resources, FSANZ has considerably reduced its evaluation capability in terms of staff and activity. FSANZ has not yet determined whether this reduction in evaluation capability at the individual standard level will affect its evidence base and risk assessments when introducing new food standards.

Setting food standards (Chapter 3)

52. In developing food regulatory measures and variations of food regulatory measures, FSANZ must meet the legislated objectives set out in section 18 of the FSANZ Act which in priority order are: (1) the protection of public health and safety; (2) the provision of adequate information relating to food to enable consumers to make informed choices; and (3) the prevention of misleading or deceptive conduct.

53. The ANAO reviewed the assessment reports for 15 applications that FSANZ had assessed against the legislated objectives. The results for the 15 applications were that: four did not address any objectives; 12 did not address all or part of Objective 1; seven did not address Objective 2; and none of the applications addressed Objective 3.

54. Overall, FSANZ's assessment reports did not document an explicit consideration of how the agency took into account the objectives of the FSANZ Act when it developed or amended a food standard.

55. An approach for FSANZ to demonstrate how it meets its legislated objectives when it develops food regulatory measures is to include more explicit information in its assessment reports for all applications and proposals that explains how the three objectives were considered. Monitoring and reporting how FSANZ's three objectives were considered at the application and proposal level could then be consolidated to enable broader reporting against FSANZ's Outcome and be an effective way of communicating to stakeholders the breadth of work that is involved in setting food standards.

56. FSANZ has developed the *Food Standards Australia New Zealand Application Handbook* (the Application Handbook) to assist it to meet its legislative obligations including assessment against the legislated objectives. The Application Handbook is also used to inform applicants of the requirements that must be met for an application to be accepted and for FSANZ to develop or amend a standard.

57. Data quality is important to FSANZ internally to support its risk assessments and externally for accountability purposes. This is because stakeholders need to know the extent to which they can rely on the data that underpins FSANZ's food regulations. However, the required supporting data was often not provided by the applicants; and FSANZ did not consistently document whether the requirements were met.

58. FSANZ has a number of committees and reference groups that contribute to the standards setting process. FSANZ also invites submissions from interested parties as part of the standard setting process to allow for comments that it states will be taken into account for the final assessments. The expert groups contribute directly to the standards setting process. The composition of the committees and reference groups also assists FSANZ to manage, in part, varying stakeholder views.

Meeting regulated timeframes (Chapter 4)

59. Over time, the Australian Government has committed to reducing the regulatory burden on Australian businesses and not-for-profit organisations within the food industry, without compromising public health and safety.

60. One of the recent legislative changes was to allow an applicant to pay a fee for FSANZ to develop or amend a standard that could give the applicant a competitive advantage. An applicant may also pay a fee to expedite the consideration of an application. These changes were designed to enable industry to have its applications dealt with more rapidly and to overcome what was seen as an impediment to an efficient and competitive food industry.

61. However, the FSANZ Act also requires that assessment of paid applications must not displace the development of, or variation to, any other food regulatory measure in a three year plan (the Work Plan).

62. Against these requirements, FSANZ met the timeframe to assess whether to accept or reject all of the 48 applications received between 1 October 2007 and 30 June 2010. The timeframe for FSANZ to consider an application was met for nine paid applications with five of these being completed one month or more ahead of schedule. Of the 12 paid applications that were not finalised, three were already exceeding the planned timeframe. Only one of the 14 unpaid applications received in the same period had commenced assessment.

63. This trend highlights that FSANZ prioritises industry applications over proposals. Industry applications are also further prioritised if a fee is paid.

64. FSANZ has advised that it now identifies in its Work Plan, any applications or proposals that have been 'displaced' by paid applications and that it intends to report in future annual reports its compliance against the requirement that paid applications must not displace the development of any other food regulatory measure in its Work Plan.

Monitoring standards and addressing market failures (Chapter 5)

65. As well as its role in setting food standards, FSANZ has a number of additional functions including: coordinating the collection of data on monitoring and surveillance activities; coordinating responses to major food incidents; coordinating food recalls; and developing stakeholder education activities. FSANZ conducts these activities for Australia only and, while FSANZ is generally effective when it carries out these additional activities, there are some matters outside of FSANZ's control that impact on the success of these activities.

66. FSANZ's collection of food surveillance data from public health units is difficult to analyse and will remain so until the data are consistently collected by the State and Territory jurisdictions.

67. FSANZ coordinates and monitors food recalls within Australia in consultation with health authorities from the affected State/s and Territory/s and the relevant sponsor (usually the product's manufacturer or importer). Recalls are carried out at either a trade or consumer level. A trade recall recovers the product from distribution centres and wholesalers. A consumer recall recovers the product from all points including from consumers.

68. The ANAO reviewed two trade recalls that highlighted issues of concern. The sponsor's report on the recall of semi-dried tomatoes potentially infected with Hepatitis A noted that 70 per cent of the fruit was not recovered. The sponsor's report for a recall of paw paws infected with a bacterial skin contamination noted that 55 per cent of the infected fruit was not recovered.

69. A more rigorous approach to assess actions detailed in sponsors' reports would assist FSANZ to determine whether the most appropriate action had been taken to reduce risks to consumers. FSANZ is working through food incident and recall protocols to address traceability issues to prevent further products entering the market in similar circumstances. In the interim FSANZ's treatment of possible recalls of a similar nature is particularly important as the information that FSANZ provides to the ACCC is used to satisfy its Minister that a recall has been conducted satisfactorily and that consumers were

protected. Additionally, the requirement for consumers to be advised only applies to a consumer recall and not a trade recall.¹³

Summary of agency response

70. The following comments are a summary of FSANZ's response to the audit. The full response is at Appendix 1.

71. FSANZ welcomes the opportunity to respond to this draft report. The draft report is a useful and informative analysis of FSANZ's approach to its primary function of developing and reviewing food standards contained in the Australia New Zealand Food Standards Code. The audit has identified a number of areas where FSANZ's administration of its food standards function could be enhanced, particularly in respect of the currency of the agency's publicly available information and the transparency of the agency's reporting. The audit also provided a good outline of the complex regulatory environment within which FSANZ operates and the many challenges that this brings for a small agency with limited resources.

72. FSANZ agrees with the three recommendations contained in the report. We are already well advanced in our work to address Recommendation 1 (Performance Indicators) and have commenced work to develop and implement the enhancements necessary to address Recommendation 2 (Legislative Objectives) and Recommendation 3 (Food Standards Development Work Plan). FSANZ also notes that a number of matters in regard to the agency's role in coordinating national food recalls have been raised. FSANZ will work with the jurisdictions to facilitate improved systems for traceability and recovery of products that may be the subject of a food recall.

¹³ Although there was no requirement for consumers to be notified there was extensive media coverage on the potentially infected tomatoes and media releases by state government health departments. For the second incident the state health department notified the public about the infected paw paws and provided information on how to treat the fruit to prevent illness.

Recommendations

Recommendation No. 1

Para 2.62

For FSANZ to be in a position to better determine its contribution to a safe food supply and well informed consumers in Australia and New Zealand, the ANAO recommends that FSANZ:

- finalises its performance information and evaluation framework, including developing effectiveness indicators for monitoring the contribution of its program in meeting FSANZ's stated Outcome; and
- report in its Annual Report against its statutory objects and functions, including its legislated requirements relating to the prioritisation of its Work Plan.

FSANZ response: Agreed

Recommendation No. 2

Para 3.24

To better enable FSANZ to assess whether it is meeting the legislated objectives set out in section 18 of the FSANZ Act when it develops food regulatory measures (that is, the protection of public health and safety; and the provision of adequate information relating to food to enable consumers to make informed choices; and the prevention of misleading or deceptive conduct), the ANAO recommends that FSANZ:

- includes more explicit information in its assessment reports for all applications and proposals that explains how the three objectives were considered; and
- uses this information to internally monitor FSANZ's consideration of the three objectives at the application and proposal level and, over time, report trends more broadly.

FSANZ response: Agreed

**Recommendation
No. 3
Para 4.41**

To improve the transparency of the approach being taken by FSANZ to prioritise its Work Plan, the ANAO recommends that FSANZ:

- assess options to obtain a more appropriate balance between meeting the regulated timeframes for paid applications while also complying with the legislative requirement that paid applications must not displace unpaid applications or proposals in its Work Plan; and
- publicly reports its compliance with this legislated requirement.

FSANZ response: Agreed

Audit Findings

1. Background and Context

The food regulatory framework and FSANZ's responsibilities within it are identified in this chapter. The audit objective, scope and methodology are also outlined.

Introduction

1.1 Australia's international and domestic reputation of producing high quality food is supported by a 2008 international study that ranked Australia fourth in the world for food safety performance.¹⁴ Australian consumers expect that governments, producers and suppliers will maintain the safety of food and ensure its quality and availability whether it is domestically produced or imported.

1.2 Food regulation is an important public function. One of the main purposes is to avoid food-borne illnesses and the associated costs for individuals and the community. These include medical costs, lost productivity, business disruptions resulting from food recalls and decreased sales, investigating and treating resulting illness and possible legal costs.

1.3 A Department of Health and Ageing (DoHA) report for calendar year 2008 estimated that 5.4 million cases of food-borne illness occur annually in Australia with a total annual cost of \$1.2 billion. For that same period, food was suspected or confirmed as the mode of transmission for 104 major outbreaks of gastrointestinal illness, affecting a reported 1454 people which resulted in 96 hospitalisations and 11 deaths.

1.4 Food regulation in Australia and New Zealand is designed to provide: an effective, transparent and accountable regulatory framework within which the food industry can work efficiently; the provision of adequate information relating to food to enable consumers to make informed choices; and the establishment of common rules and harmonisation between domestic and international food regulatory measures while maintaining public health and protecting consumers.

¹⁴ *Food Safety Performance World Ranking May 2008*, Dr. Sylvain Charlebois, Dr. Chris Yost, p.15.

Australia and New Zealand: a bi-national approach

1.5 Australia and New Zealand harmonised food standards in 1983 as part of the *Australia New Zealand Closer Economic Relations Trade Agreement*. In 1995 the *Joint Food Standards Treaty* between Australia and New Zealand committed both countries to a single set of food standards and a bi-national agency to develop those standards.

1.6 In November 2000, the Council of Australian Governments (COAG) agreed to a new food regulatory system in response to the recommendations of the Food Regulation Review (the Blair Report), including the establishment of a new standards making body.

1.7 The *Food Standards Australia New Zealand Act, 1991* (FSANZ Act) was amended in 2001 to reflect the new co-operative bi-national system for food regulation. The amendments also established Food Standards Australia New Zealand (FSANZ) as the new statutory authority to develop and maintain food standards for the production, processing and sale of food in, or from, Australia and New Zealand.

1.8 Underpinning the food regulation system in Australia is the *Food Regulation Agreement, 2008*. This agreement commits all Australian State and Territory governments to a national system of food regulation. The *Model Food Act, 2002*, is the legislation that determines how the jurisdictions¹⁵ should adopt and implement the food standards developed by FSANZ. This is aimed at achieving consistency within the jurisdictions. The overall regulatory system comprises the following elements:

- developing policy—food regulation policy is developed by DoHA; and the Food Regulation Standing Committee (FRSC) which coordinates policy advice to the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council);
- setting standards—FSANZ develops and maintains standards contained in the joint *Australia New Zealand Food Standards Code* (the Code); and

¹⁵ The jurisdictions are the State and Territory governments, local councils in Australia where applicable and New Zealand through the New Zealand Food Safety Authority (NZFSA).

- implementing and enforcing standards—implementation, compliance and enforcement of the standards is the responsibility of the State and Territory governments, and many local governments in Australia; and where applicable the New Zealand Food Safety Authority (NZFSA).

Ministerial Council

1.9 The Ministerial Council comprises Health Ministers from all Australian States and Territories, the Australian and New Zealand Governments, as well as other Ministers from related portfolios where these have been nominated by their jurisdictions. It is primarily responsible for the development of domestic food regulatory policy and the development of policy guidelines for setting domestic food standards. The Ministerial Council also determines whether to adopt, amend, or reject standards or to request that standards be reviewed.

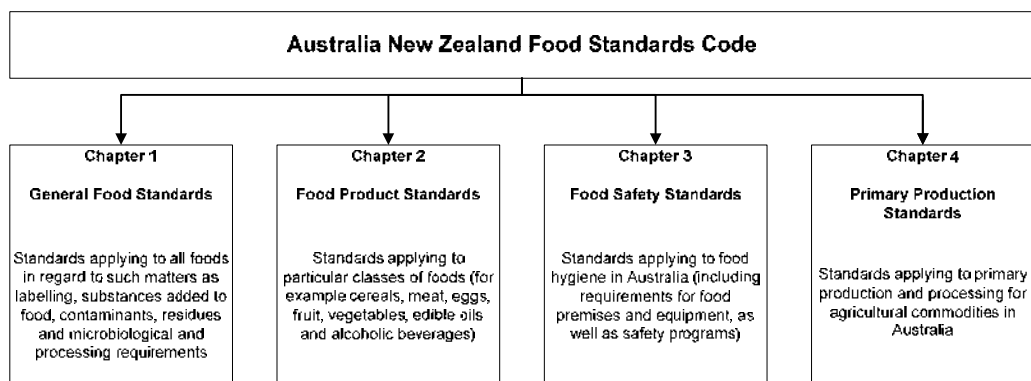
1.10 Once the Ministerial Council approves amends or rejects a standard, the variations to the Standards are gazetted and then automatically adopted by reference under food legislation of the Commonwealth of Australia, the Australian States and Territories and New Zealand.

The Australia New Zealand Food Standards Code

1.11 The Code is the collection of individual food standards. Standards on related matters are grouped together into Parts, which in turn are collected together into four Chapters. These are detailed in Figure 1.1.

Figure 1.1

The Australia New Zealand Food Standards Code



Source: ANAO analysis of FSANZ documents

1.12 Amendments to the Code are gazetted throughout the year. Gazette Notices are published in the Food Standards Gazette and registered as a Federal Legislative Instrument in Australia. The Notice is also published as part of the New Zealand Gazette which brings amendments to the Code into Commonwealth legislation.

1.13 The mechanism to give legislative force to the standards (which are set out in the Code) is by the Australian States and Territories and the New Zealand Governments adopting the Code into their own Food Acts.

Food Standards Australia New Zealand

Legislative framework

1.14 FSANZ is a statutory authority subject to the *Commonwealth Authorities and Companies Act 1997* (CAC Act). It was established as the new joint food standards body on 1 July 2002, under the FSANZ Act.¹⁶ The object of the Act is to:

ensure a high standard of public health protection throughout Australia and New Zealand by means of the establishment and operation of a joint body to be known as Food Standards Australia New Zealand to achieve the following goals:

- a high degree of consumer confidence in the quality and safety of food produced, processed, sold or exported from Australia and New Zealand;
- an effective, transparent and accountable regulatory framework within which the food industry can work efficiently;
- the provision of adequate information relating to food to enable consumers to make informed choices;
- the establishment of common rules for both countries and the promotion of consistency between domestic and international food regulatory measures without reducing the safeguards applying to public health and consumer protection.

