The Auditor-General

Audit Report No.45 1998–99 Performance Audit

Food Safety Regulation in Australia

Australia New Zealand Food Authority

Follow-up Audit

Australian National Audit Office

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Canberra ACT 2 June 1999

Dear Madam President Dear Mr Speaker

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

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

Junet

P. J. Barrett 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

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Contents

Abb	Abbreviations/Glossary		
Sum	nmary and Recommendations		
Key	Summary Key Findings Recommendations		
Aud 1.	lit Findings and Conclusions Introduction Background Audit scope and objectives Audit methodology, conduct and cost	25 25 26 26	
2.	Context for Commonwealth food safety regulation Food safety regulation in Australia Commonwealth's role in food safety regulation Current food regulation initiatives	28 28 28 31	
3.	Identifying, assessing and treating food safety risks 'Whole of agency' risk management approach Regulator's interface with the Department Risk-based approach to standard setting	36 36 41 42	
4.	Surveillance and enforcement of food safety regulations Voluntary recalls Commonwealth-initiated mandatory recalls Other treatment options Integrated national food safety strategy Assess to customs data—imported foods Commonwealth enforcement	51 59 60 62 73 76	
5.	Performance reporting	82	
Арр	endices Appendix 1 1995 Audit recommendations and summarised responses	87	
	x es Titles er Practice Guides	95 97 100	

Abbreviations/Glossary

1995 Audit	Audit Report No.12 1995–96 Risk Management by Commonwealth Consumer Product Safety Regulators
ACCC	Australian Competition and Consumer Commission
AFFA	Department of Agriculture, Fisheries, and Forestry— Australia
AFSIN	Australian Food Safety Information Network
AIEH	Australian Institute of Environmental Health
ALGA	Australian Local Government Association
ANAO	Australian National Audit Office
ANZFA	Australia New Zealand Food Authority
ANZFAAC	Australia New Zealand Food Authority Advisory Committee
ANZFSC	Australia New Zealand Food Standards Council
AQIS	Australian Quarantine Inspection Service
Codex	Codex Alimentarius Commission
FRR	Food Regulation Review
IFCA	Imported Food Control Act 1992
IFIP	Imported Food Inspection Program
JCPA	(the former) Joint Committee of Public Accounts
LGA	Local Government Authority
MOU	memorandum of understanding
NFA	(the former) National Food Authority
TPA	Trade Practices Act 1974

Summary and Recommendations

Summary

Introduction

1. In 1995, the Australian National Audit Office (ANAO) examined the operations of five Commonwealth consumer product safety regulators that manage public health and safety risks associated with consumer products (Audit Report No.12 1995–96 *Risk Management by Commonwealth Consumer Product Safety Regulators* —'the 1995 Audit'). The 1995 Audit included the then National Food Authority (NFA), now the Australia New Zealand Food Authority (ANZFA).

2. The 1995 Audit found that, overall, there was room for improvement in the effectiveness of consumer product safety regulation. This could have be achieved by the wider adoption of risk management practices at all levels within the regulators, increased collaboration and cooperation among regulators and more active enforcement of the regulations. In 1996–97, the then Joint Committee of Public Accounts (JCPA) reviewed these aspects of the 1995 Audit and concluded that audited agencies found the 1995 Audit to be useful and valuable guidance for the future. The then JCPA also noted the generally positive responses from the audited agencies and the initiatives which had been taken since the audit.

3. The ANAO has confined the scope of the follow-up audit to ANZFA because public health and safety associated with <u>food</u> is one of the most important areas of consumer product safety regulation in Australia.

Food safety regulation in Australia

4. The primary role of food safety regulation is to protect public health and safety. Responsibility for food regulation in Australia involves all three levels of government in Australia. In its simplest terms, the Commonwealth develops uniform food standards that, once approved, food products and related businesses are required to achieve; coordinates food recalls and surveillance; and has responsibility for the safety of imported food. Constitutional responsibility for food regulation rests with the States and Territories. States and Territories and local government monitor and enforce food product and food hygiene regulations, primarily through testing and inspection.

5. The Commonwealth's food regulatory responsibilities are primarily undertaken by ANZFA. ANZFA was established by legislation

as NFA in 1991, but was renamed to ANZFA in 1996 after Australia and New Zealand adopted a joint approach to food regulation. The Australia New Zealand Food Standards Council (ANZFSC), a body of Commonwealth, State/Territory and New Zealand Health Ministers (or junior Ministers), oversees ANZFA's work and approves new or varied food standards. Other Commonwealth agencies with food regulatory responsibilities include:

- the Australian Quarantine and Inspection Service (AQIS) that, with ANZFA, jointly conduct the Imported Food Inspection Program (IFIP);
- the Consumer Affairs Division of the Department of the Treasury that is responsible for mandatory product (including food) recalls; and
- the Australian Competition and Consumer Commission (ACCC) that initiates legal action against suppliers of defective products (including food) under the *Trade Practices Act 1974*.

6. Since the 1995 Audit, a number of significant food regulatory initiatives have been completed or are currently in progress, including:

- ANZFA's development of uniform national food safety (hygiene) standards;
- ANZFA's review of the food product standards;
- ANZFA's revised Food Industry Recall Protocol and introduction of a Government Health Authorities Food Recall Protocol;
- the Food Regulation Review (FRR);
- the development of uniform 'model' State/Territory Food Acts; and
- the review of the Imported Food Control Act 1992.

7. Some of the issues covered in these initiatives were considered in the ANAO's 1995 Audit and are discussed in this follow-up audit. The recommendations from this follow-up audit are consistent with these initiatives.

Audit Objectives

8. The objectives of this follow-up audit were to determine:

- the extent to which ANZFA has implemented the agreed recommendations in the 1995 Audit; and
- the effectiveness of the implemented recommendations in improving food safety regulation.

9. The follow-up audit process reinforces the ANAO's commitment to improving public administration and accountability through monitoring the implementation of recommendations made in selected audit reports.

It is apparent that accepted recommendations are only effective when actually implemented. Improved performance is clearly forgone by partial, unnecessarily delayed or quasi-implementation.

Overall conclusions

10. The ANAO concluded that, although action is now being taken in a number of areas to implement improvements in food safety regulation, ANZFA has generally been slow to take action to implement the 1995 Audit recommendations. Consultation and involvement of most stakeholders, during the development of new or varied food standards, have improved. ANZFA is also developing strategies to address stakeholder consultation and communication concerns at a broader organisational level (although the ANAO considers that these could better address local government stakeholders). ANZFA's reporting of its performance to the Parliament has slightly improved since the 1995 Audit, but still mainly describes activities undertaken or outputs produced, rather than food safety outcomes.

11. There is also a number of actions planned to improve food safety regulation. For example, a risk management strategy is currently under development by ANZFA as is the development of national standards to address food safety (hygiene). ANZFA and the Consumer Affairs Division of the Treasury are also considering options for streamlining the process for initiating mandatory food recalls at the Commonwealth level. ANZFA has also proposed a number of amendments to its legislation, *inter alia*, to improve the timeliness of its standards review/ development processes while maintaining effective stakeholder consultation.

12. Although ANZFA continues to manage the longer-term public health and safety risks associated with food products reasonably well, little progress has been made to improving other areas associated with shorter-term public health and safety risks. For example, ANZFA's coordination and knowledge of food surveillance activities and outcomes of the States/Territories and local government have improved little since the 1995 Audit, particularly in relation to food safety (hygiene) issues.

13. There have also been increasing delays completing the review of the food product standards since the 1995 audit. Although industry compliance with voluntary recall procedures has improved since 1995, ANZFA is not taking full advantage of the information provided by industry to assess the effectiveness of food recalls. The 1995 Audit considered that recall audits provide a mechanism for making food recalls more effective. However, no food recall audits have been undertaken since the 1995 Audit.

14. The recommendations made by the ANAO in the 1995 Audit were designed, inter alia, to improve food safety regulation in Australia. However, as ANZFA has only recently taken action to implement a number of the 1995 Audit recommendations, the effectiveness of the implementation of the recommendations has yet to be demonstrated. As a result, the ANAO cannot form an opinion on this matter at this time. Nevertheless, the ANAO considers that, once implemented, the food safety (hygiene) standards currently under development by ANZFA has the potential to significantly improve the protection of public health and safety. The ANAO further considers that, if ANZFA improved its food surveillance coordination in conjunction with the implementation of the food safety (hygiene) standards, together they would have a major impact on the protection of public health and safety. ANZFA would also be able to better demonstrate to the Parliament the achievement of food safety outcomes.

15. The ANAO notes that ANZFA's forward estimates have been reduced as a result of anticipated cost-recovery arrangements with the food industry. Such arrangements, however, did not eventuate because ANZFA was unable to obtain the necessary amendments to its enabling legislation. Nevertheless, the ANAO considers that the expected completion of the food product standards review and the food safety (hygiene) standards (which will reduce ANZFA's workload and change the balance of its responsibilities) gives ANZFA an opportunity to re-evaluate its priorities.