¹⁶ The National Food Authority was the first separate body to set food standards under the FSANZ Act in 1991, but was replaced by Australia New Zealand Food Authority in 1996.

1.15 Although it has no law enforcement functions FSANZ provides assistance to jurisdictions to help ensure consistency in enforcement. FSANZ also has an extensive range of related statutory functions such as: develop codes of practice; develop guidelines; promote consistency with international standards; and facilitate the harmonisation of state and territory food law.

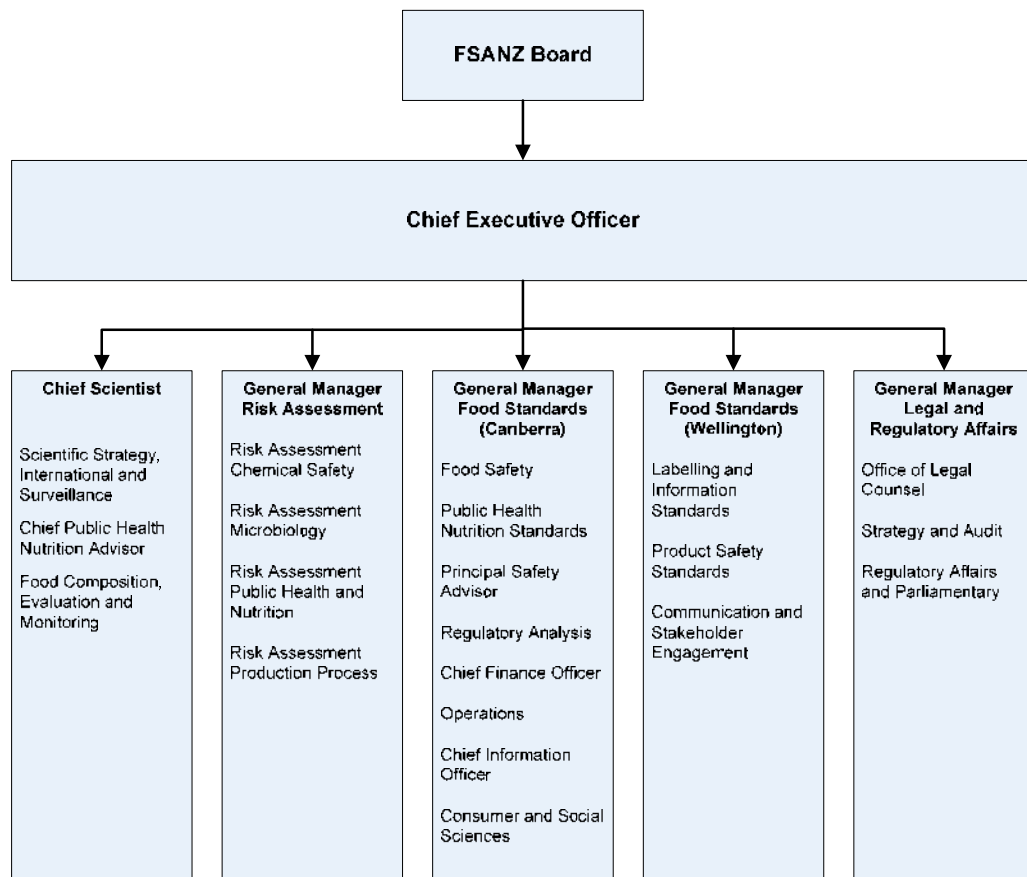
FSANZ structure and Board

1.16 FSANZ is part of the Australian Government's Health and Ageing portfolio with the Parliamentary Secretary for Health and Ageing having portfolio responsibility. The Authority has offices in Canberra and Wellington, New Zealand and employs 145¹⁷ staff in multi-disciplinary teams that work on risk assessment and risk management across: microbiology, toxicology, food technology, dietary modelling, nutrition, food surveillance, the law, communication, social sciences, economics and administration. The organisation chart for FSANZ is at Figure 1.2.

¹⁷ In this report, all references to staff numbers are based on full time equivalency.

Figure 1.2

FSANZ’s Organisation Structure



Source: ANAO analysis of FSANZ documents

FSANZ Board

1.17 The FSANZ Act establishes a twelve member board comprising eleven non-executive members and the FSANZ Chief Executive Officer (CEO). The non-executive members are appointed by the Parliamentary Secretary in consultation with the Ministerial Council. Board members have expertise covering a number of areas including public health, science, nutrition, food allergy, microbiology, food safety, biotechnology, veterinary science, production, industry, processing or retailing, trade, regulation, consumer rights and consumer affairs policy, the National Health and Medical Research Council and the public sector.

1.18 The Board is charged with setting the culture and strategic directions for the agency, while the CEO manages the day-to-day operations.

Revenue

1.19 FSANZ's total revenue for 2009-2010 is detailed in Table 1.1.

Table 1.1

FSANZ's revenue for 2009-2010

Revenue	\$'000
Funds from Government	19 566
Interest	342
Sale of goods and services (paid applications from industry)	680
Fee for service (international)	327
Other funding from Government	109
Other	83
Services to the New Zealand Government	1 423
Total Revenue	22 530

Source: FSANZ 2009-2010 audited Financial Statements

FSANZ's objectives in developing or reviewing food regulatory measures

1.20 FSANZ's objectives in developing or reviewing food regulatory measures and variations of food regulatory measures, detailed in the FSANZ Act, are 'in descending priority order':

- the protection of public health and safety; and
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.¹⁸

1.21 When it develops food standards, FSANZ also considers the COAG reform agenda, specifically the *National Partnership Agreement to Deliver a Seamless National Economy, 2008*. The reform of food regulation involves legislation, governance arrangements, uniform enforcement and setting or modifying food standards.

¹⁸ *Food Standards Australia New Zealand Act 1991*, section 18 (1).

Stakeholders' expectations

1.22 When it develops or amends food standards FSANZ must consider divergent stakeholder views and the implications of issues that are often outside of its control such as the food sector being influenced globally by: demand for low cost food; more intensive food production methods, including the genetic modification of plants; and industrialised food processing. Additionally, consumer expectations around the safety and quality of food continue to grow and that adequate information will be available when food is purchased. Conversely, food businesses expect governments to minimise the costs of any regulation and not impose any unnecessary requirements that would inhibit production efficiencies and technological improvements, meeting the aims of the COAG regulatory reform agenda.

Food standards development

1.23 FSANZ develops all domestic food standards based on what it considers to be the best available science. The standards regulate the composition and labelling of foods for sale in Australia and New Zealand. In addition, FSANZ develops food safety standards for Australia only, to regulate hygiene requirements for the preparation and handling of food. This was extended to include the primary production aspect of the food chain, the concept of regulation of food from 'paddock to plate'.

1.24 The FSANZ Act provides that when it develops these standards, FSANZ must also have regard to:

- the need for risk analysis using the best available scientific evidence;
- consistency between domestic and international food standards;
- the promotion of fair trading in food;
- an efficient and internationally competitive food industry; and
- Ministerial Council guidelines.

Implementation and enforcement of the Code

1.25 Under the Constitution, the States and Territories are responsible for the implementation and enforcement of food standards and this often involves local government. The Australian Quarantine and Inspection Service implements the food standards for foods imported into, and exported from,

Australia. The States and Territories adopt the Food Code into their own acts. A key rationale for the national system is to consistently apply the code.

1.26 Within New Zealand, NZFSA is responsible for implementation and enforcement. The New Zealand Government reserves the right not to adopt certain standards.

Other FSANZ functions

1.27 FSANZ plays a key role in coordinating the management of food incidents and recalls and providing advice on public health issues arising from food.

1.28 FSANZ administers the National Food Incident Response Protocol to coordinate major food safety incidents¹⁹ that may have an impact on more than one State or Territory. For example, FSANZ coordinated a major incident in September 2008 after it became aware that Australia may have imported Chinese infant formula that had been contaminated with melamine.

1.29 FSANZ also coordinates and monitors food recalls within Australia only. Recalls occur in consultation between state and territory authorities and a sponsor who is usually the product's supplier, for example, the manufacturer or the importer. The FSANZ website shows that the number of food recalls in Australia has fallen over the past four years from 86 in 2004 to 60 in 2009.²⁰

1.30 FSANZ and other government agencies in Australia and New Zealand monitor the food supply to ensure that it is safe, and that foods comply with standards for microbiological contaminants, pesticide residue limits and chemical contamination. FSANZ has a bi-lateral surveillance and enforcement strategy and it acts as the central point for collection of food surveillance data from public health units in Australia and New Zealand.

1.31 FSANZ also develops food education initiatives, including the publication of information to increase public awareness of food standards and food labels. Examples of the forms of communication currently used by FSANZ include food safety videos, posters, fact sheets, newsletters and webinars.

¹⁹ Major Food Safety Incidents can result in public health and safety risks among consumers and can also cause widespread consumer concern and significant disruption to domestic and international trade.

²⁰ This includes trade and consumer recalls that are detailed in Chapter 5 of this report. The statistics can be found at: <<http://www.foodstandards.gov.au/consumerinformation/foodrecalls/foodrecallstats.cfm>>.

International food regulation

1.32 The FSANZ Act provides that FSANZ must have regard to the promotion of consistency between domestic and international food standards.

World Trade Agreements

1.33 The Codex Alimentarius²¹ Commission (Codex) is the international food standards setting body recognised by the World Trade Agreements for Sanitary and Phytosanitary Measures (SPS)²² and Technical Barriers to Trade (TBT) as being the reference point for food standards applied in international trade. The Australian Government is a signatory to both agreements. Australia is also a member nation of Codex and FSANZ is directly involved in Codex technical food standards committees.

Other international food regulators

1.34 The Quadrilateral Group (the Quads) is made up of food safety experts from Australia, Canada, the United States and New Zealand. The Quads provides a forum for discussing emerging issues and international best practice standards as they affect the four countries, and offers support for shared interests at Codex sessions.

1.35 Within New Zealand, the NZFSA is responsible for developing domestic food regulatory policy. The NZFSA and FSANZ share responsibilities for administering New Zealand's food regulatory environment for only the first two Chapters of the Code, although the New Zealand Government reserves the right not to adopt certain standards.

1.36 FSANZ is developing and maintaining strong links with other leading food regulatory agencies around the world. These include the United Kingdom Food Standards Agency, the United States Food and Drug Administration, Health Canada and the European Food Safety Authority. This collaboration includes joint studies, incident response and communications on issues which may have a bearing on Australia and New Zealand.

²¹ Codex Alimentarius is Latin for 'food code'.

²² 'Sanitary and Phytosanitary' means food safety and animal and plant health (*World Trade Organisation Basic Rules*) at <http://www.wto.org/english/tratop_e/sps_e/sps_e.htm>.

Audit objectives and scope

Objective

1.37 The objective of the audit was to assess FSANZ's administration of its food standard functions, as specified in the *Food Standards Australia New Zealand Act, 1991 (amended 2002, 2007)*.

1.38 Particular emphasis was be given to whether:

- FSANZ's performance management and reporting provided effective support and ensures accountability;
- FSANZ effectively administered its food standard development and variation function, including its stakeholder management; and
- FSANZ effectively monitored the implementation of its standards and coordinates relevant jurisdictions to address market breakdowns.

Scope

1.39 The scope of the audit included FSANZ's: development and amendment of food standards; coordination and surveillance activities; coordination of food incidents and recalls; provision of information to consumers; and supporting corporate processes. The scope of this audit did not include the bodies primarily involved in food regulation policy or the bodies responsible for the implementation, compliance and enforcement of the standards.

Audit methodology

1.40 In order to form an opinion against the audit objective the ANAO:

- examined policy documents, guidelines, procedures, operational documents and reports;
- interviewed FSANZ staff; and
- reviewed and analysed stakeholder surveys, files, records, systems and publications.

The audit forms part of the ANAO's strategic focus on regulators within the Health and Ageing portfolio.

1.41 The audit was conducted in accordance with ANAO auditing standards at a cost of \$449 227.

Structure of the Report

1.42 This report is structured as follows:

- Chapter 2 – Planning, Risk Management and Performance Information;
- Chapter 3 – Setting Food Standards;
- Chapter 4 – Meeting Regulated Timeframes; and
- Chapter 5 – Monitoring Standards and Addressing Market Failures.

2. Planning, Risk Management and Performance Information

FSANZ's approach to planning, risk management and its use of performance information to monitor and report progress against its objectives is examined in this chapter.

Introduction

2.1 One of the main elements of sound governance is an effective planning and reporting regime. Such a regime provides a framework within which an organisation operates to achieve its objectives. Being clear on goals, allocating responsibilities, setting timeframes and reporting against performance indicators, provides the basis for assessing performance. Planning should also address the risks to the successful achievement of stated objectives.

2.2 Within this context, the ANAO examined whether FSANZ had:

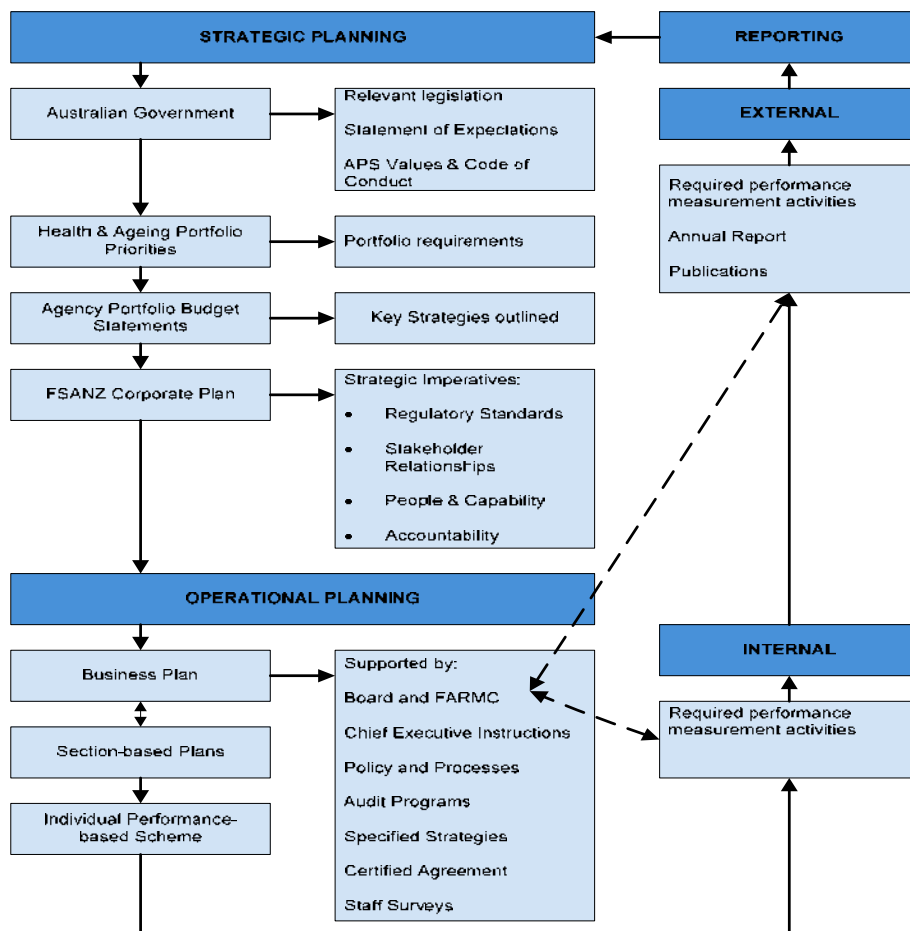
- an effective planning framework, including the consideration of strategic risks;
- arrangements in place to engage with stakeholders to manage strategic risks that have the potential to impede the achievement of its objectives; and
- an appropriate performance information framework that supported effective internal and external reporting.