16. The ANAO has made five recommendations aimed at addressing the shortcomings identified.

ANZFA response

17. ANZFA agreed or agreed with qualification to all five recommendations. The qualifications relate to ANZFA's inability to obtain sufficient information to assess recall effectiveness and ANZFA's view that current imported food categorisation and testing procedures means that imported food posing a high risk to human health would not normally reach retail or consumer levels.

Key Findings

'Whole of agency' risk management

18. ANZFA's 'whole-of-agency' risk management approach is not yet fully established. However, risk management within ANZFA has improved through its involvement in the development of uniform food safety (hygiene) standards that address the shorter-term food safety risks (primarily from microbiological contamination but also chemical and physical hazards) identified as a concern in the 1995 Audit. ANZFA's draft Risk Management Strategy, developed some three years after the 1995 Audit and around the time the FRR final report was published, identified a need for a coordinated system of food monitoring and surveillance that would better identify public health and safety risks associated with food to enable ANZFA to evaluate its regulatory outcomes and provide the basis for setting new priorities.

Consultation with stakeholders

19. ANZFA has maintained its links with key domestic and international stakeholders involved in food regulation that allows ANZFA to identify new risks and incorporate them into its standard setting priorities. In response to a recommendation in the 1995 Audit, a forum of Commonwealth consumer product safety regulators was established. However it was disbanded after two meetings as participants could not decide how to usefully share information relevant to regulators of different consumer products. In its stead, ANZFA has established and maintained separate links with other Commonwealth consumer product safety regulators—particularly those located in the Health portfolio.

20. In line with the ANAO's comments in 1995, ANZFA now seeks to appoint stakeholders with relevant technical expertise and experience to be members of project teams developing/reviewing food standards. Although little action has yet taken place, ANZFA is considering its consultation and communication with stakeholders—for example, in 1998 it developed a Consultation Strategy and a Communications Strategy. However, there should be concerns about the delays in implementing improvements and the limited consideration of local government in these strategy documents, and local government involvement in ANZFA standard setting processes generally.

21. Local government has a significant role to play in the success of food regulation in Australia. In State/Territory jurisdictions, local government environmental health officers conduct food product and food

business inspections. The ANAO notes that ANZFA has attempted to involve representatives from the Australian Institute of Environmental Health (AIEH) and the Australian Local Government Association (ALGA) and its State/Territory affiliate organisations in ANZFA issues, with limited success. Given that there are over 700 local governments in Australia, the ANAO acknowledges that consultations can be difficult but this is all the more reason for:

- developing communication and consultation strategies that consider local government as an important group of stakeholders in their own right; and
- involving local government in the development of a national surveillance and enforcement strategy and supporting information technology infrastructure projects.

22. The ANAO considers that ANZFA would benefit from the inclusion of representatives from local government (or local government associations or AIEH) on the two major advisory groups of ANZFA—ie. the Australia New Zealand Food Authority Advisory Committee (ANZFAAC) and the Senior Food Officers working group. AIEH indicated that it would welcome representation on the advisory groups.

Developing and reviewing standards

23. The overwhelming majority of ANZFA's standards development work is currently focused on completing the planned five-year review of the food product standards and the development of food safety (hygiene) standards. With respect to the former, the 1995 Audit noted that the review had already been delayed by one to two years and the then NFA was allocating it a higher priority. However, consecutive NFA/ANZFA Annual Reports have identified further delays in completing the review. Completing the development of the food safety (hygiene) standards was also delayed by some nine months during 1997–98.

24. In the 1995 Audit, the ANAO considered that proposals to develop food product standards usually took considerably longer than the timeframe that the then NFA attempted to meet (ie. one year). The ANAO, however, is not in a position to form a view as to whether the timeliness of food standard proposals has improved because ANZFA is currently reviewing all of the food product standards together rather than individual standards as was the case in 1995.

25. ANZFA indicated that it is looking to improve the timeliness of its standards review/development processes by introducing amendments to its enabling legislation in the Autumn 1999 session of Parliament to allow greater flexibility in statutory stakeholder consultation timeframes

in line with level of assessed risk and stakeholder interest. The ANAO supports any such approach designed to hasten the completion of new or varied food standards while maintaining effective stakeholder consultation.

Management of food recalls

26. Industry compliance with voluntary recall procedures has improved since 1995 but ANZFA is not taking full advantage of the information provided by industry to assess the effectiveness of voluntary and State-initiated mandatory food recalls. No food recall audits have been undertaken since the 1995 Audit but the recall audit program developed by the Consumer Affairs Division of Treasury(for its own purposes) provides a good model to assist ANZFA to develop a food recall audit program.

27. The complex arrangements for initiating mandatory food recalls at the Commonwealth level described in the 1995 Audit are still in place today. These arrangements have the potential to inhibit the effectiveness of mandatory food recalls because of their time critical nature. However, ANZFA has made representations at officer and Ministerial level for ANZFA to obtain mandatory food recall powers. A review of the mandatory recall provisions of the Trade Practices Act is also considering the delegation of mandatory recall powers from the Minister for Financial Services and Regulation to, in the case of food, the Minister for Health.

Progress towards an Integrated National Food Safety Strategy

28. In 1997, ANZFA and the Department of Agriculture, Fisheries and Forestry—Australia (AFFA) jointly developed a model for National Safe Food System. The report described a model for a National Safe Food System designed to encompass the entire food supply chain and integrate and commit all food stakeholders, including industry and government, to the goal of producing safe food. ANZFA and AFFA recommended its adoption and implementation by all stakeholders. The need for a National Safe Food System was more recently considered by the FRR. Further progress towards endorsing/developing and implementing a National Safe Food System is, understandably, unlikely until Commonwealth and State/Territory endorsement of the FRR is received.

Coordination of food surveillance

29. ANZFA's coordination of food surveillance and enforcement activities of the States/Territories and local government has improved little since the 1995 Audit, particularly in relation to food safety (hygiene) issues. ANZFA manages the longer-term food safety risks addressed through the food product standards reasonably well through the work

it or other Commonwealth agencies conduct (including food and diet surveys, nutritional modeling and food contamination exposure assessments). However, the ANAO considers that, as was the case at the time of the 1995 Audit, ANZFA's ability to address shorter-term food safety risks associated with food hygiene issues are hampered somewhat by the lack of:

- a risk-based national surveillance and monitoring strategy (that outlines, *inter alia*, the agreed roles and responsibilities of all levels of government, national priorities, audit/inspection coverage and approach, and timely reporting mechanisms); and
- appropriate and sufficient information on the current food monitoring and surveillance activities and outcomes of the States/Territories and local government.

30. Although ANZFA does not have the power to directly monitor and enforce food product or food safety (hygiene) standards, its statutory food coordination role can be seen as adding a <u>national</u> perspective to food monitoring and surveillance. A national approach provides a basis for: greater consistency of food safety outcomes between jurisdictions; and the aggregation of food surveillance results to identify food safety trends/risks that, without ANZFA's involvement, could be overlooked at the individual State or Territory level.

National Surveillance and Monitoring Strategy

31. Although the States and Territories have expressed support for a national surveillance and monitoring strategy (at the time of the 1995 Audit and more recently), it has not progressed far. ANZFA contends that the States and Territories were, and are still. hesitant to allow ANZFA a substantial role in food surveillance and monitoring. Nevertheless, the ANAO considers that the development of food safety (hygiene) standards and overwhelming support from food stakeholders for a national surveillance and monitoring system or strategy expressed at the time of the FRR now provides a real opportunity for the Commonwealth to set up such a system or strategy. ANZFA indicated that a working group involving itself and the States/Territories was established in March 1999 to develop a national surveillance and enforcement strategy for consideration by ANZFAAC at some (unspecified) future date. A detailed plan for its development would be drafted in 1999–2000. A national surveillance and enforcement strategy is a key element in improving the protection of public health and safety and its introduction is considered to be a high priority by key stakeholders.

32. At the national level, an effective food surveillance and monitoring system would allow ANZFA to better manage public health and safety as well as report to the Parliament through its annual report on:

- the extent of industry compliance with food product/safety standards;
- whether risks to public health and safety are occurring despite food product/safety standards being complied with;
- whether there are gaps in food regulation that might need addressing; and
- the incidence of food-borne illness with greater precision than would otherwise be the case.

33. ANZFA considers that a sensitive approach to its food surveillance coordination work needs to be taken because ANZFA's legislative role, particularly in respect of food safety (hygiene) standards, is based on an 'invitation' from the States and Territories. ANZFA also cited a current lack of resources and a significant reduction in its budget after 1999–2000 as constraining factors for achieving improvement in food surveillance and enforcement. The ANAO considers that ANZFA has taken rather a restricted view of its functions. The ANAO acknowledges that work on the national food safety (hygiene) standards commenced only after State/ Territory agreement but notes that ANZFA's food surveillance coordination role is a separate statutory function that is independent of its standard-setting role. ANZFA's legislation also specifically states that its coordination of food surveillance function can be conducted on its own initiative or in consultation with the States and Territories.

34. The ANAO notes that ANZFA's forward estimates have been reduced as a result of anticipated cost-recovery arrangements with the food industry. Such arrangements, however, did not eventuate because ANZFA was unable to obtain the necessary amendments to its enabling legislation. As a result, the ANAO estimates that ANZFA has 15–20 per cent less financial resources than would otherwise be the case had the cost-recovery arrangements been in place. Nevertheless, the ANAO considers that the expected completion of the food product standards review and the food safety (hygiene) standards (which will reduce ANZFA's workload and change the balance of its responsibilities) gives ANZFA an opportunity to re-evaluate the proportion of its resources it devotes to monitoring and surveillance issues. The ANAO also notes that ANZFA has recently proposed amendments to its legislation that, inter alia, will allow for the introduction of cost-recovery arrangements at some future date.

Information on food safety issues

35. The ANAO acknowledges that reliable data on the incidence and impact of food-borne illness is difficult to obtain—not only in Australia but overseas as well. ANZFA hopes that its involvement in a project funded by the NSW Government will allow it to better understand the incidence and impact of food-borne illness in Australia. The ANAO considers that there is also scope for ANZFA to more closely monitor and, where possible, influence the direction of scientific research on food-borne illness issues.

36. The ANAO found that ANZFA's knowledge of State/Territory food surveillance is limited primarily to ad-hoc information provided orally at Commonwealth-State forums. The ANAO acknowledges that obtaining information on the food monitoring and surveillance activities of the States/Territories and local government is difficult to obtain for a variety of reasons. However, the ANAO considers that obtaining more comprehensive information on the food surveillance activities and outcomes of the States/Territories and local government is essential for ANZFA to better fulfil its role of protecting public health and safety. A significant step forward would be achieved if ANZFA was to seek access to information recorded on State/Territory food management information systems (or summaries thereof).

37. At the time of the 1995 Audit, the then NFA considered that AFSIN would facilitate greater sharing of information on State/Territory food surveillance and monitoring activities. However, AFSIN has not progressed far since the 1995 Audit. ANZFA indicated that it now plans to introduce AFSIN's first module sometime in 1999. ANZFA advised that its information technology infrastructure needs would be considered during the development of a national surveillance and enforcement strategy.

38. Overall, the Imported Food Inspection Program (IFIP) still exemplifies the successful use of Customs data to target surveillance of high risk products as well as randomly sample others. However, there should be some concern about the lack of action that is needed to determine whether previous shipments of (not inspected) imported food should be examined/recalled when a later shipment of that food (or food from that supplier) fails inspection and that failure poses a 'high risk to human health'.

Commonwealth enforcement

39. Although ANZFA has no statutory powers to directly enforce food standards, Commonwealth legislation administered by the ACCC (ie. Part VA of the *Trade Practices Act 1974*) imposes strict liability on manufacturers and importers for injuries caused by defective products (including food). As well as facilitating private actions, Part VA allows the Commonwealth (through the ACCC) to undertake representative actions on behalf of one or more persons who have suffered loss. The ANAO notes that the ACCC has not undertaken any representative actions in relation to food products to date.

40. However, the ACCC indicated that in the near future it will be seeking assistance from consumer product safety regulators (including ANZFA) to assess appropriate cases for ACCC representative action under Part VA of the *Trade Practices Act 1974* against suppliers of defective food products. The ANAO considers that, for ANZFA to provide an effective supporting role to the ACCC, ANZFA must have access to management information relevant to defective food products. Most of this information is currently held by the States and Territories.

41. ANZFA considers that the States/Territories are better placed to take enforcement action under their own Food Acts instead of the Commonwealth taking enforcement action under Part VA of the *Trade Practices Act 1974*. However, there is reason to believe that a State/ Territory decision to prosecute (or not) under its own food legislation will not necessarily meet the objectives or purposes of Part VA. A State/ Territory prosecution is only one factor that should be considered when determining whether an action under Part VA should proceed.

Reporting

42. ANZFA's reporting of its performance to the Parliament has slightly improved since the 1995 Audit due to better alignment of its organisational structure to its outputs and the inclusion in ANZFA's Annual Report of some measurable performance indicators and targets for some of ANZFA's programs. However, the finding of the 1995 Audit that performance reporting describes activities undertaken or outputs produced rather than food safety outcomes still holds true. The ANAO considers the greatest hindrances to improving ANZFA's reporting of outcomes are the lack of information on the impact and incidence of food surveillance activities and outcomes of the States/Territories and local government.

Recommendations

Recommendation No.1	The ANAO <i>recommends</i> that, in the interests of more comprehensive stakeholder input, ANZFA includes:
Para 3.35	a) local government as an important group of stakeholders in their own right in its future Consultation and Communication strategies; and
	b) local government representation on the Australia New Zealand Food Authority Advisory Committee and the Senior Food Officers working group.
	ANZFA response: Agreed.
Recommendation No.2 Para 4.18	The ANAO <i>recommends</i> that, to enhance the food recall framework agreed between the Commonwealth and the States/Territories, ANZFA:
	a) explicitly assess the effectiveness of each food recall by focussing on the proportion of recalled product (which is commensurate with the recall level) that has not been returned; and
	b) pursue the establishment of a risk-based audit program for food recalls, similar to the one used currently by the Consumer Affairs Division of the Department of the Treasury.
	ANZFA response: Agreed with qualification.
Recommendation No.3 Para 4.65	The ANAO <i>recommends</i> that, in the interests of nationally consistent protection of public health and safety, ANZFA improve its national coordination of food surveillance by:
	a) seeking access to appropriately summarised State/ Territory-based information on the food surveillance, monitoring and enforcement activities and outcomes of the States/Territories and local government;
	b) developing, as a matter of priority, a national surveillance and enforcement strategy and

supporting information technology infrastructure that involves the Commonwealth, States and Territories and local government and determining the roles and responsibilities of each party; funding allocated by each party towards its development; and timetables for its introduction and trialing with all parties; and

- c) including, as part of the proposed auditing framework guidelines for the food safety (hygiene) standards, mechanisms and processes that:
 - (i) will allow ANZFA to coordinate food surveillance effectively and influence national priorities;
 - (ii) are based on sound risk-based methodology; and
 - (iii) will allow ANZFA to receive sufficient, relevant and timely information on the implementation of, and compliance with, the food safety (hygiene) standards.

ANZFA response: Agreed.

RecommendationThe ANAO recommends that ANZFA improve its
coordination of imported food by seeking
amendments to its memorandum of understanding
with AQIS, in the case of imported food inspection
failures that pose 'high risks to human health', to
provide for AQIS to:

- a) notify ANZFA and the relevant State/Territory Health official(s) immediately of such events; and
- b) provide ANZFA and the relevant State/Territory Health official(s) with a timely report on any recent previous (not inspected) shipments of that food and/or other foods from that supplier that might pose the same risks.

ANZFA response: Agreed with qualification.

Recommendation	The ANAO recommends that ANZFA develop a
No.5	memorandum of understanding with ACCC in
Para 4.89	relation to legal actions under Part VA of the Trade
	Practices Act 1974 setting out:

- a) the roles and responsibilities of both parties;
- b) the *prima facie* circumstances that would need to be met before a legal action under Part VA would be considered by the ACCC; and
- c) the approach to be adopted with respect to the concurrent operation of any other food law in another jurisdiction.

ANZFA response: Agreed.

Audit Findings and Conclusions

1. Introduction

Background

1.1 In 1995, the Australian National Audit Office (ANAO) examined the operations of five Commonwealth consumer product safety regulators that manage public health and safety risks associated with consumer products (Audit Report No.12 1995–96 *Risk Management by Commonwealth Consumer Product Safety Regulators* —referred to as 'the 1995 Audit'). The 1995 Audit included the then National Food Authority (NFA), now the Australia New Zealand Food Authority (ANZFA).

1.2 The regulators audited in the 1995 Audit Report were the:

- Federal Bureau of Consumer Affairs (now the Consumer Affairs Division of the Department of the Treasury);
- Federal Office of Road Safety;
- National Food Authority (now the Australia New Zealand Food Authority);
- Therapeutic Goods Administration; and
- Trade Practices Commission (now part of the Australian Competition and Consumer Commission).

1.3 The 1995 Audit sought to determine the extent to which risk management approaches had been successfully adopted by Commonwealth regulators of consumer product safety. The ANAO found that, overall, there was room for improvement in the effectiveness of consumer product safety regulation. This could be achieved by the wider adoption of risk management practices at all levels within the regulators, increased collaboration and cooperation among regulators and more active enforcement of the regulations. Audited agencies (including the then NFA) generally agreed or agreed in principle with the 18 recommendations. Of the recommendations applicable to NFA, it disagreed only with the recommendation relating to the establishment of a 'forum' of Commonwealth consumer product safety regulators to be chaired by the then DHSH (now Health). See Appendix 1 for a complete list of recommendations made in the 1995 Audit, together with the summarised responses of the audited agencies.