FSANZ's planning framework

2.3 FSANZ's planning and reporting framework is provided in its 2009-2012 Corporate Plan. The framework details legislated and operational plans, and the linkages to related plans. FSANZ also considers additional and emerging issues in its planning processes such as the *2009 National Preventative Health Strategy*, the Government's current *Review of Food Labelling Law and Policy* and the Council of Australian Governments' (COAG) reform agenda. The COAG reform of food regulation involves legislation, governance arrangements, uniform enforcement and setting or modifying food standards. FSANZ's planning and reporting framework is shown in Figure 2.1.

Figure 2.1

FSANZ Planning and Reporting Framework



Source: FSANZ 2009-12 Corporate Plan

Incorporating risk into planning processes

2.4 Managing risk involves systematically identifying, analysing and mitigating risks which could prevent an agency from achieving its business objectives. Risk management includes putting control activities and treatments in place to manage significant risks facing an organisation and monitoring their success in ameliorating identified risks. In the case of FSANZ a structured and systematic approach to managing its strategic risks, would include:

- consideration of the former Parliamentary Secretary's Statement of Expectations, FSANZ's Statement of Intent and its legislated objectives;
- the identification of strategic risks to meeting these objectives; and

- incorporating and managing these risks within FSANZ's planning and reporting processes.

Statements of Expectations and Intent

2.5 As a result of the Government's acceptance of the recommendation of the Review of the Corporate Governance of Statutory Authorities and Office Holders (widely known as the Uhrig Review), Ministers are required to outline their expectations of agencies in a public Statement of Expectations. Each agency must then respond with a Statement of Intent which details how they will fulfil the Minister's expectations.

2.6 The former Parliamentary Secretary issued his first Statement of Expectations to the FSANZ Board Chair on 10 August 2009. The Statement outlines short and long-term requests to support the Government's pursuit to reduce the regulatory burden on Australian businesses and not-for-profit organisations within the food industry, without compromising public health and safety.

2.7 To meet this aim FSANZ has been asked to: align its work with the Government's strategic directions and priorities; facilitate the harmonisation of standards between jurisdictions to contribute to more consistent implementation of standards; deliver final outputs 'well within' its legislated timeframes; and conclude some long standing projects listed on its work plan.

2.8 FSANZ responded with its Statement of Intent on 17 September 2009. FSANZ stated that while it commits to the suggested performance targets it would not compromise quality of output for reduced timeframes. This is particularly pertinent in respect of some of the more recent applications relating to genetically modified food which are more complex and require careful scientific evaluation. FSANZ also stated that it supported the Australian and New Zealand Governments' focus on deregulation.

Legislated objectives

2.9 FSANZ's objectives when it develops or reviews food regulatory measures and variations are detailed in the *Food Standards Australia and New Zealand Act, 1991* (FSANZ Act). They are, in priority order: the protection of public health and safety; and the provision of adequate information relating to

food to enable consumers to make informed choices; and the prevention of misleading or deceptive conduct.²³

Strategic risks to meeting FSANZ's objectives

2.10 Managing risk requires the design and implementation of procedures that treat unacceptable risks. It is an ongoing process of deciding where to apply resources that will reduce risks to a tolerable level. Agencies need to identify the significant risks which may impact upon the achievement of their goals and objectives, and have in place a risk management strategy to mitigate their effect and/or treat them positively.

2.11 There are two main levels or categories of risk which are: strategic risks including the concern that major strategic alternatives may be ill-advised given an organisation's external and internal circumstances, including environmental risks such as political, economic and market factors; and operational risks including compliance and process risks.

2.12 At the operational level, risk assessment and risk management are the foundation of FSANZ's standard setting processes and its coordination of incidents and recalls. In fact, FSANZ was highly commended in the 2009 ComCover Awards for Excellence in Risk Management for its publication *The Analysis of Food-Related Health Risks*.

2.13 However, FSANZ does not formally identify, document, assess and manage its risks at the strategic level. While FSANZ will need to undertake its own risk assessments that reflect its operating environment, the ANAO notes that a number of strategic risks that FSANZ faces were identified in responses to stakeholder surveys. These include: differing views on FSANZ's objectives and meeting the diverse, and sometimes divergent, expectations of its many stakeholders that include Governments, consumers, food businesses, and public health groups.

Stakeholders' views on FSANZ's objectives

2.14 There is a broad range of views held by FSANZ's stakeholders as to what is meant by protecting public health and safety, and there is a variety of views on what constitutes the provision of adequate information to enable consumers to make informed choices. For some consumers, this means

²³ *Food Standards Australia New Zealand Act 1991*, section 18 (1).

labelling the major ingredients while others consider that every item that is, or may be, found in a labelled food should be included.

2.15 Consumers and consumer representative groups, industry and industry groups also hold different views on the degree of regulation required in the food industry. They range from the view that governments should stringently regulate all food through to fully informing consumers so they are able to make their own decisions. A selection of the views held by FSANZ’s stakeholders is outlined in Table 2.1.

Table 2.1

Stakeholders’ expectations

Stakeholder Group	Expectation
Governments	The Australian and New Zealand Governments have a strong focus on reducing the regulatory burden on the food industry, without compromising public health and safety. FSANZ recognises that one of its challenges is to develop food standards and other measures that aim for ‘minimum effective regulation’.
Consumers	Consumer expectations concerning the safety, quality and availability of food continue to grow. Increasingly, consumers expect a safe food supply and that adequate information is provided to them when buying food. FSANZ faces the challenge of ensuring a safe food supply and informing consumers while reducing the regulatory burden for industry.
Industry	The profitability and sustainability of the food industry is contingent upon operational economies and efficiencies, or technological advancement and innovation. FSANZ faces the challenge of anticipating potential areas for regulatory standards and ways to ensure food safety.
Public Health Groups	Health professionals and consumer groups promote the use of food to address longer term population health challenges such as obesity and diabetes. This greater focus on aspects of preventative health has grown over time and the information that FSANZ obtains in gathering and testing evidence would also support the development of standards and strategies that contribute to broader population health goals such as preventative health.

Source: ANAO analysis of FSANZ documents, including stakeholder surveys.

2.16 These divergent views constitute a key risk affecting FSANZ’s ability to meet stakeholder expectations. For example, is protection of public health and safety provided by maintaining the status quo; allowing changes that do not apparently damage health at least in the short term (minimising harm); or actively promoting better health (for example, fortifying food)?

2.17 The multi-jurisdictional nature of FSANZ's operating environment is another risk factor. In considering the roles and responsibilities for public health across Australian jurisdictions, a Choice submission to a Productivity Commission review²⁴ stated that, whilst FSANZ maintains and amends the Code under the guidance of the Ministerial Council....

it is the responsibility of the state and territory governments to enforce the Food Standards Code. This is done through state government food acts. CHOICE believes that confusion over the responsibilities of state governments and their relevant enforcement agencies lies partly in the fact that the FSANZ objectives are not replicated in all state government food acts.

2.18 Developing food standards that promote regulatory consistency is one of the objects of the FSANZ Act as well as being a matter that FSANZ must have regard to. FSANZ has a number of processes in place that contribute to this objective (see Chapter 3 for further details).

Managing strategic risks

2.19 FSANZ advised in July 2010, that it has identified its Enterprise Strategic and Operational risks and its Fraud Control Strategic and Operational Risk issues with the assistance of its current internal auditors. FSANZ provides a report identifying the actions taken to mitigate each *high risk* item to each meeting of the Finance and Risk Management Committee. The report identifies who within FSANZ has responsibility and sets out the actions that have been taken and will be taken. It also provides evidence of activity and response in mitigation.

2.20 The risk assessment and rating tables are living documents and the enterprise risk assessment has been added to since its development in late 2009. For example, the FSANZ Board recently identified reputation management as a strategic risk and it has now been listed for future action.

2.21 Identifying and managing risks in this way should assist FSANZ to have a shared view of: its strategic risks; how they impact on FSANZ meeting its overall objectives; the risk treatments being implemented; who within FSANZ is responsible for monitoring the treatments; and whether the treatments are working. This approach would also assist FSANZ to better

²⁴ CHOICE submission: *Productivity Commission Review of Regulatory Burden – Manufacturing and Distributive Trades*, 31 July 2008, p.5.

prioritise its overall work program and available resources based on the areas of greatest risk.

2.22 Although FSANZ reports on risk treatments and whether they are effective to the Finance and Risk Management Committee, the treatments are not documented in the agency's risk register. Documenting the treatments is particularly important when an identified risk has an initial assessment of 'high' or 'significant' with a residual assessment of 'low'. This approach would assist FSANZ to monitor and track its progress in managing its strategic risks and to assess overall whether the treatments are effective and strategic risks are being appropriately managed.

2.23 FSANZ has advised that it intends to link risk treatment reports to its risk register to enable staff to access information about the treatments and their effectiveness.

Stakeholder engagement

2.24 The relationships that an agency such as FSANZ has with its stakeholders can make an important contribution towards the management of strategic risks likely to impede the delivery of key objectives and increase public confidence in its regulatory decisions. Setting food standards (regulations) is assisted by effective communications and relationship management with government partners, consumers and consumer organisations, industry, public health bodies and other key stakeholder groups.

2.25 In examining how FSANZ manages its relationship with stakeholders involved in the food sector, the ANAO assessed FSANZ's:

- objectives, strategies and performance measures for stakeholder relationships, contained in FSANZ's Corporate Plan for 2009-12;
- arrangements for stakeholder participation in FSANZ's standards development process and communication strategies for specific changes to the Standards (see Chapter 3);
- management of stakeholder expectations for timeliness of developing or amending food standards (see Chapter 4); and
- FSANZ's food education activities (see Chapter 5).

2.26 In its Corporate Plan for 2009-12, FSANZ identified three specific objectives to build stronger stakeholder relations which are:

- a shared understanding of FSANZ's role; a reputation for being proactive and alert; and credibility and trust in FSANZ.

2.27 FSANZ's specific strategies to support its efforts to deliver on this imperative include:

- developing and implementing a dedicated stakeholder engagement strategy which will strengthen communication and engagement with its regulatory partners, industry, consumers and the general community;
- providing communication mechanisms to ensure stakeholders are appropriately informed about FSANZ standards setting processes, approaches and outcomes;
- improving the readability and accessibility of documents and mechanisms for comment; and
- tracking the reputation and standing of FSANZ amongst stakeholders and international peers.

2.28 The following performance measures were identified to determine whether the strategies are successful:

- stakeholders clearly understand the role of FSANZ;
- increased credibility and trust in FSANZ expertise; and
- increased levels of confidence in the robustness of standards developed by FSANZ.

2.29 As well as assisting its stakeholders to be informed about its activities, FSANZ monitors stakeholder satisfaction and reports this in its Annual Report. For example, in November 2008, FSANZ undertook an evaluation to determine the effectiveness of its Science Strategy 2006-09. The evaluation targeted both external and internal stakeholders of the strategy.

Performance information framework and reporting

2.30 The Australian Government's Outcomes and Programs Framework provides the basis of the Government's approach to budgeting and reporting for public sector departments and the means by which the Parliament appropriates funds in the annual budget context. The key elements of the framework are:

- specification of the outcomes the Government is seeking to achieve in the community;
- identification of programs and their associated deliverables (for example, benefits, services or transfer payments provided to individuals, business or the community);
- establishment of a performance management regime that enables the measurement and assessment of the contribution of programs to their respective outcomes; and
- annual performance reporting by departments on their delivery of programs.

2.31 This framework replaced the Outcomes and Outputs Framework that was in place from 1999 to 2010. As part of its transition to the new arrangements, FSANZ adopted a new Outcome/Program structure in the agency's 2009-10 Portfolio Budget Statements (PBS).

FSANZ's Outcomes and Programs

2.32 In its 2010-11 PBS, FSANZ identifies a single Outcome:

A safe food supply and well-informed consumers in Australia and New Zealand, including through the development of food regulatory measures and the promotion of their consistent implementation, coordination of food recall activities and the monitoring of consumer and industry food practices.

2.33 Within this Outcome, FSANZ has a single Program 1.1: *Food Regulatory Activity and Services to the Minister and Parliament*. The objective of this program is to:

- manage the development and maintenance of effective, evidence-based food standards contributing to the provision of a safe food supply;
- ensure effective engagement with regulatory partners in the implementation of food standards to protect public health and safety; and
- strengthen engagement with industry, consumers and the general community to increase awareness of the food regulatory system.

2.34 The aim of the Australian Government's Outcomes and Programs Framework is to provide a transparent and consistent framework for reporting across the Government. Programs are the primary means by which agencies

address and achieve government outcomes. To assess the approach taken by FSANZ to plan and report against its single program, the ANAO assessed the agency's:

- program deliverables; and
- program key performance indicators.

FSANZ's program deliverables

2.35 Deliverables are the goods and services produced and delivered by a program in meeting its objective. Collectively, the deliverables represent the intervention government has chosen to take to meet a policy problem. They are expected to bring about results outlined in the objective which can be identified and measured through program performance indicators. To allow for consistent estimation over time, deliverables should be measurable and quantifiable units or activities.

2.36 Agencies are required to determine and report on the deliverables for each agency program. This can include quantity, cost/price, and quality indicators where:

- quantity is typically the number of products and/or services that are produced for a given cost;
- over time, program support information allows judgements to be made about the cost of administration and to ascertain whether there are more efficient ways of achieving program objectives; and
- quality relates to attributes such as timeliness, coverage, accuracy and conformity to specifications. Although more difficult to measure, criteria such as client satisfaction and public perception can also be used to assess quality.

2.37 The deliverables identified by FSANZ for its Program 1.1: *Food regulatory activity and services to the Minister and Parliament* are summarised in Table 2.2.

Table 2.2

Deliverables identified for FSANZ’s Program 1.1

Major Activity	Example of a Typical Deliverable	Qualitative Indicator provided?	Quantitative Indicator provided?	Target provided?
Effective evidence-based food standards	Conducting evaluation surveys to measure consumer understanding of fortified foods and their consumption behaviour patterns	✓	×	✓
Protect health and safety	Management of National Food Incident Response and Industry Food Recall Protocols	✓	×	✓
Citizen and stakeholder engagement	Provide access to publications and information on the food regulatory system	✓	✓	✓

Source: Portfolio Budget Statements 2010-11, Health and Ageing Portfolio

2.38 Overall, in its publicly available documentation, FSANZ identifies a range of quality indicators and targets for its Program 1.1: *Food Regulatory Activity and Services to the Minister and Parliament*.