1.4 In 1996–97, the then Joint Committee of Public Accounts (JCPA) reviewed aspects of the 1995 Audit, particularly in terms of risk identification and management, the sharing of information among

Commonwealth consumer product safety regulators and the enforcement of regulations. The then JCPA considered that audited agencies found the 1995 Audit to be useful and valuable guidance for the future. The then JCPA also noted the generally positive responses from the audited agencies and the initiatives which had been taken since the audit.¹

Audit scope and objectives

1.5 The ANAO has confined the scope of this follow-up audit to ANZFA because public health and safety associated with food is one of the most important areas of consumer product safety regulation in Australia. The ANAO considered it timely to conduct a follow-up audit as ANZFA has had nearly three years to implement the recommendations of the 1995 Audit or make significant progress towards their implementation.

1.6 The follow-up audit process reinforces the ANAO's commitment to improving public administration and accountability through monitoring the implementation of recommendations made in audit reports. It is apparent that accepted recommendations are only effective when actually implemented. Improved performance is clearly forgone by partial, unnecessarily delayed or quasi-implementation action.

1.7 The objectives of this follow-up audit were to determine:

- the extent to which ANZFA has implemented the agreed recommendations contained in the 1995 Audit Report; and
- the effectiveness of the implemented recommendations in improving food safety regulation.

1.8 Although New Zealand has become a party of the Food Authority since the 1995 Audit, the follow-up audit focuses on the operations of ANZFA as they impact Australia only.

Audit methodology, conduct and cost

1.9 The methodology used to produce this report involved:

- examining key files, documents and meeting minutes maintained by ANZFA;
- examining reports and reviews related to food regulation produced by third parties;
- discussions with ANZFA officials; and

¹ Joint Committee of Public Accounts (1997) *Report 349: Review of Auditor-General's Reports 1995-96*, pp. 7-10.

• examining comments received from key food regulation stakeholders in the course of the audit.

1.10 The food regulation stakeholders included other Commonwealth agencies, state and territory government departments, local government associations, and selected peak industry and consumer organisations. Not all stakeholders provided comments (eg. consumer organisations) in the follow-up audit process. However, their views were often reflected in comments to the FRR and were taken into account in this context.

1.11 The follow-up audit was conducted in accordance with the ANAO Auditing Standards and cost approximately \$72 000. The majority of the fieldwork was undertaken between September and November 1998 with ANZFA providing additional information in March 1999.

2. Context for Commonwealth food safety regulation

Food safety regulation in Australia

2.1 The primary role of food safety regulation is to protect public health and safety.

2.2 Although Australia has had a relatively stable food regulatory framework for most of this decade, there has been a <u>reported</u> rise in the incidence of food-borne illnesses in Australia.² It is generally considered that increases in reported food-borne illnesses can be explained by greater consumer awareness (and thus reporting) of food-borne illness and increased food safety risks from a ever-changing Australian diet. Australians have increased their consumption of take-away or restaurant meals involving relatively under-prepared or 'fresh' foods, compared to the traditional thoroughly cooked or salted foods.³

2.3 Responsibility for food safety regulation in Australia involves all three levels of government. In its simplest terms, the Commonwealth develops uniform food standards that, once approved, food products and related businesses are required to achieve; coordinates voluntary and State-initiated mandatory food recalls and surveillance; and has responsibility for the safety of imported food. Constitutional responsibility for food regulation rests with the States and Territories. States and Territories and local government monitor and enforce food product and hygiene regulations by inspecting food production facilities and wholesale/retail outlets.

Commonwealth's role in food safety regulation

2.4 Most of the Commonwealth food regulatory responsibilities rest with ANZFA. ANZFA was formally NFA until July 1996, when New Zealand became a party to the uniform food standards development process operating between the Commonwealth and the States/Territories. ANZFA's legislation and operations changed little as a result of New Zealand's involvement.

² Imported Food Control Act Review Committee (1998) Imported Food: National Competition Policy Review of the Imported Food Control Act 1992, p. 11.

³ *Ibid.*, p. 7.

ANZFA's functions and objectives

2.5 Section 7 of the *Australia New Zealand Food Authority Act 1991*, sets out ANZFA's functions which include:

- a) to deal with applications⁴ for the development or variation of standards in accordance with this Act;
- *b)* to prepare proposals⁵ for the development or variation of standards and to deal with those proposals in accordance with this Act;
- c) to prepare draft standards and draft variations to standards and make recommendation to the [Australia New Zealand Food Standards Council] in respect of those draft standards or draft variations;
- d) to review standards;
- e) in consultation with the States and Territories, or on its own initiative, to coordinate the surveillance by the States, the Territories and any other bodies or persons of food available in Australia; ...
- h) in cooperation with the Department administering Division 1A of Part V of the Trade Practices Act 1974, to coordinate the recall of food under that division;
- *i)* at the request of the States and Territories, to coordinate action by the States and Territories to recall food under State and Territory laws ...

2.6 ANZFA's legislation does not contain objectives for ANZFA itself.⁶ However, the ANZFA Act specifies that ANZFA's <u>highest priority</u> objective in developing standards and variations to standards (its most resource intensive function) is '*the protection of public health and safety*'.⁷ It was this objective that the ANAO focussed its attention on in the 1995 Audit and again is the focus of this follow-up audit of 1995 Audit recommendations.

2.7 Approval of new or revised standards recommended by ANZFA is the responsibility of the Australia New Zealand Food Standards Council (ANZFSC), a body of Commonwealth, State/Territory and New Zealand Health Ministers (or junior Ministers). Once approved, food standards are adopted without variation in each State/Territory and New Zealand.

⁴ Applications to review or develop a standard come from outside of ANZFA (eg. industry, consumers, government agencies).

⁵ Proposals to review or develop a standard come from within ANZFA itself.

⁶ In August 1998, the FFR Committee recommended that overall objectives of the ANZFA Act be established. The proposed wording of such objectives emphasises the '*protection of public health and safety*' as do ANZFA's objectives in developing standards and variations to standards.

⁷ Australia New Zealand Food Authority Act 1991, s10.

2.8 The greatest change to ANZFA's operations since the 1995 Audit has been the decision by the State/Territory Health Ministers, in their capacity as ANZFSC, to allow ANZFA to develop uniform food safety (hygiene) standards that will be adopted without variation by the States/Territories once approved by Australia New Zealand Food Standards Council (ANZFSC). This is discussed in greater detail below.

Funding for ANZFA's operations

2.9 Since the 1995 Audit ANZFA's annual government contributions have increased by some 10 per cent to \$8.5 million in 1997–98. This includes an annual contribution from the New Zealand government that amounted to some \$1 million in 1997–98. For 1998–99, the Australian government's contribution to ANZFA is some \$7.7 million which represents a 2.5 per cent increase on the previous year's contribution. Staff numbers at ANZFA have remained stable since the 1995 Audit at around 81 temporary and permanent staff located in Canberra and Wellington, New Zealand. ANZFA's annual level of funding will reduce by some 30 per cent from 2000–01 to coincide with a reduction in workload with the expected completion of the food product standards review and food safety (hygiene) standards. Chapter 4 includes a more detailed analysis of ANZFA's current and future funding levels.

Imported food

2.10 ANZFA and the Australian Quarantine and Inspection Service (AQIS) jointly conduct the Imported Food Inspection Program (IFIP). ANZFA conducts food risk assessments that assist AQIS to develop and maintain appropriate systems and procedures, including imported food inspection and sampling procedures. The IFIP is discussed in greater detail in Chapter 4.

Other Commonwealth agencies with food regulatory roles

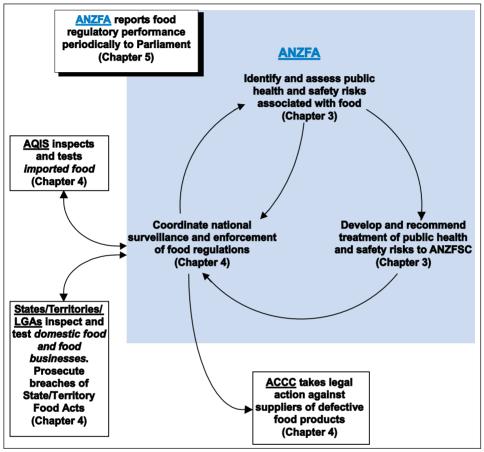
2.11 Other Commonwealth agencies with food regulatory roles (under the *Trade Practices Act 1974*) include:

- the Consumer Affairs Division of the Department of the Treasury that is responsible for instituting all Commonwealth mandatory product (including food) recalls (discussed in Chapter 4); and
- the Australian Competition and Consumer Commission that is responsible for taking legal action against suppliers of defective products (including food) under Part VA of the Trade Practices Act (discussed in Chapter 4).

2.12 Figure 1 illustrates the roles and responsibilities of each jurisdiction that are addressed in this report cross-referenced to the applicable chapter of the report.