Program key performance indicators

2.39 Using the Australian Government’s Outcomes and Programs Framework, key performance indicators (KPIs):

- should demonstrate the performance of the program in achieving its objectives and contributing to its respective outcome. As many programs will be long term (that is, 10+ years), the projected time scale for the KPIs is at the discretion of the agency and can go beyond the forward years; and
- are not a measure of the output of the program (that is, quality and quantity indicators which are included in the deliverables section) but the effectiveness of the program in achieving its objective.²⁵

FSANZ’s effectiveness indicators

2.40 FSANZ’s program and major activities are intended to produce a stated Outcome including a safe food supply and well-informed consumers in

²⁵ Department of Finance and Deregulation, *Portfolio Budget Statements Constructors Kit, 2010-11*.

Australia and New Zealand. An effective program is one that makes a difference in meeting this Outcome.

2.41 The effectiveness indicators set by FSANZ for its Program 1.1: *Food Regulatory Activity and Services to the Minister and Parliament* are shown in Table 2.3.

Table 2.3

Performance Indicators identified for FSANZ Program 1.1

Major Activity	Example of a Typical Deliverable	Qualitative Indicator provided?	Quantitative Indicator provided?	Target provided?
Effective evidence-based food standards	Increased knowledge on food fortification	✓	✓	✓
Protect health and safety	No Performance Indicator provided	×	×	×
Citizen and stakeholder engagement	No Performance Indicator provided	×	×	×

Source: Portfolio Budget Statements 2010-11, Health and Ageing Portfolio

2.42 Currently, FSANZ’s effectiveness indicators for its Outcome focus on one major activity: *Effective evidence-based food standards*. These indicators are not sufficient to capture the intended overall impact of FSANZ’s Outcome, effectiveness indicators for: *Protect health and safety*; and *Citizen and stakeholder engagement* should also be included.

Identifying appropriate indicators

2.43 While identifying measures of effectiveness for standard setting is particularly challenging, it is important that effectiveness indicators are defined, measured and reported for internal management and external accountability purposes. Below are some examples that FSANZ could refer to as a guide when developing performance indicators:

- *Protect health and safety*: performance indicators could measure the responsiveness/timeliness of FSANZ’s management of food issues requiring urgent action (for example, FSANZ coordinated a major incident in September 2008 after it was notified that Australia may have imported Chinese infant formula that had been contaminated with melamine); and

- *Citizen and stakeholder engagement:* through consumer surveys, FSANZ could track public confidence in food safety. A clear causal link would need to be established to food standards developed by FSANZ and subsequent changes in food control practices.

Use of stakeholder feedback

2.44 When considering effectiveness, it is useful to take into account the perspectives of a range of stakeholders or to seek their views. While stakeholders are likely to make judgements based on their perceptions, the attitudes of stakeholders can also have a significant impact on the success of a program and its contribution to broader outcomes.

2.45 FSANZ's Corporate Plan includes qualitative KPIs for its Stakeholder Relationship strategic imperative, however, this information is not provided in the agency's PBS.

FSANZ's contribution to wider government outcomes

2.46 In seeking to measure the performance of its program, FSANZ faces the challenge of determining the specific contribution that its program makes towards the achievement of the Outcome. How much of the success (or failure) can be attributed to the FSANZ program? What has been the contribution made by the program?

2.47 In its submission to a recent Productivity Commission Research Report, FSANZ stated.

At the time of introduction of the Food Safety Standards, it was decided that FSANZ would evaluate their impact. It was acknowledged that it was not possible to measure the effect of implementing the Standards on the end objective of setting those Standards—the protection of public health and safety. This is because the external influences on public health and safety as a whole are so complex and influenced by many external factors that a measured change to the level of health and safety of a given population group cannot generally be attributed to a single influence, a single agency or action by an agency, such as a change in food regulatory measures.²⁶

2.48 Given that a range of factors affect public health and safety, only some of which are under the control of, or subject to the influence of, FSANZ, it is

²⁶ Productivity Commission Research Report, *Performance Benchmarking of Australian and New Zealand Business Regulation: Food Safety*, December 2009.

appropriate for FSANZ to consider a range of supplementary measures to help explain its contribution to broader government outcomes. Such measures include the use of contextual trends and, although not as timely, information obtained through evaluations.

Contextual trends

2.49 Contextual information is helpful to describe the broad environment in which an agency is operating and the general trends in the area targeted by a program. Reporting on the trends in the area targeted by FSANZ's Outcome, for example, trends in food-borne outbreaks in Australia and New Zealand would provide useful background information. FSANZ could, for example, consider greater use of information that it already obtains through surveys and trend data available from the Australian Institute of Health and Welfare that is collected on FSANZ's behalf.

Evaluations

2.50 Review and evaluation are important elements in assisting agencies to assess the impact of their work. The benefits in undertaking evaluations include: a better understanding of the achievements of a program; clarification of performance information; and an assessment of the continued relevance and priority of a program in the light of current circumstances.

2.51 FSANZ planned to conduct scientific and technical evaluation of the impact, effectiveness and appropriateness of implementing individual food regulatory measures. The agency's aim is to build up an evidence base for future decision making in relation to the development of food standards.

2.52 Although it is FSANZ's aim to have an evidence base for future food standards development, it has advised that it has considerably reduced its evaluation capability in terms of staff and activity owing to very limited resources. FSANZ has not yet determined whether this reduction in evaluation capability will affect its evidence base and risk assessments when introducing new food standards.

Reporting

2.53 The *Commonwealth Authorities and Companies Act 1997* (CAC Act) and regulations outline FSANZ's reporting requirements, corporate planning obligations including the setting and reporting of objectives (including Outcomes), assessment of the operating environment, strategies and the necessity of adequate record keeping.

External Annual Reporting

2.54 Under the *Commonwealth Authorities and Companies (Report of Operations) Orders 2008* (CAC Orders), FSANZ must provide a review of how the agency has performed in relation to ‘its statutory objects and functions, as the case requires; its corporate plan, where applicable; and its principal Outputs and contribution to Outcomes;’ as well as other statutory requirements. The FSANZ Act outlines the requirements of FSANZ and its Board in relation to these activities.²⁷

2.55 In its two most recent Annual Reports, FSANZ reported against the KPIs in its 2006-09 Corporate Plan and relevant PBS. FSANZ also reported on its lower level legislated processing requirements for applications and proposals. This included: number of applications accepted or rejected; applications withdrawn; applications not yet assessed; applications that span more than one financial year; and number of unpaid/paid applications. This information, which is required to be reported by financial year, provides an indication of when applications or proposals that were completed in the reporting period were commenced and consequently whether regulated timeframes were met.

2.56 Over time, the KPIs in FSANZ’s PBS have remained consistent and included qualitative and quantitative measures. The CAC Orders, however, also require FSANZ to report against its statutory objects and functions (as detailed in paragraph 2.9 of this report); and its legislated requirements relating to the prioritisation of its annual work program (as detailed in paragraph 4.23 of this report). FSANZ should take steps to address these requirements.

Internal reporting

2.57 FSANZ has mechanisms in place to consolidate project level information and report this to its management and executive and then to the Board.

2.58 FSANZ has Executive and management meetings weekly where updates are provided by attendees. The Executive attends both of these meetings and, to keep them brief, the reporting usually focuses on highlights

²⁷ These activities include: the powers of the Board and agency; membership of and appointments to the Board; Board procedures; planning and accountability (both content and reporting procedures); the appointment and duties of the Chief Executive Officer; and financial arrangements.

and exceptions. The information is mostly at the project level although there may be more strategic reporting from sponsors of particular corporate projects. Some examples of these projects are: stakeholder management; the science strategy; and new databases. Minutes are posted to the Intranet. This appears to work well.

2.59 All of FSANZ's available Executive attend all Board meetings and provide regular status updates on applications, proposals and relevant corporate projects. More urgent updates are issued to Board members out-of-session and if further discussion is required these are teleconferenced. Staff developing the standards or managing the projects are always acknowledged by the executive member who is providing the update.

2.60 The Executive's regular updates on performance are not, however, aligned with FSANZ's legislated objectives or the KPIs in its corporate plan or PBS. The reports are mostly progress reports on standards being amended or developed and do not inform the Board on quality or effectiveness. Reports also tend to focus on individual activities and not FSANZ's overall performance against its Food Standards Development Work Plan (Work Plan).

2.61 The aim of reports to the FSANZ Board should be to allow the Board more opportunity to strategically assess the success or otherwise of FSANZ's overall program and adjust strategies when necessary. To support this approach, FSANZ's reporting to the Board could include updates on achievements against FSANZ's statutory objects, the KPIs in its PBS and Corporate Plan, and progress overall against FSANZ's Work Plan.

Recommendation No.1

2.62 For FSANZ to be in a position to better determine its contribution to a safe food supply and well-informed consumers in Australia and New Zealand, the ANAO recommends that FSANZ:

- finalises its performance information and evaluation framework, including developing effectiveness indicators for monitoring the contribution of its program in meeting FSANZ's stated Outcome; and
- report in its Annual Report against its statutory objects and functions, including its legislated requirements relating to the prioritisation of its Work Plan.

FSANZ response

2.63 Agreed. We are already well advanced in our work to address this recommendation.

3. Setting Food Standards

The development of food regulatory measures by FSANZ, as required by the *Food Standards Australia New Zealand Act, 1999*, is examined in this chapter.

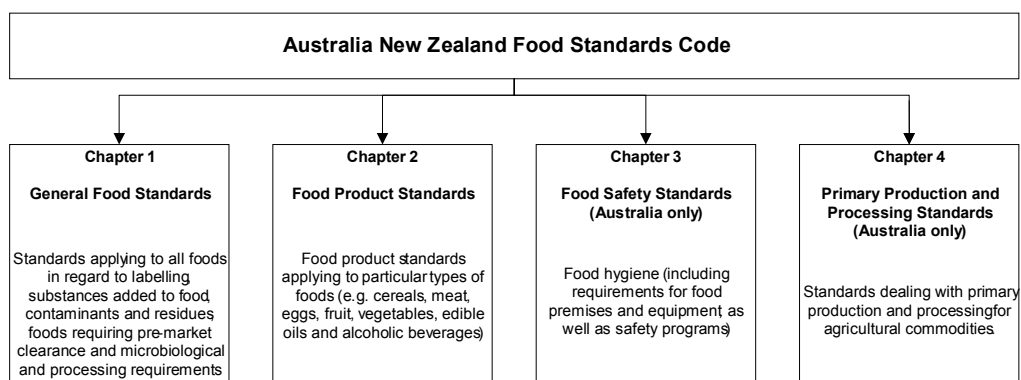
Introduction

3.1 FSANZ develops regulatory measures in the form of food standards. When developing food standards, FSANZ must operate in accordance with the *Food Standards Australia New Zealand Act, 1991* (FSANZ Act). The standards are published in the *Australia New Zealand Food Standards Code* (the Code) which is available on FSANZ's website.

3.2 Food standards contain requirements for the composition, labelling and handling of food for sale in Australia and New Zealand. These standards apply to imported foods as well as to domestic production and are incorporated into the Code which is divided into four chapters, as shown in Figure 3.1.

Figure 3.1

The Australia New Zealand Food Standards Code



Source: ANAO analysis of FSANZ documents

3.3 In developing food regulatory measures and variations of food regulatory measures, FSANZ must meet the legislated objectives set out in the FSANZ Act (including the protection of public health and safety), as well as 'having regard to' a number of other matters (such as the need for risk analysis using the best available scientific evidence).

3.4 Within this framework, the ANAO identified and reviewed a sample of applications to vary the Code and, in doing so, assessed FSANZ's food standards development and review process to determine whether FSANZ:

- set food standards in accordance with section 18 of the FSANZ Act; and
- gave appropriate consideration to other matters as required by the FSANZ Act.

Setting food standards in accordance with section 18 of the FSANZ Act

Applications and proposals

3.5 Food standards are developed or amended in response to:

- applications by a body or a person; or
- proposals developed by FSANZ.

3.6 Proposals address aspects of the Code that need to be developed or revised arising from: major clarification, corrections or reviews; changes to Council of Australian Governments (COAG) or whole-of-Government policy (for example, removing trade restrictions); policy of the Ministerial Council or the Food Regulation Standing Committee; and public submissions.

Applications received by FSANZ between October 2007 and June 2010

3.7 From 1 October 2007 to 30 June 2010, FSANZ received 52 applications to amend the Code. Initially, FSANZ conducts an administrative assessment process to determine whether applications should be accepted or rejected. At 30 June 2010: three applications had not been assessed; 40 were accepted; seven were rejected; one was withdrawn by the applicant before the administrative assessment was completed; and one further application was rejected during the consideration period. Of the 40 accepted applications, 39 were from the food industry.

3.8 The 40 accepted applications resulted in 80 proposed changes to the Code because an application may apply to more than one area. For example, an application for a new food additive may also require a labelling change. The applications were, for the most part, to vary Chapter One of the

Code—General Food Standards²⁸, particularly labelling, new foods and new food technologies, additives and processing aids.

3.9 The results of ANAO’s analysis of categorising the applications against the part of the Code potentially affected are provided in Table 3.1.

Table 3.1

Areas of Code change requested from 1 October 2007

Code Ref.	Area of Code	Proportion of applications (%)
1.2	Labelling	15.38
1.5.2	Gene Technology	15.38
1.3.1	Processing Aids	15.38
1.3.3	Food Additives	12.82
1.3.4	Identity and Purity	11.54
1.5.1	Novel Foods	7.69
various	Other ^a	21.81
Total		100.00

Note^a: Other comprises: maximum residue limits (Australia only), dairy products non-alcoholic beverages, alcoholic beverages with each accounting for around three per cent of the total; and contaminants and natural toxicants, prohibited /restricted plants & fungi, irradiation and meat eggs fish with each accounting for one per cent of the total.

Source: ANAO analysis of FSANZ data.

Proposals generated by FSANZ between October 2007 and 30 June 2010

3.10 FSANZ placed 17 proposals on its Food Standards Development Work Plan (Work Plan) between October 2007 and 30 June 2010 which addressed: food regulatory policies and requests issued by the Ministerial Council; public health issues; requests to vary Maximum Residue Limits; maintenance of the Code; reviews of the Code not including currency; and in one instance, to consolidate three similar applications.

Section 18 of the FSANZ Act

3.11 When FSANZ develops and varies food regulatory measures to be included in the Code, its must operate in accordance with the FSANZ Act. In

²⁸ These are standards that apply to all food matters such as labeling, additives, contaminants, residues and microbiological and processing agents.

particular, FSANZ must meet the objectives set out in section 18 which are (in descending priority order):

- the protection of public health and safety; and
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.²⁹

FSANZ's Application Handbook

3.12 To assist FSANZ to meet its legislative obligations, and to inform applicants of its requirements, FSANZ has developed the *Food Standards Australia New Zealand Application Handbook* (the Application Handbook).³⁰ The Application Handbook is a legislative instrument. Although the Application Handbook was last updated in July 2010, the 2009 version applied to the period of this audit.

FSANZ's assessment of applications

3.13 Prior to submitting an application and the subsequent assessment process, applicants are encouraged to consult with FSANZ to ensure that the application contains all necessary information. Once this consultation occurs and an application is submitted, it is subject to a two-part assessment process: an administrative assessment to determine whether the application is accepted or rejected; and consideration (an evidence based risk assessment) to determine whether the Code should be amended.³¹

3.14 The Application Handbook, used by FSANZ to make these assessments requires an applicant to include a statement justifying the application including as much information as is readily available in relation to the cost and benefits associated with the proposed change. This assists FSANZ to aim to meet the COAG principle of minimum effective regulation and also to prepare a Regulatory Impact Statement (RIS) if required by the Office of Better Practice Regulation (OBPR).

²⁹ *Food Standards Australia New Zealand Act 1991*, section 18 (1).

³⁰ This handbook is available on the FSANZ website at:
< <http://www.foodstandards.gov.au/foodstandards/changingthecode/applicationshandbook.cfm> >

³¹ These two processes are also required to meet legislated timeframes (see Chapter 4).

3.15 To assist FSANZ in its assessment, the Application Handbook specifies what information on any social, economic and/or environmental impacts is required to support the application. The application must also contain sufficient supporting information or data to enable the legislated objectives to be addressed by FSANZ's assessment.³²

3.16 The ANAO reviewed the 47 applications received between 1 October 2007 and 30 June 2010 that had undergone an administrative assessment. Of these (40 Accepted and seven rejected), the ANAO examined five rejected applications and 10 accepted applications to determine whether the mandatory requirements in the Application Handbook had been addressed. Where this could not be determined the ANAO further examined the information contained in the applications, excluding scientific evidence. This further assessment was necessary because FSANZ did not document specific conclusions against the mandatory requirements in its assessment reports.

3.17 Of the 15 applications assessed by the ANAO:

- 5 of the 10 accepted applications, and 3 of the 5 rejected applications did not address the Health aspect of Objective 1 (*the protection of public health and safety*);
- 2 of the 10 accepted applications, and 2 of the 5 rejected applications did not address the Safety aspect of Objective 1;
- 5 of the 10 accepted applications, and 2 of the 5 rejected applications did not address Objective 2 (*the provision of adequate information relating to food to enable consumers to make informed choices*); and
- none of the applications addressed FSANZ's Objective 3 (*the prevention of misleading or deceptive conduct*).

3.18 Overall, FSANZ's assessment reports did not document an explicit consideration of how the agency took into account the objectives of the FSANZ Act when it developed or amended a food standard. The results of the ANAO's review are summarised in Table 3.2.

³² *Application Handbook - General Requirements 3.1.5, p.36.*

Table 3.2

ANAO testing of 15 applications to change the Code: summary findings

General Application Procedure	FSANZ Mandatory Requirement	ANAO Finding/ Comment					
1. Justification for application	The application must contain a statement regarding the justification for the application.	<p><u>Compliance:</u> Four of the 15 applications did not contain a statement justifying the application. Although two of these were rejected, two were accepted.</p> <p><u>ANAO comment:</u> Where no justification was provided, FSANZ did not document whether it had considered the lack of a statement when determining whether to accept or reject the application, or pursue the applicant to supply further information.</p>					
2. Costs and benefits provided	The applicant should provide as much information relating to the impact on industry, consumers and government as is readily available to enable FSANZ to prepare a Regulatory Impact Statement based on this information or sourced from elsewhere.	<p><u>Compliance:</u> Six of the 15 applications did not contain information on costs and benefits. Although three of these were rejected, three were accepted.</p> <p><u>ANAO comment:</u> FSANZ expected specific data to be provided that could be beyond the reach of individual applicants. Where an application was rejected despite having provided such information as far as possible, FSANZ made the comment that 'while the general statements in relation to benefits of proposed labelling change for consumers were comprehensive, the statements provided about the costs to industry, consumers and government were minimal.'</p>					
3. Supporting information against FSANZ objectives	The application must contain sufficient supporting information or data to enable FSANZ to meet the legislative objectives (see paragraph 3.11).	<p><u>Compliance:</u> None of the 15 applications addressed Objective 3, 'prevent deceptive and misleading conduct'. Four of the applications did not address any Objectives. The 11 remaining applications were assessed against Objective 2, informed consumers and Objective 1 although these were assessed separately as 1a protecting public health and 1b protecting public safety.</p> <table border="1" data-bbox="502 1283 1194 1340"> <tr> <td data-bbox="502 1283 740 1340">1a Health - 7</td> <td data-bbox="740 1283 915 1340">1b Safety - 11</td> <td data-bbox="915 1283 1194 1340">2 Informed Consumers - 8</td> </tr> </table> <p><u>ANAO comment:</u> FSANZ did not document whether applications had met the legislated objectives. FSANZ also often stated that labelling requirements were outside the scope of its consideration. This requirement, however, may have been partially addressed when applicants provided information to support Objective 2.</p>			1a Health - 7	1b Safety - 11	2 Informed Consumers - 8
1a Health - 7	1b Safety - 11	2 Informed Consumers - 8					

Source: ANAO analysis of FSANZ's assessment reports

Definitions for FSANZ's objectives

3.19 As highlighted above, when FSANZ develops or amends food standards, it must meet its legislated objectives which are: the protection of public health and safety; the provision of adequate information relating to food to enable consumers to make informed choices; and the prevention of misleading or deceptive conduct.

3.20 These legislated objectives are relatively broad. During the 2007 second reading debate in the Senate, the then Parliamentary Secretary to the Minister for Health and Ageing, noted the concerns about the definition of public health, but stated that *'there is a need to avoid any clarification of a definition of public health that would result in unintentionally narrowing the scope of the FSANZ Act's objectives'*.

3.21 This view is consistent with principles of administrative law. When exercising powers under the FSANZ Act to assess or approve standards, FSANZ is essentially making administrative decisions and any internal definitions should not be applied by FSANZ if they redefine the legislation in such a way so as to restrict or eliminate the level of discretion that the legislation provides FSANZ.

3.22 Having said that, other important principles of administrative law require accountability and transparency in decision making, including informing the public about how legislation is applied. Administrative law also makes administrators accountable for their decisions through external scrutiny, review and transparency measures that can require agencies to provide reasons for decisions. In this regard, the FSANZ Act provides for external review subject to the *Administrative Appeals Tribunal Act 1975*.

3.23 While FSANZ advised that it does take into account its legislated objectives when it considers applications and proposals, information on how the objectives were considered is not included in FSANZ's assessment reports. The ANAO considers that FSANZ should better document and report how it is meeting its objectives when it develops or amends food standards.

Recommendation No.2

3.24 To better enable FSANZ to assess whether it is meeting the legislated objectives set out in section 18 of the FSANZ Act when it develops food regulatory measures (that is: the protection of public health and safety; and the provision of adequate information relating to food to enable consumers to make informed choices; and the prevention of misleading or deceptive conduct), the ANAO recommends that FSANZ:

- includes more explicit information in its assessment reports for all applications and proposals that explains how the three objectives were considered; and
- uses this information to internally monitor FSANZ's consideration of the three objectives at the application and proposal level and, over time, report trends more broadly.

FSANZ response

3.25 Agreed. We have commenced work to develop and implement the enhancements necessary to address this recommendation.

Appropriate consideration of other matters as required by the FSANZ Act

3.26 In developing food regulatory measures and variations of food regulatory measures, FSANZ must also have regard to the following:³³

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

³³ *Food Standards Australia New Zealand Act 1991*, section 18 (2).

The need for standards to be based on risk analysis using the best available scientific evidence

3.27 The Australian Government has highlighted the need for regulation to be evidence based. The need for such an approach is also identified in the FSANZ Act. Before FSANZ considers changes to the Code, it gathers information about the nature of the risk and the likely impact of new or amended food standards on the community. This body of evidence is known as the evidence base. The purpose of risk analysis is to identify any potential risks to introducing new food standards or amending existing ones.

3.28 FSANZ states that it bases its scientific risk assessments on the best available existing evidence and does not commission laboratory studies for applications.³⁴ FSANZ obtains most of the scientific information from the applicant. If an applicant is unable to supply the data, FSANZ can reject an application at an early stage. FSANZ's Application Handbook provides details of the data it requires for particular situations, including data:

- from literature searches;
- related to safety guides;
- related to surveys on chemicals in food; or
- related to consumer research.

Managing risk: data quality and the level of assurance provided

3.29 FSANZ has adopted a range of guidelines and standards to assist it to assess the quality of the data provided by applicants. Applicants are required to provide information to support their claims based on guidelines and standards for data: from literature searches; related to safety guides; related to surveys on chemicals in food; and related to consumer research.

3.30 Of the applications received by FSANZ between 1 October 2007 and 30 June 2010, the ANAO reviewed FSANZ's assessment of the quality of the data provided for a sample of 10 accepted applications. The review did not include any rejected applications because FSANZ only analyses the quality of data during the consideration period. The results of the ANAO's review are summarised in Table 3.3.

³⁴ FSANZ, *Annual Report, 2008–09*, p 15.

Table 3.3

FSANZ testing of data quality in 10 accepted applications

Supporting evidence	FSANZ's key requirements	ANAO Finding/ Comment
1. Quality of data	FSANZ will assess all the available data presented in support of an application.	<u>Compliance:</u> Supporting data was provided for all 10 applications <u>ANAO comment:</u> FSANZ assesses all data provided with an application.
2. All types of data	The data provided should be analysed using appropriate statistical techniques.	<u>Compliance:</u> Seven of the applications provided extensive data. Two of the applications were for reinstating previously allowable additive or processing agent. One was for an additive already approved for other products to be extended to cheese. These latter three applications were not required to provide as much data. <u>ANAO comment:</u> Although data was provided, FSANZ assessment reports did not specify if it was analysed using appropriate statistical techniques.
3. Data from literature searches	Literature searches should identify all of the papers identified in the search and provide an analysis according to the NHMRC <i>Guidelines for the review of scientific literature</i> .	<u>Compliance:</u> Seven of the applications included extensive lists of papers including studies or reports produced by Codex and other international standards setting bodies. The three remaining applications were the same three referred to in section 2 of this table. <u>ANAO comment:</u> FSANZ assessment reports did not specify whether this requirement was met for the seven applications that included reports.
4. Data related to safety guides	Safety studies should contain full details of the conduct of the study and its results, including raw data where appropriate. Summaries alone of study results are not adequate for safety assessment purposes.	<u>Compliance:</u> All of the applications contained comprehensive data to support this requirement. <u>ANAO comment:</u> FSANZ assessments report did not specify whether this requirement was met.
5. Data related to surveys on chemicals in food	Laboratories must provide evidence of accreditation to the International Organisation for Standardization standard <i>ISO 17025 – General Requirements for the Competence of Calibration and Testing Laboratories</i> . In Australia, laboratories should be NATA accredited.	<u>Compliance:</u> Only one of the applications included information that met this requirement. <u>ANAO comment:</u> While only one application met this requirement, three cited that the laboratory studies met OECD or FDA good laboratory practices, multiple ethical, clinical and food laboratory practices. One application also had laboratory studies based on the Simulated Gastric Fluid assay protocol after it was standardised by the International Life Sciences Institute. Three of the remaining applications are the ones referred to in sections 2 and 3 in this table.
6. Data related to consumer research	In Australia, such research should comply with the Australian Standard <i>AS44752 Australian and Social Research Standard</i> or its equivalent.	<u>Compliance:</u> This requirement did not apply to six applicants because the research was not conducted in Australia. The remaining applications did not address this requirement. <u>ANAO comment:</u> FSANZ assessment report did not document whether this requirement was met for the Australian applications.

Source: ANAO analysis of applications and FSANZ reports

3.31 Data quality is important to FSANZ; internally to support its risk assessments and externally for accountability purposes because stakeholders need to know the extent to which they can rely on the data that underpins FSANZ's food regulations and that this data incorporates the best available science. However, the gaps in the supporting data identified in Table 3.3 were because either the information was not provided by the applicants; or FSANZ had not documented whether the requirements were met.

Managing risk: ensuring data quality

3.32 While FSANZ has arrangements in place to assist it to assess the quality of the data provided by applicants, this does not address the possibility, or the perception, that an applicant may provide supporting documentation or scientific studies that could be incorrect or incomplete, whether this is intentional or not.

Managing risk: ensuring FSANZ staff have appropriate qualifications

3.33 To manage the risks associated with developing or amending a standard, FSANZ requires technical staff with wide-ranging and relevant food science skills and qualifications. To enable FSANZ to assess the best available scientific evidence, particularly in the areas of new technologies that regularly arise, FSANZ assists its staff to maintain an appropriate mix of skills and keeps up to date with current technology. To address, for example, future applications related to nanotechnology, FSANZ successfully applied for innovation funding to upgrade skills in this area.

3.34 FSANZ also collaborates widely to continue to build capacity and knowledge of food regulatory science internally and with national and international partners.³⁵ Additionally, a peer review of FSANZ's dietary modelling procedures in relation to international best practice has been conducted. Although there are a number of recommendations to improve FSANZ's processes the review found that 'the data available and the levels of expertise within the team are of sufficient quality to enable it to accomplish its tasks and that FSANZ can look forward to considerable success from its continued support of its dietary modelling team's efforts'.

³⁵ FSANZ Science Strategy 2010-2015 Strategic Area 6.

Managing risk: stakeholder participation

3.35 FSANZ states on its website that transparency and public consultation are an important part of the Standards development process.³⁶ FSANZ calls for public comment or submissions, based on the type of procedure to be conducted and the period that will be available for comments.

3.36 These opportunities are notified via email alerts to stakeholders and also published on the FSANZ website. FSANZ states that these comments will be taken into account for the final assessments and they are also a mechanism to partly address the risk of varying stakeholder views. When advertising the opportunities for comment, FSANZ often states that it has found no reason to reject an application or that it intends to approve an application.³⁷

3.37 FSANZ also has a number of committees and reference groups that contribute to the standards setting process. These groups include specific advisory groups such as: catering or food composition; consumer liaison committee; retailers and manufacturers liaison committee; scientific advisory groups; stakeholder advisory groups; the Maori Reference Group-Ng a Kaitohutohu Kounga Kai; and standards development committees.

3.38 These committees and groups usually comprise a broad membership of consumers, government and the food industry, and experts that contribute to scientific risk management. This provides a number of forums for the diverse stakeholder views and contributes to transparency of the standards setting processes and better understanding of FSANZ's role.

3.39 In November 2008, FSANZ undertook an evaluation to determine the effectiveness of its *Science Strategy 2006-09* in meeting its objectives. The evaluation targeted both external and internal stakeholders of the strategy. Feedback from external stakeholders showed that most were satisfied with FSANZ's current scientific expertise/skill-base, credibility, transparency and the relevance of evidence used in risk assessments. Stakeholders also appeared satisfied with the use of the peer review process, the development of FSANZ's evidence base and the skills of its scientific workforce.³⁸

³⁶ <<http://www.foodstandards.gov.au/foodstandards/changingthecode/>>

³⁷ This can be found at:
<<http://www.foodstandards.gov.au/scienceandeducation/newsroom/mediareleases/mediareleases2009/16december2009propos4606.cfm>>

³⁸ *FSANZ Annual Report 2008-09*, p. 15.