Figure 1

Food regulation: roles and responsibilities



Source: ANAO analysis 1999

Current food regulation initiatives

2.13 Since the 1995 Audit, a number of significant food regulation initiatives have been completed or are currently in progress including:

- ANZFA's development of uniform national food safety (hygiene) standards;
- ANZFA's review of the food product standards;
- ANZFA's revised Food Industry Recall Protocol and introduction of a Government Health Authorities Food Recall Protocol;
- the FRR;

- the development of uniform 'model' State/Territory Food Acts; and
- the review of the Imported Food Control Act 1992.

2.14 Some of the issues covered in these initiatives (outlined below) were considered in the ANAO's 1995 Audit and are discussed in this follow-up audit. The recommendations from this follow-up audit are consistent with these initiatives.

Food safety (hygiene) standards

2.15 At the time of the 1995 Audit, food hygiene regulation was a State/Territory responsibility with each jurisdiction having its own legislation independent of each other. The complexity of food hygiene regulation was further increased by varying local government by-laws.

2.16 In October 1994, the then NFA produced a discussion paper on its vision for the future direction of food hygiene regulation in Australia that proposed, *inter alia*, the development of a national uniform food hygiene standard by the NFA. In June 1995, the State/Territory Health Ministers first affirmed their support for reforming food hygiene regulation in Australia. It was decided that ANZFA should take on the role of developing uniform food safety (hygiene) standards using ANZFA's process for developing and reviewing food product standards.

The food safety (hygiene) standards cover all aspects of food 2.17 handling (from food receival to food disposal); the health and hygiene of food handlers; and cleaning of food premises and equipment. It is expected that the food safety (hygiene) standards will receive ANZFSC approval in the second half of 1999. To fulfil the requirements of the standards, all food businesses will have to develop and implement Food Safety Programs (with general assistance from ANZFA and industryspecific guidance from relevant food industry associations) progressively over the six years after the commencement of the standards.⁸ The Food Safety Programs will be based on the Hazard Analysis and Critical Control Point (HACCP) system adopted by the Codex Alimentarius Commission (the international food standards-setting body) that scientifically and systematically identifies and assesses specific hazards in the food production process and establishes measures for their control. It is these food production process controls that the States and Territories and/or local government would audit to determine compliance with the standards as opposed to solely testing the end product.

⁸ Food businesses dealing with foods that pose the greatest risk will be the first required to develop and implement food safety programs.

Food product standards review

2.18 A review of food product standards against Council of Australian Governments competition policy principles originally began in 1994 with a five year timetable but was refocussed in 1996 with New Zealand's adoption of ANZFA's food products standard setting process. ANZFA intends to make the standards more generic and more outcomes focused (ie. less reliance on prescriptive controls)—with an overarching requirement to produce safe food. To this end, ANZFA is focusing its efforts towards standards that cover public health and safety, fraud and deception issues and other standards where justified on cost-benefit grounds. The review will give priority to general standards which cover all foods. Generic food standards will require all foods not to exceed certain maximum contaminant requirements, which will be supplemented by more stringent contaminant requirements for certain food groups (eg. mercury in fish). Specific commodity standards will be retained where justified to address issues specific to the commodity.

2.19 ANZFA consider that the revised standards, to be substantially completed by the end of 1999, will allow for more innovation in the food industry and greater compliance with World Trade Organization requirements, while maintaining public health and safety.

Food Industry and Government Health Authorities Food Recall Protocols

2.20 Voluntary food recall practices and procedures have not changed significantly since the 1995 Audit. In 1998, however, ANZFA updated its Food Industry Recall Protocol and for the first time produced a Food Recall Protocol for Government Health Authorities. The latter protocol covers all levels of government—Commonwealth, State/Territory and local government. ANZFA considers that the Government Health Authorities Food Recall Protocol, together with its food recall checklist proforma for health authorities, will help achieve greater consistency in actions across all three government jurisdictions. The ANAO found that stakeholder feedback on the clarity and scope of the Protocols received thus far has been positive.

Food Regulation Review

2.21 In March 1997, the Prime Minister announced the intention of the governments of Australia to undertake a review of food regulation in Australia. The key objectives of the FRR were:

While protecting public health and safety, to:

• reduce the regulatory burden on the food sector, and examine those regulations which restrict competition, impose costs or confer benefits on business; and

• improve the clarity, certainty and efficiency of food regulatory arrangements.⁹

2.22 The FRR Committee, comprising industry, consumer and government representatives from all jurisdictions, examined all food regulatory matters, involving the three levels of government and covered the whole of the domestic and imported food industry, including primary production, processing and retail. The FRR Committee consulted widely with through written submissions, public hearings in every State and Territory, focus, workshops, and face-to-face meetings. The FRR Committee also held interviews with organisations to discuss the Review's Draft Recommendations and received written comments on them. Where relevant, the ANAO has used the consolidated stakeholders comments that appear in the FRR Report to supplement the stakeholder views obtained directly by the ANAO.

2.23 The Final Report of the FRR of August 1998 concluded that the 'food regulatory system in Australia generally delivers safe food and Australia enjoys an enviable international reputation in this regard'. However, occasional significant lapses in food safety indicates scope for improving the effectiveness of the food safety system. The FRR Committee also indicated that 'there is an urgent need for governments to implement an integrated and coordinated national food regulatory system to replace the fragmented and piecemeal system of food regulation in place at the moment'.¹⁰ The Review contains recommendations and strategies aimed at:

- implementing an integrated and coordinated national food regulatory system;
- improving compliance and enforcement arrangements;
- improving legislation and national decision making processes;
- improving monitoring and surveillance systems;
- improving communications to industry and consumers; and
- amending the Australia New Zealand Food Authority Act 1991.^{11,12}

2.24 The FRR received widespread stakeholder support with stakeholder agreement with each of the FRR draft recommendations ranging from 73 to 98 per cent of respondents to the FRR draft report.

⁹ Food Regulation Review Committee (1998), Food - a growth industry: The report of the Food Regulation Review, Commonwealth of Australia, p. x.

¹⁰ *Ibid.*, pp. xiv-xvi.

¹¹ *Ibid*., pp. xvii, xviii.

¹² Changes to the ANZFA Act recommended by the FRR relate primarily to inserting objectives for the ANZFA Act, and amending ANZFA's functions (s7) and ANZFA's objectives when developing or varying standards (s10).

Model Food Act

2.25 Currently, each State and Territory has its own Food Act developed, for the most part, independent of each other. The different wording of each piece of legislation makes consistent enforcement across jurisdictions difficult and creates additional compliance costs for food businesses distributing food across State/Territory borders.

2.26 In March 1997, a working group involving government, consumers and the food industry began a review of Australia's Food Acts to enable the food safety (hygiene) standards to be effectively implemented when completed. The review, coordinated by ANZFA, examined the provisions of the Food Acts in each State and Territory and New Zealand to develop a model for all Food Acts in Australia (and New Zealand) containing consistent wording and coverage of issues.

2.27 After the release of a three volume discussion paper in February 1998 and receipt of written submissions, a draft Food Act was prepared for public comment in the latter half of 1998. It is expected that the model Food Act will receive approval from the Council of Australian Governments in September 1999 and be enacted in each State/Territory jurisdiction in the first half of 2000.

Imported Food Control Act Review

2.28 In 1998, the *Imported Food Control Act 1992* ('the IFCA') was reviewed against the Council of Australian Governments' national competition policy. The IFCA is administered by AQIS in the Department of Agriculture, Fisheries and Forestry—Australia. Under the IFCA, AQIS is responsible for developing and maintaining systems and procedures, including imported food inspection and sampling procedures. ANZFA has a close relationship with the work done by AQIS under the IFCA through the Imported Food Inspection Program (IFIP). Under a memorandum of understanding between ANZFA and AQIS, ANZFA conducts food risk assessments to assist AQIS to better target its work.

2.29 The IFCA Review Committee found a number of factors that can lead to market failure in the food industry and that the financial benefits arising from the IFCA (mainly avoidance of costs of illness) outweigh the costs of the scheme. The IFCA Review Committee recommended that 'the Imported Food Control Act be retained and that changes be made to the legislation and the operation of the scheme to increase its effectiveness and efficiency'.¹³

¹³ Op. cit., Imported Food Control Act Review Committee (1998), p. x.

3. Identifying, assessing and treating food safety risks

'Whole of agency' risk management approach

Recommendation No.1 from the 1995 Audit: The ANAO recommends Commonwealth consumer product safety regulators adopt and use a structured 'whole of agency' strategically-based risk management approach, involving a systematic, data-driven approach to identifying, analysing and ranking risks, and assessing treatment options.

NFA Response: Agreed.

ANZFA context: The ANAO observed that risk management in the then NFA was limited to scientific risk assessment when developing a particular food product standard and not adopted at a 'whole of agency' level. The NFA did not have a systematic process of identifying and analysing food safety risks before assessing, prioritising and treating these risks, for example by setting a standard. Food safety risks generally became evident at the public consultation phase of setting a standard.