Managing risk: developing proposals

3.40 Proposals provide FSANZ with the opportunity to address risks to the currency and accuracy of the Code that may not be covered by an application. It also allows FSANZ to set standards that could better address their legislated objectives rather than relying on each applicant's specific interests.

3.41 When it assesses a proposal, FSANZ's assessment follows the same processes for its consultation and scientific risk assessment as it does for applications.

Managing risk: conducting code reviews

3.42 FSANZ's 2008–09 Annual Report states that it aims to maintain currency by reviewing and updating the Code on a regular basis.³⁹ However, FSANZ has advised that it has delayed implementing any reviews because of 'the demands of routine standards-setting activities on our resources. This resource constraint has also led to timelines for reviews already in progress being extended'.

3.43 Notwithstanding these comments, FSANZ engaged the Office of Legislative Drafting and Publishing to review the code for consistency, content and useability. FSANZ advised that the report has been received and work had commenced on responding to the matters raised. The jurisdictions will be engaged in the resulting work.

Managing risk: potential gaps in the Code

3.44 However, the above review did not address currency of the Code and, coupled with FSANZ's previously stated considerably reduced evaluation capability in terms of staff and activity, resulted in FSANZ focusing its operations on assessing applications. This has meant that the mechanisms to assess and manage potential gaps in the existing standards, that is, proposals, code reviews and evaluations are not occurring or they have a much lower priority.

Developing food standards that promote domestic and international regulatory consistency

3.45 Developing food standards that promote regulatory consistency is one of the objects of the FSANZ Act as well as being a matter that FSANZ 'must

³⁹ For example, a general labelling review.

have regard to'. FSANZ has a number of processes in place that contribute to this objective including membership of international forums such as the Codex Alimentarius Commission (Codex) and the Quadrilateral Group (Quads).

Codex

3.46 Australia is one of the 183 member countries of Codex. Consequently, when FSANZ amends existing or develops new standards, it advised that any relevant existing Codex standards and World Trade Organization provisions are assessed to determine if they are applicable to Australia and New Zealand. FSANZ has regard for the international standards and agreements but its main focus is the health and safety of Australian and New Zealand consumers.

3.47 Codex states that:

International harmonization based on Codex standards, guidelines and recommendations is essential to promoting a global approach to consumer health protection, including systems for the reduction of food-borne risks, and minimizing the negative effects of technical regulations on international trade.

3.48 FSANZ has advised that many of the standards that have been incorporated into the Code are more stringent than the Codex standards, and could be considered to protect Australians' health and safety to a higher degree. These include, for example, lower approval levels of a number of additives and residue limits in the Australian standards. In these instances harmonisation for Australia means that FSANZ develops standards that meet Codex standards as a minimum requirement but often improve on this.

Quadrilateral Group

3.49 Australia, through FSANZ is also a member of the Quads. The Quads which is made up of food safety experts from Australia, Canada, the United States and New Zealand provides a forum for discussing emerging issues and international best practice standards as they affect the four countries.

3.50 Such forums allow FSANZ to: participate in Codex working groups to positively influence other member countries; share information and scientific expertise with countries that are similar to Australia; remain current with emerging food science technology and issues; and work towards international harmonisation of its standards setting.

3.51 FSANZ's participation is also an important risk mitigation strategy for standards setting that is to be underpinned by up to date science. The information gathered from FSANZ's participation may allow it to streamline

some of its processes because of research that may have already been conducted elsewhere.

Domestic consistency

3.52 As previously noted, the enforcement of food safety is the responsibility of the States and Territories, and the Australian Government has no explicit constitutional power to regulate food produced or sold in Australia. In most jurisdictions, local government also plays a significant role.

3.53 To achieve national consistency, the States and Territories agreed in 1991 to unilaterally adopt common food standards. This agreement⁴⁰ was subsequently updated and confirmed by COAG in 2000, 2002 and 2008. The agreement was to form the basis for domestic consistency of the implementation, monitoring, surveillance, compliance and enforcement of food standards. Notwithstanding this, a Productivity Commission report in 2009 stated that ‘this objective has not been achieved to date’.

3.54 The report identified that implementation of food standards in Australia is hampered because each jurisdiction continues to implement regulation inconsistently. ‘The legislation that has actually been adopted by the Australian states and territories is not always consistent with the Model Food Act—even with regard to the compulsory Annex A.’⁴¹ For example: Queensland and Victoria both use a different definition of food to that in the FSANZ Act. Another example is the varying inspection powers granted by the jurisdictions.⁴² Additionally, the New Zealand Government reserves the right not to adopt certain standards.

Implementation Sub Committee

3.55 The activities of the States and Territories to implement and enforce the Code are co-ordinated through the Implementation Sub Committee (ISC) of FRSC, which advises the Ministerial Council. The membership of ISC comprises senior staff from the state and territory departments that are responsible for implementing and enforcing the Code within their

⁴⁰ The *Model Food Act, 1 December 2002*, provides the mechanism by which jurisdictions should consistently adopt and implement food standards developed by FSANZ.

⁴¹ The Annex includes definitions, offences and resulting penalties, applicable defences for transgressions, emergency powers and proceedings for offences.

⁴² Productivity Commission Issues Paper, *Performance Benchmarking of Australian Business Regulation: Food Safety*, April 2009, p. 20.

jurisdictions. Although FSANZ has no direct role in the implementation of food standards, it advised that it has worked closely with ISC since 2006 to develop an integrated approach to the development and implementation of standards.⁴³

3.56 The ISC is supporting FSANZ and the states and territories to develop an implementation plan for a food safety standard⁴⁴ in parallel with the standard, instead of after its completion. The aim is that such a concurrent approach will impose a greater discipline in FSANZ's legal drafting of standards and improve national consistency of implementation.⁴⁵

Consistency for imports

3.57 The Australian Quarantine and Inspection Service (AQIS) enforces the Code for imported foods under the Imported Food Inspection Scheme for Australia. However, it is not possible to inspect every food item that is imported for all potential compliance issues. Inspections are therefore risk and intelligence based, targeting food products that may pose a risk to public health or may not comply with the legal requirements set out in the Code. FSANZ provides advice to AQIS on risk levels for imported food, which determine the level and frequency at which they are tested at the border.⁴⁶

3.58 However, 20 (34.5 per cent) of the 58 food recalls between March 2009 and April 2010 were of imported foods.⁴⁷ Recalls of imported food items are: small in comparison to the amount of imports overall; often similar in nature; and 17 of the 20 originated from the same region. These results could be because of: FSANZ not providing sufficient appropriate risk assessments; AQIS not implementing the Scheme adequately; or the rapidly increasing number of imported foods.

3.59 FSANZ has advised that it has agreed with AQIS to undertake a joint independent review of the Imported Food Inspection Scheme which will include the advice provided to AQIS.

⁴³ DRAFT 21 July FSANZ Response to ANAO Report 45 and updated context, p. 5.

⁴⁴ This is being trialled with the food safety standard for the egg industry.

⁴⁵ FSANZ Fact Sheet on Proposal P301, Primary Production and Processing Standard for Eggs and Egg Products, April 2009. This can be found at:
<[Fact Sheets 2009 - Food Standards Australia New Zealand](#)>

⁴⁶ *FSANZ Annual Report 2008–09*, p. 73.

⁴⁷ See paragraph 5.16.

Contributing to an efficient and internationally competitive food industry

3.60 The FSANZ Act provides that any body or person can apply to FSANZ to amend an existing food standard or develop a new one. From 1 October 2007 to 30 June 2010, FSANZ accepted 41 applications to amend the Code. Of these 40 were from the food industry. The applications from industry reflected the specific interests of the applicants and were primarily to amend Chapter One of the Code⁴⁸, particularly labelling, new foods and new food technologies, additives and processing aids.

Regulatory impact statement

3.61 Applications for new or amended food standards, with a high impact for business, individuals or the economy, are subject to a regulatory impact statement (RIS) that FSANZ develops to assess the likely costs and benefits to government, industry and consumers.

3.62 The Office of Best Practice Regulation (OBPR) has six principles of good regulatory processes on its website that assist government agencies to address the principle of ‘minimum effective regulation’. However, FSANZ as a national standard setting body with a Ministerial Council as the decision maker is subject to the COAG principles of best practice regulation rather than the OBPR principles.

3.63 The OBPR assisted FSANZ to develop RISs and provided guidance on the adequacy of the analysis against the relevant set of principles.⁴⁹ Although these two sets of principles do not differ greatly, COAG principle 4 is not reflected in the OBPR principles. COAG Principle 4 states that:

in accordance with the Competition Principles Agreement, legislation should not restrict competition unless it can be demonstrated that:

- the benefits of the restrictions to the community as a whole outweigh the costs, and
- the objectives of the regulation can only be achieved by restricting competition.

⁴⁸ These are standards that apply to all food matters such as labeling, additives, contaminants, residues and microbiological and processing agents.

⁴⁹ These can be found at: <http://www.finance.gov.au/obpr/proposal/coag-requirements.html>.

Exclusive capturable commercial benefit

3.64 If an applicant or FSANZ determines that there is an exclusive capturable commercial benefit⁵⁰ for the applicant, a fee must be paid. This resulted in 19 applicants paying a fee because they would derive a financial gain from the resulting food standard/s. This also allowed the applicant to potentially charge other entities that wished to use or benefit from the approved standard, for example, via a licence to use novel foods including additives and genetically modified organisms. For all accepted applications FSANZ sought advice from OBPR to determine whether a RIS was required.

Developing standards with regard to the promotion of fair trading in food

3.65 All food sold in Australia, including imported foods, must comply with state and territory food legislation and other legislative requirements such as trade practices law and fair trading legislation. This legislation contains provisions governing false, misleading and deceptive conduct in the supply of food in trade and commerce, including requirements concerning the place of origin of goods. Manufacturers, suppliers and retailers of food must therefore apply the provisions in the Code in conjunction with these other applicable laws.

3.66 Ensuring that consumers are not misled or deceived requires them to be well informed about food risks, and being informed has particular relevance for FSANZ's standards setting in relation to labelling requirements. It is difficult if the consumer is not provided with all the information that they require to make an 'informed choice'. Stakeholder surveys have shown that this depends on satisfying consumers' requirements regarding information, which varies depending on the stakeholder. Labelling has been identified in surveys as one of the more emotive and publicly controversial issues FSANZ regularly faces. FSANZ's approach to progressing the part of its Outcome focused on 'well-informed consumers' may be influenced by the results of the Government's current *Review of Food Labelling Law and Policy*.

⁵⁰ *Food Standards Australia New Zealand Act 1991*, section 8: (the applicant may derive a financial gain from the resulting standard; and any other entities would require the applicant's agreement to benefit financially from the approval of the application.)

Developing standards with regard to Ministerial Council guidelines

3.67 The Ministerial Council is responsible for developing domestic food regulation policy and policy guidelines for the setting of domestic food standards. When it develops policy, the Ministerial Council takes advice from FRSC and both bodies consult with stakeholders before the policy guidelines are developed.

3.68 Once the Ministerial Council develops a guideline, it notifies FSANZ and FZANZ must publish the new guideline as part of the existing list on its website. Although the policy guidelines must not be inconsistent with the legislated objectives of the FSANZ Act, they are not legislative instruments.⁵¹

3.69 There are currently 10 policy guidelines that cover topics such as novel food, fortification, residues and addition of substances other than vitamins and minerals. These guidelines vary in intent and may require FSANZ to: maintain the 'status quo'; amend an existing standard; or develop new standards through proposals and regulatory frameworks. The changes to the standards are to ensure wherever possible that the Code is consistent with the guidelines.

3.70 FSANZ must have regard to policy guidelines notified by the Ministerial Council. FSANZ may suspend its consideration of an unpaid application if the Ministerial Council has notified FSANZ that it is formulating a policy guideline if⁵², in the opinion of FSANZ, the application would be affected by the guideline once formulated. FSANZ cannot, however, suspend work on a paid application without the consent of an applicant. The maximum period of time for suspension is 18 months.

Ministerial Council Reviews

3.71 The FSANZ Board has responsibility for developing and reviewing amendments to the Code and notifying its decisions to the Ministerial Council. Once this occurs the Council⁵³ has 60 days to either request FSANZ to review the draft or notify FSANZ that it does not intend to request a review.

3.72 The *Australia New Zealand Food Regulation Agreement, 2008* and the *Joint Food Standards Treaty* list the grounds on which the Ministerial Council can

⁵¹ *Food Standards Australia New Zealand Act 1991, section 18 (3), (3A), (6).*

⁵² *Food Standards Australia New Zealand Act 1991, section 109 (9).*

⁵³ *Food Standards Australia New Zealand Act 1991, Part 3 Division 3.*

require FSANZ to review a standard. These are that the standard: does not protect public health and safety; is difficult to enforce or comply with in both practical or resource terms; places an unreasonable cost burden on industry or consumers; does not provide adequate information to enable informed choice; is not consistent with the objectives of the legislation which establishes FSANZ; is not consistent with existing policy guidelines set by the Ministerial Council; and does not promote consistency between domestic and international food standards where these are at variance.

3.73 Until recently one or more Ministers could request FSANZ to review a standard. However, changes to the FSANZ Act and the *Australia New Zealand Inter-governmental Agreement* from 6 July 2010 now require the Ministerial Council to have a simple majority to request FSANZ to review a standard.⁵⁴

3.74 FSANZ must complete the review within three months unless the Council allows a longer period. After conducting the review, FSANZ must: reaffirm; reaffirm with amendments or withdraw its approval of the draft. The Ministerial Council then determines whether it will accept, amend or reject the draft standard.

3.75 The Ministerial Council has only requested three reviews since the October 2007 legislative amendments. Consequently, the ANAO examined all review requests since mid-2004⁵⁵, to enable sufficient comparison. FSANZ generally met or bettered the timeframes to complete the requested reviews and the Ministerial Council did not reject any standards that were subject to the 29 reviews that it had requested since mid-2004.

⁵⁴ The Council is limited to reasons and criteria specified in the *Australia New Zealand Inter-governmental Agreement 2010*.

⁵⁵ These were the review requests that were published on FSANZ's website at 10 February 2010.

4. Meeting Regulated Timeframes

In developing food regulatory measures, FSANZ must meet its legislative objectives including legislated timeframes for assessing and considering applications. FSANZ's approach to managing these requirements is assessed in this chapter.

Introduction

4.1 Over time, the Australian Government has committed to reducing the regulatory burden on Australian businesses and not-for-profit organisations within the food industry, without compromising public health and safety. Amendments to the FSANZ Act in 2007 specified the objectives FSANZ must meet when it develops or amends food standards. While the focus is on satisfying customer protection matters, FSANZ must also have regard to 'the desirability of an efficient and internationally competitive food industry'.

4.2 The 2007 amendments were designed to streamline FSANZ's application procedures and enhance the efficiency of the regulatory process. These amendments included the introduction of processes to consider applications according to complexity, with reduced legislated timeframes for most applications.