3.1 In August 1998, the ANZFA Board of Management acknowledged that there was no fully integrated risk management strategy in ANZFA and that one should be developed. In November 1998, some three years after the 1995 Audit and around the time the FRR final report was published, the ANZFA Board considered a paper recommending the adoption of a comprehensive Risk Management Strategy for ANZFA. ANZFA expects to incorporate the Risk Management Strategy into the 1999–2000 ANZFA Strategic Plan in the first half of 1999.

3.2 Despite the delay in adopting a formal risk management strategy, ANZFA's whole of agency risk management has improved somewhat as a consequence of its involvement in the development of uniform food safety (hygiene) standards (scheduled for completion in the second half of 1999). At the time of the 1995 Audit, the ANAO considered that ANZFA's management of public health and safety risks associated with food were focused primarily on the longer-term risks associated with inorganic contamination of food and short-term risks from allergens. However, since ANZFSC gave ANZFA the responsibility for developing food safety (hygiene) standards, the ANAO considers that ANZFA has better focussed its attention on addressing the short-term (and sometimes acute) public health and safety risks associated with microbiological food

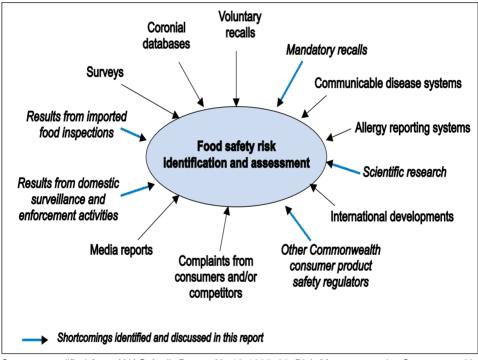
contamination from food handling, food handlers' hygiene and food businesses cleanliness.

Sources of food safety information

3.3 Before ANZFA can assess risks to consumers from food, it first must obtain relevant and timely information on these risks. The 1995 Audit noted that there are many sources that can be used to identify consumer product safety risks. Figure 2 highlights a number of possible sources relevant to food regulation.

 Figure 2

 Food safety risk identification and assessment



Source: modified from ANAO Audit Report No.12 1995–96 *Risk Management by Commonwealth Consumer Product Safety Regulators.*

Relationships with stakeholders involved in food regulation

3.4 The ANAO found ANZFA has maintained its links with key domestic and international stakeholders involved in food regulation that allows ANZFA to identify new risks and incorporate them into its standard setting priorities. For example, ANZFA:

 holds regular meetings and teleconferences with a working group of Senior Food Officers from the States/Territories and participants on the Australia New Zealand Food Authority Advisory Committee (ANZFAAC) in relation to technical and other advice on food matters and uniform interpretation and enforcement of food standards;

- is involved closely with the Public Health Division of the Department of Health and Aged Care—particularly the Communicable Diseases Network;
- has representatives on committees and sub-committees of the World Health Organization and Food and Agriculture Organization; and
- actively participates in Codex Alimentarius Commission (the international food standards setting body) meetings and activities.

Australian Total Diet Survey (formerly the Australian Market Basket Survey)

3.5 Since the 1995 Audit, ANZFA has further improved its ability to identify and assess longer term public health and safety risks associated with dietary exposure to food chemicals (including additives, contaminants, agricultural and veterinary drug residues and nutrients). Every two years, ANZFA conducts and coordinates the Australian Total Diet Survey (formerly the Australian Market Basket Survey) which covers the chemical content of selected foods from all major food group that form a significant part of the diet of Australians and sub-populations of Australians. Results are then modelled against six age-sex simulated diets (determined from National Dietary Surveys also conducted every two years) to arrive at dietary exposure levels for each food chemical. The dietary exposure levels are then checked against reference health standards (ie. the amount of food chemical that is considered safe to be exposed to over a lifetime) for each food chemical to determine the risk to public health and safety. The Australian Market Basket Survey 1996 published recently concluded that 'Australians can be confident that the food they eat is very low is pesticide residues and contaminants'.¹⁴ Had any public health and safety risks been identified from the Survey, these would have fed into ANZFA's standard setting priorities. In addition, ANZFA uses dietary modeling to assess affects of proposed variations to any food product standard.

3.6 In 1995, the ANAO noted that the latest Australian Market Basket Survey of the time (1992) included only a small range of foods (62). The ANAO also considered the Survey was not timely in that it took some two years from the time of food sampling to publication of the Survey. In the current audit, the ANAO found that the latest Australian Market Basket Survey in 1996 included a slightly larger range of foods (76). However, the timeliness of 1996 Survey has not improved from the 1992 Survey as it took over two years from the last food sampling period (October 1996) to the publication of the final Survey report (November

¹⁴ ANZFA (1998), Australian Market Basket Survey 1996 including the 1997 South Australian Backyard Egg Survey: a total diet survey of pesticides and contaminants, Commonwealth of Australia, p.xiv.

1998). ANZFA indicated that due to budget constraints, Surveys have a two year planning and funding cycle where samples are collected and analysed in Year 1 and data collated, analysed and reported on in Year 2. ANZFA further indicated that as a result of staff changes and shortages the 1996 Survey publication target of earlier in 1998 was not met.

3.7 Given that food samples are analysed by the Australian Government Analytical Laboratory and results are forwarded to ANZFA within three to six months of sample selection, the ANAO considers that the timeframe for ANZFA to produce the Survey report means the survey information is dated. The 1998 Survey currently in train has a scheduled reporting timeframe of late 1999/early 2000. The ANAO considers that the usefulness of the Survey would improve if this timeframe is met.

ANZFA's Risk Management Strategy

3.8 ANZFA's Risk Management Strategy, currently under consideration by management,¹⁵ identified a need for a coordinated system of food monitoring and surveillance that would better identify public health and safety risks associated with food to enable ANZFA to evaluate outcomes and provide the basis for setting new priorities. Consistent with this need identified by ANZFA, the ANAO considers that ANZFA's whole of agency risk management approach would further improve by:

- better coordinating food surveillance and enforcement (discussed in Chapter 4); and
- obtaining reliable data on the incidence and impact of food-borne illness.

Information on food-borne illness

3.9 The ANAO acknowledges that reliable data on the incidence and impact of food-borne illness is difficult to obtain. The FRR Committee considered that:

Australia has a passive system of food-borne illness surveillance which does not provide early warning of disease outbreaks or trend analysis. ... The fragmented nature of the current system can be attributed to consumers infrequent reporting of food-borne illness incidents to general practitioners, a general lack of laboratory isolation data, a lack of epidemiological studies and population-based surveys to determine more accurate levels of morbidity.¹⁶

¹⁵ ANZFA's risk management strategy was first put to the ANZFA Board in August 1998. It was subsequently refined and presented to the ANZFA Board again in November 1998.

¹⁶ Op. cit., Food Regulation Review Committee (1998), p. 97.

ANZFA estimates that 'there are 2.1 to 3.5 million cases of food-borne illness each year' costing 'in the vicinity of \$4 and \$7 billion every year'.¹⁷ Underreporting of food-borne illness and their impacts is also a problem in other countries.¹⁸

3.10 ANZFA's involvement in scientific research on food-borne illness can be improved. The ANAO considers that there is scope for ANZFA to more closely monitor and, where possible influence the direction of, scientific research on food-borne illness issues. Monitoring and liaising with research units domestically (eg. Food Science Australia,¹⁹ various research units in food science and microbiology etc. in Australian universities) and internationally (eg. Current Research Information System maintained by the US Department of Agriculture, Center for Food Safety and Applied Nutrition maintained by the US Food and Drug Administration) that regularly conduct research into food-borne illness issues is one method of improving in this area.

3.11 On a more positive note, ANZFA has recently become more actively involved in a project funded by the NSW Government that ANZFA hopes will allow it to better understand the incidence and impact of food-borne illness in Australia. This project will measure the incidence of food-borne illness in an area of NSW that is representative of the broader Australian community. Health care providers in this area have been primed to report incidences food-borne illness. Over time, these

¹⁷ Senator the Hon Grant Tambling, Parliamentary Secretary to the Minister for Health and Aged Care (1999) *Costs of Food Poisoning Cannot be Underestimated*, ANZFA Media Release on 14 February 1999.

¹⁸ A few studies have variously estimated the rate of incidences of gastroenteritis (which can be spread through contaminated food) at between 0.62 and 0.76 cases per person per year.^[a] If these estimates are extrapolated, it can be assumed that there are between 10 and 15 million cases of gastroenteritis in Australia each year.[b] In the United States, only 2090 of the estimated 1.4 million incidences of salmonella were reported in 1997.^[c] {[a] Monto AS, Koopman JS, The Tecumseh study XI Occurrence of acute enteric illness in the community, Am J Epidemiol (1980) 112(3) pp. 323-333; Gastrointestinal Illness, In: Dingles JH, Badger GF, Jordon WS, editors, Illness in their Home: A Study of 25,000 Illnesses in Group of Cleveland Families, Cleveland: The Press of Western Reserve University, 1964: pp. 188-218; Garthright WE, Archer DL, Kvenberg JE, Estimates of incidence and costs of intestinal infectious diseases in the United States, Public Health Reports 1988 103(2) pp. 107-115; and Payment P, Richardson L, Siemiatychi J, Dewar R, Edwardes M, Franco E, A randomised trial to evaluate the risk of gastrointestinal disease due to consumption of drinking water meeting current microbiological standards, Am J Public Health 1991 81(6) pp. 703-708|| [b] Department of Human Services (1997) A Fresh Approach -Victoria's Food Hygiene Strategy || [c] Tauxe RV (1998) Public health surveillance of foodborne infections: New challenges and new solutions, Codex Meeting in Orlando (Florida) on October 26 1998 - data from the Foodborne Diseases Active Surveillance Network (FoodNet) (involving United States DA, Centres for Disease Control, Food and Drug Administration & 7 US State health departments).}

¹⁹ Food Science Australia is a joint venture of the Commonwealth Science and Industrial Research Organisation (CSIRO) Division of Food Science Technology and the Australian Food Industry Science Centre.

incidences will be tabulated and results extrapolated across Australia to determine trends in food-borne illness. The ANAO supports initiatives such as this that will enable ANZFA to identify food safety risks, take steps to prevent food-borne illness and measure objectively one of its desired outcomes—a reduction in food-borne illness in Australia.

Regulator's interface with the Department

Recommendation No.3 from the 1995 Audit: The ANAO recommends that consumer product safety risk management be improved by ... the Department of Human Services and Health [now the Department of Health and Aged Care] chairing a forum of regulators to discuss common issues, such as standard-setting approaches and compliance activities, and to improve the level of cooperation and collaboration.

NFA Response: Disagreed, but the then NFA subsequently participated in the forum.

3.12 In July 1996, the then Department of Health and Family Services indicated to the then JCPA at a public hearing into the 1995 Audit that it had convened a forum of Commonwealth consumer product safety regulators (including ANZFA). However, ANZFA indicated that the forum quickly disbanded after two meetings as participants could not decide how to usefully share information relevant to regulators of different consumer products.

3.13 ANZFA finds it more efficient and effective to deal with those agencies which have the most in common with ANZFA's regulatory responsibilities. To this end ANZFA has established and maintained separate links with other Commonwealth agencies with some direct or incidental association with food. These include:

- Therapeutic Goods Administration—Food/Drug Interface committee;
- Department of Health and Aged Care—regular contact with the Public Health Division and the Communicable Diseases Network of Australia and New Zealand; and
- Department of Agriculture, Fisheries, Forestry-Australia:
 - Imported Food Inspection Program (administered by the Australian Quarantine Inspection Services in the Department);
 - Animal Industries Public Health Committee;
 - National Registration Authority for Agricultural and Veterinary Chemicals; and
 - National Residue Survey.

3.14 ANZFA also has links with other Commonwealth consumer product safety regulators with broader responsibilities than just food. For example, ANZFA deals with the ACCC on ad-hoc issues primarily related to:

- country of origin matters;
- the trade practice concerns of specific sectors of the food industry; and
- the degree of overlap between the Trade Practices Act and food-specific regulation (particularly in relation to uniform interpretation and enforcement of misleading and deceptive advertising and labelling).

3.15 In relation the last issue, ANZFA has taken the first steps towards developing a memorandum of understanding with ACCC *et al.*

3.16 Although a previous attempt at establishing a Commonwealth consumer product safety regulators forum was not successful, the ANAO considers that the basic concept of having regulators canvassing opinions and share experiences would aid Commonwealth consumer product safety regulation generally. There are issues common to some or all Commonwealth consumer product safety regulators. Such issues include common sources of injury/illness data, State/Territory (and sometimes local government) participation in the regulatory process, and Commonwealth enforcement issues (particularly, under the *Trade Practices Act 1974*). In this context, the ANAO considers that there would be benefits in ANZFA strengthening its links with non-health related consumer product safety regulators including the Federal Office of Road Safety and the Consumer Affairs Division of Treasury.

Risk-based approach to standard setting

Recommendation No.4 from the 1995 Audit: The ANAO recommends that the Federal Bureau of Consumer Affairs [now the Consumer Affairs Division of the Department of the Treasury] and the NFA develop product performance standards using a structured risk-based strategic approach.

NFA Response: Agreed.

ANZFA context: The ANAO found that:

- public health and safety risk was not always fully considered when developing food product standards;
- the development of food product standards proposals were generally not timely;
- greater involvement by other food regulation stakeholders was needed when deciding food regulatory priorities;

- greater involvement by other food regulation stakeholders was needed when developing individual food standards; and
- the review of the food product standards had been delayed and should be considered a priority.

3.17 The process of developing a new food standard or varying an existing standard has changed little, if any, since the 1995 Audit. The process for recommending and approving new or varied food standards, illustrated in Figure 3, involves numerous rounds of public consultation (ie. at the application/proposal stage, draft standard or variation stage and inquiry/public hearing stage).

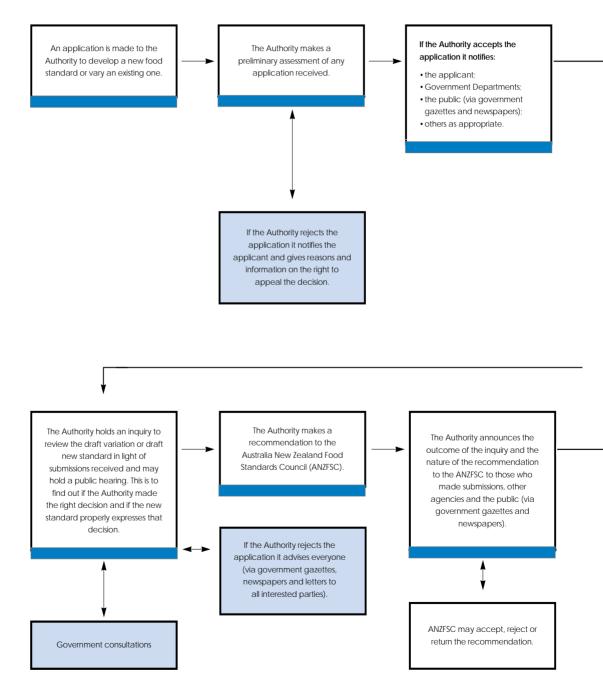
3.18 The overwhelming majority of ANZFA's standards development work is currently focused on completing the planned five-year review of the food product standards and the development of food safety (hygiene) standards. ANZFA indicated that there are very few active standard development proposals or applications outside the work being undertaken on these two sets of standards.

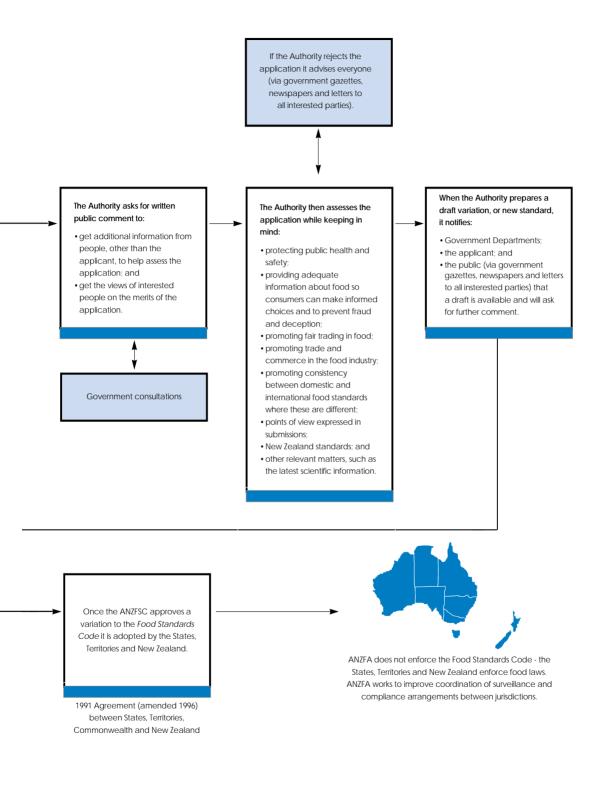
Consideration of public health and safety risks

ANZFA indicated that public health and safety issues, and to a 3.19 lesser extent, fraud and deception issues are at the heart of the review of the food product standards. Once the review is complete, the revised food product standards will be fewer in number, more generic, outcomesoriented food product standards opposed to the highly prescriptive standards that are currently in place—with an overarching requirement to produce safe food. The regulatory impact assessment approach adopted by ANZFA addresses identified market failures through appropriate and fully justified regulatory mechanisms. As a result, issues not related to public health and safety or fraud and deception will be removed from the standards unless the regulation is justified on costbenefit grounds. ANZFA considers that the revised standards will allow for more innovation in the food industry and greater harmonisation of Australia's food standards to those of Codex (thus fulfilling Australia's obligations to the World Trade Organization), while addressing public health and safety risks.