4.3 Another of the legislative changes was to allow an applicant to pay a fee for FSANZ to develop or amend a standard that will give the applicant a competitive advantage. An applicant may also submit an application and pay a fee to expedite the consideration of an application. These changes were designed to enable industry to have its applications dealt with more rapidly and to overcome what was seen as an impediment to an efficient and competitive food industry.

4.4 The ANAO reviewed FSANZ's approach to managing these requirements including:

- meeting its regulated timeframes; and
- prioritising its work program and food regulatory measures.

Regulated timeframes

4.5 As indicated in Chapter 3, applications are subject to a two-part assessment process. Both of these processes are subject to regulated timeframes.

Timeframes for administrative assessments

4.6 When FSANZ receives an application it conducts an administrative assessment to meet the legislative requirement to accept or reject an application within 15 business days of receipt. During this assessment FSANZ considers whether: the application meets the application requirements; the application relates to a matter that may be developed as a food regulatory measure or variation of a food regulatory measure; the application is so similar to a previous application or proposal that it ought to be rejected; or there are any other relevant matters.

4.7 The ANAO reviewed the reports for all of the 47 applications received by FSANZ between 1 October 2007 and 30 June 2010 that had undergone administrative assessments. The ANAO determined that FSANZ met the legislated administrative assessment timeframe for all of these applications.

4.8 The details of accepted applications are placed on the Food Standards Development Work Plan (Work Plan) that FSANZ develops and publishes on its website.⁵⁶ The Work Plan is further covered later in this chapter.

Timeframes to consider applications

4.9 The 2007 legislative amendments changed the procedures from dealing with all applications generically, to introducing four types of procedures with mandatory timeframes. These timeframes were determined according to each procedure's scope—general, minor, major and urgent (see Table 4.1).

⁵⁶ When FSANZ develops its own proposal to change the Code, it issues a notice to the public that it intends to assess a proposal, and places the details of its proposal on the Work Plan.

Table 4.1**Procedures, their timeframes and applicable fees at 30 June 2010**

Procedure	Hours allowed	Regulated Timeframe	Public Consultation	Fees
General ^a Level 1	< 500	9 months	Once—after draft regulatory measure developed	\$53 500
General ^a Level 2	500–850	9 months	Once—after draft regulatory measure developed	\$90 950
Minor	<175	3 months	Once—after the draft regulatory measure is developed—targeted to the applicant and appropriate government agencies only	\$18 725
Major	>1050	12 months with a possible extension of 6 months	Twice—once after assessment and again after the draft regulatory measure or variation has been developed	\$112 350, plus \$107 per hour after 1 050 hours
Urgent (standard approved and issued prior to assessment)		Assessment to be completed within 12 months of gazettal	Twice—after the draft regulatory measure is developed before publication of approved standard; and after assessment of standard prior to its re-affirmation	N/A

Source: FSANZ legislation (Act and Regulations)

4.10 The legislated timeframes are based on the elapsed period from commencement of consideration to the date of the Board’s approval of the draft food regulatory measure. However, FSANZ is able to ‘stop the clock’ if it needs further information from the applicant before the consideration can be completed.⁵⁷

Timeframes to consider proposals

4.11 Proposals are also considered under the most appropriate procedure. However, unlike applications, FSANZ is not bound by a legislated timeframe (with the exception of Maximum Residue Limits). Nevertheless, FSANZ has stated that it intends to process proposals within similar timeframes to applications.

⁵⁷ *Food Standards Australian New Zealand Act 1991*, s108, s109 Part (6).

Cost recovery when considering applications

4.12 FSANZ recovers costs from applications that have an exclusive capturable commercial benefit or where applicants wish to expedite consideration of their application. The cost recovery arrangements are set out in the FSANZ Act and Regulations.⁵⁸

4.13 The assessment period for an application begins on the day a charge or first instalment has been paid if a fee is payable.⁵⁹ If no fee is payable, it is on the day FSANZ begins its assessment. The fees for each type of application are provided in Table 4.1.

4.14 FSANZ recently announced two proposed charges in its fee structure that cover:

- growing statutory administrative costs relating to newspaper notifications for approval and gazettal of amendments to the Code, which are not covered under the current arrangements; and
- the increased costs resulting from the setting up of the Federal Register of Legislative Instruments, which are not taken into account in FSANZ's current cost recovery arrangements.

4.15 From 1 July 2010, FSANZ increased its fees from \$107 to \$115 per hour.

4.16 As well as processing applications, FSANZ staff regularly spend additional time providing pre-application guidance and ongoing advice to assist in the preparation of paid and unpaid applications with further advice provided if the application is initially incomplete or rejected. Although this contributes to a successful relationship with the applicant and applications meeting FSANZ's requirements, the additional time taken for paid applications is not included in the fee, so is not recoverable.

4.17 FSANZ has also advised that project teams commence their planning up to eight weeks prior to the planned consideration start date. The planning includes a range of activities that are not included in the fee and also not recoverable. These include: allocation of work; commencing the risk assessment; determining the key assessment questions; identifying problems or issues; commencing a cost benefit analysis; completion and submission of

⁵⁸ *Food Standards Australia New Zealand Act*, section 146.

⁵⁹ *Food Standards Australia New Zealand Act*, section 109 (2).

the Office of Best Practice Preliminary Assessment Report; determining the extent of consultation; and commencing the analysis of consumer issues.

Food Standards Development Work Plan

4.18 The FSANZ Act requires FSANZ to develop and publish a three year forward plan for applications and proposals on which it intends to develop standards or variations to standards. It must also consult interested persons during this process.⁶⁰

4.19 To meet the above requirement, FSANZ developed the Work Plan. The Work Plan groups applications and proposals into two parts—applications and proposals received since 1 October 2007; and applications and proposals initiated or received prior to this date.

4.20 FSANZ is required to update and review the Work Plan at least quarterly. However, FSANZ generally updates the Work Plan monthly or when new applications or proposals are listed, then publishes the updated plan on its website.

4.21 FSANZ also amends the Work Plan to reflect ongoing changes to the expected timetable for consideration of applications and proposals. These changes, which arise as the assessment progresses, override the timeframes notified to the public in the administrative assessment report or any subsequently updated timeframes on the Work Plan. Consequently there is no history in the Work Plan of the original, planned timeframes.

4.22 If FSANZ maintained a history in the Work Plan of all timeframes this would track all changes in the plan and total timeframes from receipt of the application to Board approval and Ministerial sign-off. This would allow FSANZ to review any slippage as it re-prioritises its work and inform interested parties, particularly applicants.

⁶⁰ *Food Standards Australia New Zealand Act 1991*, s20.

Prioritising food regulatory measures

4.23 The FSANZ Act provides that:

The consideration of an application in relation to which a charge is fixed under subsection (6) must not displace the development of, or variation to, any other food regulatory measure in a three year plan.⁶¹

4.24 That is, the assessment of paid applications must not displace unpaid applications and proposals, in a three year plan. Although this requirement does not apply to applications or proposals listed on the Work Plan prior to 1 October 2007, the ANAO analysed reports for these applications and proposals to determine whether any were delayed and the reasons for the delay.

4.25 Despite the above legislative requirement, FSANZ's Application Handbook states that FSANZ prioritises its work rather than process 'unlimited numbers of applications within a fixed period'. The Application Handbook also states that unpaid applications should be processed in the order of their receipt.

4.26 Under its regulations, FSANZ must commence consideration of paid applications as soon as a fee is paid or a first instalment if applicable, resulting in compression of the timeframe between the administrative assessment and the consideration period.

4.27 Applicants that do not pay a fee have the same regulated consideration timeframes, but the start of consideration is significantly delayed. The consideration of unpaid applications can be deferred for months—often until the subsequent financial year. Consequently, the assessment timeframes introduced in the amendments to the FSANZ Act in 2001 have had much less impact on the actual time for processing unpaid applications.

Prioritisation of paid and unpaid applications

4.28 The Work Plan listed five applications received prior to 1 October 2007. Three of these have been grouped into a single proposal and the remaining two are waiting for a policy review or advice from the applicant. The oldest active application in this group was received 17 February 2006.

⁶¹ *Food Standards Australian New Zealand Act 1991*, s146, Part (7).

4.29 To determine whether paid applications had displaced other food regulatory measures since 1 October 2007 and any trends for applications or proposals that had not commenced, the ANAO reviewed the Work Plans that were published on the FSANZ website during 2010. This was to compare the timeframe between the administrative assessment and start of consideration for the 41 accepted applications.⁶² The results are summarised in Table 4.2.

Table 4.2

Applications—timeframe between the administrative assessment and the consideration period

Application type	Number	15-30 days	6 months	9-12 months	13 months
Paid (all started)	27	27			
Unpaid (started)	1			1	
Unpaid (not started) Planned start	12		4	4	4

4.30 The average delay between the administrative assessment and the actual start of scientific consideration is 21 days for paid applications and 10 months for the planned start for unpaid applications.⁶³

4.31 Once the ‘clock’ starts on the consideration of an application, the regulated timeframes apply. The planned consideration timeframes published in the Administrative Assessment all complied with the regulated timeframes. However, the actual consideration times often exceeded the regulated timeframe.

Unpaid applications

4.32 As previously stated, at 30 June 2010 FSANZ had commenced consideration of only one application received since 1 October 2007. The consideration of this application started two months later than planned.

⁶² The Work Plans were dated: 11 February, 26 May, 25 June, 2 July and 28 July.

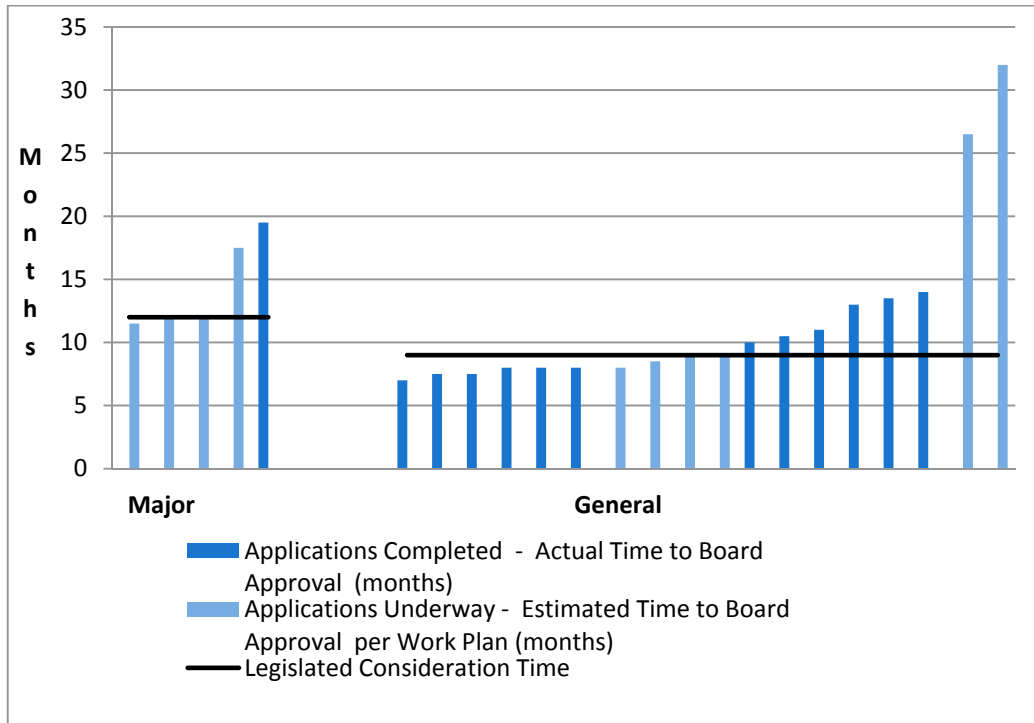
⁶³ The delay for the only unpaid application for which FSANZ had started its consideration was 9.5 months.

Paid applications

4.33 Figure 4.1 compares the planned to the actual time for finalised applications. It also shows the revised timeframe if an application was still being considered.

Figure 4.1

Legislated, planned and actual timeframes for paid application received since 1 October 2007



Source: ANAO analysis of FSANZ data at 30 June 2010

4.34 The planned consideration timeframes published in the administrative assessment reports all complied with the regulated timeframes. Additionally, some timeframes published in the Work Plan do not match the regulated timeframes.

Proposals

4.35 Once a proposal is listed on the Work Plan, it also must not be displaced by a paid application. In the majority of cases, FSANZ is exceeding the time planned to develop proposals. Proposals do not have a legislated timeframe unless they are developed to set standards for maximum residue limits (MRLs). Generally, FSANZ met the timeframe for MRLs so these proposals were not included in the ANAO's further assessment of proposals.

4.36 The ANAO reviewed the FSANZ Work Plans published on the FSANZ website on 11 February, 26 May, 25 June, 2 July and 28 July. FSANZ had listed 17 proposals, three were for MRLs, which were listed on the February Work Plan or had been added to subsequent plans.

4.37 The ANAO analysed the time taken to complete all of the proposals that appeared on these Work Plans. The results are summarised in Table 4.3.

Table 4.3

Timeframes for proposals

Timeframe	Number of proposals (out of 14)
Post 1 October 2007	
Completed proposals that met or bettered the planned timeframe	2
Completed proposals that exceeded the planned timeframe by 3 and 4½ months	2
Incomplete proposals expected to meet the planned timeframe	2
Incomplete proposals expected to exceed the planned timeframe between 4½ and 9 months	3
Pre October 2007	
Completed proposal timeframe 90 months	1
Incomplete proposals timeframe estimated between 55½ to 114½ months	4
Total	14

Source: ANAO analysis of FSANZ Work Plans and assessment reports.

Prioritising FSANZ’s overall work program

4.38 FSANZ has advised that the payment of a fee to consider an application was to be allocated to additional resources for unpaid applications so these would not be delayed. Employing additional staff is sometimes difficult for FSANZ to manage because there is a limited pool of qualified and experienced people available in Australia. This was also aggravated by the reduction in staff numbers from 158 at 30 June 2008 to 118 at December 2009, although this had risen to 140 by 30 June 2010. Estimating the timing and amount of fees that will be paid is also difficult.

Table 4.4**Fees for paid applications compared to total revenue for 2007-08 to 2009-10 inclusive**

	2007-08	2008-09	2009-10
Application fees (\$'000)	\$600	\$389	\$680
Total revenue (\$'000)	\$22 059	\$20 614	\$22 526
Fees as a percentage of total revenue (%)	2.8%	1.8%	3.0%

Source: FSANZ Annual Reports for relevant years – notes to Financial Statements.

4.39 As indicated in the preceding paragraphs, the capacity for FSANZ to suitably balance competing priorities is influenced by its resourcing and approach to prioritisation. Whereas FSANZ receives very little of its income from paid applications (see Table 4.4) the bulk of its standards setting between 2007-08 and 2009-10, resulted from these applications.⁶⁴ While all government agencies need to balance their priorities with respect to available resources, any underlying reasons for not being able to consistently comply with legislative requirements should be examined. Many factors can influence an agency's performance, including workload, how resources are allocated to different functions and the productivity achieved. Understanding these factors would better position FSANZ to assess its current approach and, as necessary, discuss its resourcing with government and stakeholders.

4.40 FSANZ has advised that although it is unable to meet all of its legislated requirements owing to resource constraints, it now identifies in its Work Plan any applications or proposals that have been displaced. FSANZ also advised that it intends to report in future annual reports its compliance against the requirement that paid applications must not displace the development of any other food regulatory measure in its Work Plan. This approach will improve the transparency associated with FSANZ's prioritisation of its Work Plan.

⁶⁴ Although standard setting constitutes FSANZ's major responsibility it also carries out a number of other activities (further detailed in Chapter 5) such as coordinating: food incidents; recalls; monitoring and surveillance; and educating and providing information to stakeholders.

Recommendation No.3

4.41 To improve the transparency of the approach being taken by FSANZ to process applications, the ANAO recommends that FSANZ:

- assess options to obtain a more appropriate balance between meeting the regulated timeframes for paid applications while also complying with the legislative requirement that paid applications must not displace unpaid applications or proposals in its Food Standards Development Work Plan; and
- publicly reports its compliance with this legislated requirement.

FSANZ response

4.42 Agreed. FSANZ has commenced work to develop and implement the enhancements necessary to address this recommendation.

5. Monitoring Standards and Addressing Market Failures

FSANZ's approach to monitoring the implementation of food standards and its role in coordinating responses to major food incidents and recalls is summarised in this chapter.

Introduction

5.1 As well as its role in setting food standards, FSANZ has a number of additional functions. Most of these functions are incorporated into FSANZ's standard setting processes (see Chapter 3 of this report). Of the remaining functions, this chapter examines how FSANZ:

- coordinates the collection of data on monitoring and surveillance activities;
- coordinates responses to major food incidents;
- coordinates food recalls; and
- develops stakeholder education activities.

FSANZ conducts these activities for Australia only.

Monitoring and surveillance

5.2 FSANZ and other government agencies in Australia and New Zealand monitor the food supply to determine whether it is safe, and that foods comply with standards for microbiological contaminants, pesticide residue limits and chemical contamination. FSANZ has a bi-national surveillance and enforcement strategy which allows food/health agencies to discuss and share information about monitoring and surveillance of the food chain.

5.3 FSANZ acts as the central point for collection of food surveillance data from public health units. This data includes the results of general compliance testing, and specifically targeted surveys conducted in the various jurisdictions. FSANZ regularly conducts and publishes a number of studies including the Australian Total Diet Study (ATDS) and National Food Handling Surveys.

5.4 Using the biennial ATDS and the National Nutrition Survey, FSANZ develops a mix of prescriptive and outcomes based standards. FSANZ's ability to report against outcomes based standards is reliant on the quality and availability of data from a number of sources that may include other

Commonwealth agencies and jurisdictions including New Zealand. Unless data is consistently collected and of sufficient quality, FSANZ's collection and analysis of this food surveillance data can not be fully effective.

5.5 Also data that are collected and reported for individual standards do not always link to higher level KPIs. Once baselines are determined for individual standards FSANZ could consider how it could link these and subsequent comparative reports to its higher level KPIs to enable it to measure the effectiveness of its standards setting.

Major food incidents

5.6 Major food incidents can result in public health and safety risks for consumers and can also cause widespread consumer concern and significant disruption to domestic and international trade. A major food incident is usually triggered when one or more standards are not met. Incidents can involve microbiological, chemical, radiological, physical or unknown hazards. Incidents may occur regardless of whether the food is domestically produced or imported.

5.7 FSANZ administers the National Food Incident Response Protocol (the Incident Protocol) to coordinate major food safety incidents that could, or are expected to impact on multiple government jurisdictions.

5.8 The Incident Protocol does not, however, override existing response protocols of individual agencies or jurisdictions. Instead it provides a link between the protocols of Australian Government and state and territory agencies responsible for food safety and food issues. Under the Incident Protocol, FSANZ provides the central notification point. If an incident escalates, specific roles and responsibilities (for example, lead agency, risk assessor, risk communicator) are assigned to the appropriate officers and agencies.

5.9 FSANZ has coordinated 14 incidents under the Incident Protocol since it was introduced in late 2006. The Incident Protocol was reviewed after each incident, and is currently being revised to clarify more fully the roles of government agencies and to provide improved guidance in relation to the development of risk assessments during the response to food incidents.

Food recalls

5.10 A food recall is an action taken to remove from sale, distribution and consumption foods which may pose an unacceptable safety risk to consumers. A major food incident could result in a recall or it may be initiated from a variety of sources such as manufacturers, wholesalers, retailers, medical practitioners, government agencies (for example, the police or a health authority) and consumers.⁶⁵ Recalls occur in consultation between state and territory health authorities and a sponsor who is usually the product's manufacturer or the importer.⁶⁶

5.11 To help food businesses plan for and respond to an incident where the recall of potentially unsafe food is required, FSANZ in consultation with state and territory food authorities and the food industry developed the *Food Industry Recall Protocol* (the Recall Protocol).⁶⁷

5.12 Recalls are carried out at either a trade or consumer level. A trade recall involves recovery of the product from distribution centres and wholesalers and may also involve recovery of product from hospitals, restaurants and other major catering establishments, and outlets that sell food manufactured for immediate consumption or food that is prepared on the premises.

5.13 A consumer recall involves recovery of the product from all points in the production and distribution networks/chains including from consumers. This also includes any affected product in the possession of consumers.⁶⁸

5.14 FSANZ provides the Australian Competition and Consumer Commission (ACCC) with reports obtained from the sponsors for trade and consumer food recalls it coordinates. This enables the ACCC to meet its obligation to satisfy its Minister⁶⁹ (the Treasurer) that a voluntary recall has been conducted satisfactorily and that consumers have been protected.

⁶⁵ FSANZ website: <http://www.foodstandards.gov.au/consumerinformation/foodrecalls/foodrecallstats.cfm>

⁶⁶ FSANZ website: <http://www.foodstandards.gov.au/consumerinformation/foodrecalls/foodrecallstats.cfm>.

⁶⁷ *Food Industry Recall Protocol*, 6th Edition, September 2008.

⁶⁸ This can be found at: <http://www.foodstandards.gov.au/consumerinformation/foodrecalls/foodrecallstats.cfm>.

⁶⁹ At the time the audit was conducted this was the Minister for Competition Policy and Consumer Affairs.

Sponsors' reports

5.15 FSANZ lists consumer recalls on its website on a 12-month rolling basis. At the time of audit, 47 consumer recalls were recorded for the period March 2009 to March 2010. These were all reconciled to the food recalls listed on the ACCC website.

5.16 The ANAO reviewed FSANZ's files for recalls received between 7 March 2009 and 16 April 2010 including trade recalls where information was available. Of the 58 recalls, FSANZ closed five of the files without receiving a sponsor's report.⁷⁰

5.17 Although it has developed the Recall Protocol, in cases where the sponsor refuses to submit a recall report, FSANZ advised that:

it has no power to require that the sponsor submits a recall report. The jurisdictions have indicated in the past that they can assist in these situations. While they may be reluctant to exercise their legal powers, the fact that they have powers to fall back on can be used by them to encourage the sponsor to comply with their recall responsibilities.

5.18 While, FSANZ has no power to request a sponsor's report, the Recall Protocol⁷¹ states that if the sponsor's report is not received or it is unsatisfactory, FSANZ will refer the matter to ACCC. FSANZ advised that an unsatisfactory report would be one where there was a failure by the sponsor to answer one or more of the required questions. Although FSANZ advised that there were no instances of it referring an unsatisfactory report to ACCC, it had notified the ACCC when sponsors' reports were not received. FSANZ's actions met the protocol's requirements about sponsors' reports.

Trade recalls for foods not fully recovered

5.19 FSANZ also coordinates trade recalls that are not detailed on its website and public notification is not required. In the six months from 1 July 2009 to 31 December 2009, there were six trade recalls. Of these, two highlight issues of concern.

⁷⁰ Of these 58 recalls, 20 (34 per cent) were for imported products.

⁷¹ *Food Industry Recall Protocol*, 6th Edition, September 2008, p. 38.

Recall 2009/51—semi-dried tomatoes

5.20 One trade recall (October 2009) was for semi-dried tomatoes potentially infected with Hepatitis A. The decision was made within a State jurisdiction to undertake a voluntary trade recall. Although there was no requirement for public notice, the incident received extensive media coverage. Throughout this incident, state and territory health departments issued media releases advising consumers not to eat particular semi-dried tomato products.

5.21 FSANZ received the sponsor's report that noted 70 per cent of the potentially infected tomatoes were not recovered. However, the tomatoes could not be reliably traced once they had been distributed to wholesalers and retailers. FSANZ subsequently developed an urgent proposal to address the lack of traceability of semi-dried tomatoes although this was put on hold. However, the agency has advised that the proposal has since been abandoned 'as current arrangements allow these issues to be managed and the need for any additional measures will be considered in future horticulture work'.

5.22 Although FSANZ received a report that showed that 70 per cent of the possibly infected tomatoes were not recovered, no further immediate action was taken by any of the parties involved to address the potential risk.

Recall 2009/41—paw paw

5.23 Another trade recall (September 2009) was for paw paws infected with a bacterial skin contamination. The decision was made within a State jurisdiction to undertake a voluntary trade recall. The sponsor's report was subsequently received by FSANZ and submitted to ACCC. The report noted that 55 per cent of affected units were not recovered. The sponsor commented in the report that the unrecovered stock had been 'already on-sold to the public'. As it was treated as a trade-level recall, no public notice was required. However, the sponsor worked with the State health department, which had a public health notice published in newspapers that included how to treat the fruit to combat the health risk.

5.24 FSANZ could make more rigorous assessment of the actions detailed in sponsors' reports which would assist it to determine whether the most appropriate action was taken to reduce risks to consumers. This would also help inform future reviews of the appropriate safety standards within the Code. FSANZ has advised that it continues to work through the Incident Protocol with the States and Territories to resolve the traceability issues and prevent any further contaminated product reaching the market.

Stakeholder education

5.25 FSANZ's guidance and education activities in relation to standards take a two-pronged approach. Under the FSANZ Act, FSANZ's legislated functions include:

- the development of guidelines to assist the interpretation of the Code;⁷² and
- in co-operation with the States and Territories, developing food education initiatives, including the publication of information to increase public awareness of food standards and food labels.⁷³

User guides to the Food Standards Code

5.26 On its website, FSANZ provides a comprehensive number of 'simple' user guides to help manufacturers, retailers and food officers interpret and apply the Code. This contributes to the legislated objectives of protecting public health and safety and preventing misleading or deceptive conduct. FSANZ has advised that five user guides, focussed on labelling, have been recently updated and will be published on its website.

5.27 The guides cover matters that include mandatory fortification, food safety programs, labelling and additives, meat and meat products and, microbiological limits. The guidelines also assist industry and enforcement officers to interpret the Code, and are a legislated function of FSANZ.

5.28 There is no similar guide to the Code aimed at consumers. A brief practical insight to the Code, its contents and application to the food supply, and the relationship between each party to food regulation, would be valuable. This could manage, in part, some of the stakeholder misunderstanding of FSANZ's actual remit. It would also help FSANZ to satisfy the legislated objective of providing adequate information relating to food to enable consumers to make informed choices.⁷⁴ Educating consumers about the Code overall, would assist FSANZ to assess the impact of informing consumers against individual standards in the Code.

⁷² *Food Standards Australia New Zealand Act 1991*, section 13 (1) (c).

⁷³ *Food Standards Australia New Zealand Act 1991*, section 13 (1) (i).

⁷⁴ *Food Standards Australia New Zealand Act 1991*, section 18 (1) (b).

Consumer information

5.29 On its website, FSANZ provides consumer information on various subjects that may be of concern to the public or relevant to food consumption. These include fact sheets, videos, posters, brochures and pocket guides. While not related directly to the development of regulatory measures, these initiatives may contribute to the achievement of the objective of providing adequate information to enable consumers to make informed choices. The information covers: labelling of food; advice for pregnant women; food safety (including handling and hygiene tips); new foods and technologies; food additives; food allergies; and fortification.

5.30 Although this material covers a wide range of topics and addresses information about individual food standards it does not provide an overall view of the Code. Nevertheless, this material contributes in part, to the legislated objective of providing adequate information to enable consumers to make informed choices.

5.31 To be informed however, consumers need to be internet capable, aware of FSANZ and access its website. FSANZ website statistics, for the 100 web pages it considers are aimed at consumers, showed that between 1 December 2009 and 30 June 2010 these pages were viewed 3.09 million times, with 1.05 million of these being unique views.

5.32 An example of the information provided is the advice that FSANZ developed for women who are in the early stages of pregnancy or are intending to become pregnant. This information provides a 'package' that includes information on fortification, diet, talking to a GP and supplementation.

5.33 While this is very helpful for the targeted group these issues relating to food, health, hygiene, supplementation and similar matters are within the purview of Commonwealth agencies such as DoHA, schools and State and Territory agencies. FSANZ could assess as part of its planning processes, whether it is the agency best placed and resourced to take the lead for these types of functions.

5.34 Additionally, Choice, the major Australian consumer advocate, has a community of more than 200 000 people. The Choice website includes a brief explanation of the food regulation system and a link to FSANZ. This affords FSANZ a mechanism that connects interested consumers to the organisation. This is particularly valuable if consumers were previously unaware of FSANZ's existence or its role in food regulation.



Ian McPhee
Auditor-General

Canberra ACT
18 November 2010

Appendices

Appendix 1: Agency's response



Office of the Chief Executive Officer

Mr Matt Cahill
Group Executive Director
Performance Audit Services Group
Australian National Audit Office
19 National Circuit
Barton ACT 2601

Dear Mr Cahill

Thank you for your letter of 6 October 2010 requesting comments on the proposed audit report on Food Standards Australia New Zealand (FSANZ). FSANZ welcomes the opportunity to respond to this draft report.

The draft report is a useful and informative analysis of FSANZ's approach to its primary function of developing and reviewing food standards contained in the *Australia New Zealand Food Standards Code*. The audit has identified a number of areas where FSANZ's administration of its food standards function could be enhanced, particularly in respect of the currency of the agency's publicly available information and the transparency of the agency's reporting. The audit has also provided a good outline of the complex regulatory environment within which FSANZ operates and the many challenges that this brings for a small agency with limited resources.

FSANZ agrees with the three recommendations contained in the report. We are already well advanced in our work to address Recommendation 1 (Performance Indicators) and have commenced work to develop and implement the enhancements necessary to address Recommendation 2 (Legislative Objectives) and Recommendation 3 (Food Standards Development Work Plan). FSANZ also notes that a number of matters in regard to the agency's role in coordinating national food recalls have been raised. FSANZ will work with the jurisdictions to facilitate improved systems for traceability and recovery of products that may be the subject of food recall.

FSANZ wishes to acknowledge the very constructive and professional approach demonstrated by the ANAO staff engaged in this audit. Their engagement with staff, in particular, was instructive and helpful.

Should you require any further information, please contact me on 02 6271 2200.

Yours sincerely


Steve McCutcheon
Chief Executive Officer

3 November 2010

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