3.20 The ANAO's review of the draft food safety (hygiene) standards found that public health and safety risks are of paramount concern to ANZFA in its ongoing development. The ANAO considers this to be an improvement over ANZFA's focus at the time of the 1995 Audit. Chapter 2 describes the risk-based Hazard and Critical Control Point (HACCP) systems that underpin the food safety (hygiene) standards.

Figure 3 Procedure for developing or review food standards





Source: ANZFA's Annual Report 1997-98

Timeliness of standard development

3.21 The 1995 Audit noted that the then NFA did not set time limits for developing food product standards proposals but it attempted to meet the same processing time targets as for applications (ie. one year). At that time, the ANAO considered that NFA proposals usually took considerably longer than one year to complete.

3.22 The FRR Committee noted that the main criticism it received of the ANZFA standard setting process was that '*in some cases, it is too slow, relying, as it does, on two and sometimes three rounds of public comment*'.²⁰ Comments from stakeholders received by the ANAO on standard development timeframes were mixed. The Health Department of Western Australia considered the timeframes to be '*the shortest achievable times to give due consideration and ensure adequate consultation*'. The Victorian Department of Human Services also expressed satisfaction with the timeframes. The NSW Health Department expressed concern about continuing delays in the development of food safety (hygiene) standards whereas the Queensland Health Department were concerned that ANZFA's 'fast-tracking' of an issue associated with a food standard/ code of practice omitted usual public consultation.

3.23 ANZFA explained that many food standard setting issues covered by an ANZFA proposal were more complex than applications received from elsewhere and that twelve months would be insufficient time to complete the standard proposal. In some cases, ANZFA may choose to develop a proposal covering common issues from multiple applications. Timeframes for all standard proposal or application projects are outlined in project plans early into the standard review/development process. ANZFA indicated that stakeholders are notified as these timeframes are updated over the life of the project as and when required. The ANAO did not test ANZFA's assertions on this issue as it was outside the scope of the audit.

3.24 ANZFA has not been able to demonstrate any improvement in the timeliness of finalising food product standards proposals has occurred since the 1995 Audit because ANZFA is currently reviewing all of the food product standards together rather than individual standards as was the case in 1995. Nevertheless, ANZFA considers that its timelines for developing standards compare favourably with Codex and standard setting bodies in Europe and the United States, but the ANAO did not sight any evidence to support these claims.

²⁰ *Op. cit.*, Food Regulation Review Committee, p. 46.

3.25 ANZFA considers that the statutory consultation timeframes make any substantial improvements in the timeliness of its standards review/ development processes difficult to achieve. ANZFA indicated that it intends to introduce amendments to its enabling legislation in the Autumn 1999 session of Parliament to allow greater flexibility in stakeholder consultation timeframes in line with the level of assessed risk and stakeholder interest. The ANAO supports any such approach designed to hasten the completion of new or varied food standards while maintaining effective stakeholder consultation.

Greater involvement from stakeholders needed when setting priorities and developing individual standards

3.26 The 1995 Audit considered that the then NFA had not adopted an inclusive approach to deciding national priorities and developing individual standards. The 1995 Audit indicated that States/Territories and local government wanted greater involvement in setting the agenda for standards development and considered that the inclusion of stakeholder representatives on individual project teams would improve stakeholder involvement.

3.27 In line with the ANAO's comments in 1995, ANZFA now seeks to appoint stakeholders with relevant expertise from the food industry, government and consumer groups to become members of project teams developing/reviewing food standards. ANZFA considers that this arrangement works well except for consumer groups that do not necessarily have the resources for hands-on involvement. ANZFA indicated that, in such circumstances, it involves consumer groups through face-to-face meetings and teleconferences.

3.28 The FRR Committee noted that the States and Territories '*praise* [ANZFA's] open, accountable and consultative [standard setting] processes'.²¹ The ANAO also received similar comments from the States and Territories. However, the FRR received contrary comments from other stakeholders. In this respect ANZFA noted that:

recent stakeholder feedback through the [FRR], particularly from consumer and small business groups, has indicated that there is a perception that ANZFA's consultation can be exclusive, specifically directed at big business, disregarding of input, and unrepresentative generally of these groups.²²

²¹ *Ibid.*, p. 46.

²² Background information for ANZFA's draft Consultation Strategy paper considered at the August 1998 meeting of the ANZFA Board.

3.29 Although little action has yet taken place, ANZFA is considering its consultation and communication with stakeholders. In 1997 ANZFA was developing a Consultation Strategy—a draft of which was presented to the ANZFA Board meeting of August 1998. The Consultation Strategy identified ANZFA's consultation shortcomings, methods and options for improvement, and recommendations for action in the short and medium term. At the same ANZFA Board meeting, the ANZFA Board considered its 1998–99 Communications Strategy that critically analysed the various mediums of communication that ANZFA uses generally, and the specific communication strategies in place for all of ANZFA's important current issues.

3.30 The ANAO supports ANZFA's approach to identifying and correcting its consultation shortcomings and re-examining its communication approaches on important issues. However, the there should be concerns about delays in implementing improvements and the limited consideration of local government communication and consultation issues in these documents, and local government involvement in ANZFA standard setting processes generally. One State Local Government Association expressed the view to the ANAO that 'ANZFA does not adequately understand, or take into account, the views of Local Government'.

3.31 Local government has a significant role to play in the success of food regulation in Australia. In State/Territory jurisdictions, local government environmental health officers conduct food product and food business inspections. In some jurisdictions (eg. Victoria) local governments are the only level of government conducting these inspections and operate virtually independent from the State/Territory government. As was the case at the time of the 1995 Audit, the ANAO considers that local government authorities still have little influence in setting the agenda for the food standards they are supposed to enforce or the content of these standards.²³ The ANAO notes that ANZFA has attempted to involve representatives from the Australian Institute of Environmental Health (AIEH) and the Australian Local Government Association (ALGA) and its State/Territory affiliate organisations in ANZFA issues, with limited success. Given that there are over 700 local governments in Australia, the ANAO acknowledges that consultations can be difficult-but this is all the more reason for developing

²³ Office of Regulation Review (1995) Enforcing Australia's food laws—A survey of the practices of Australian agencies responsible for enforcing domestic food safety regulations, Draft Discussion Paper, p. A-49.

communication and consultation strategies that consider local government as an important group of stakeholders in their own right.

3.32 In addition, local government is not specifically represented on the two major advisory groups of ANZFA—ie. ANZFAAC and the Senior Food Officers working group. ANZFA advised that it intends to invite AIEH to attend SFO meetings to discuss particular topics, as appropriate. The ANAO considers that ANZFA would benefit from the inclusion of representatives from local government (or local government associations or AIEH) on both advisory groups as full members.²⁴ ALGA advised that it is not keen to be represented on the advisory groups although AIEH indicated that it would welcome representation on ANZFAAC and the Senior Food Officers working group.

Timeliness of food product standards review and development of food safety (hygiene) standards

The 1995 Audit noted that a recent evaluation of the then NFA 3.33 concluded that the review of the food product standards was 'already 1 to 2 years delayed'.²⁵ At the time, the then NFA indicated that a higher priority had been allocated to the review. In the current audit, however, the ANAO found that delays in the review's completion have continued to increase each year since the 1995 Audit. The 1994-95 NFA Annual Report tabled in Parliament in October 1995 indicated that the review would be completed by October 1997. However, subsequent NFA/ANZFA Annual Reports have reported extensions in the completion date to *'early* in 1999' (1995-96), '1 January 2000' (1996-97) and 'substantially completed by the end of 1999' (1997-98). ANZFA indicated that delays since 1995–96 have occurred due to the inclusion of New Zealand (from 1995–96), staff reductions in 1996–97 and problems with external contractors in 1997–98. ANZFA has recently advised that the review will be substantially complete by the end of 1999 but a final completion date cannot be provided as:

- unexpected and/or externally-driven delays in the completion of projects might arise; and
- completion is dependant on ANZFSC agreeing to all ANZFA's review recommendations.

²⁴ The ANAO notes that although ANZFAAC is a statutory committee established under the ANZFA Act, ANZFA's Chief Executive Officer can appoint members to the Committee 'for a specific purpose' {s42(4)}.

²⁵ Wright M. (1994) Review of the National Food Authority Operating Procedures: Report to the Parliamentary Secretary to the Minister for Human Services and Health and Minister for Human Services and Health, p. 22.

3.34 The most recent ANZFA Annual Reports also indicate that the completion of the food safety (hygiene) standards has been delayed. The 1996–97 ANZFA Annual Report stated that all food safety (hygiene) standards would go before ANZFSC by early 1998. The following year's annual report indicated that the standards would go before ANZFSC in the latter third of 1998. The December 1998 meeting of ANZFSC gave in-principle approval to the new food safety (hygiene) standards. ANZFSC is expected to make its final decision on the standards in July 1999 once ANZFA has completed some additional work.²⁶

Recommendation No.1

3.35 The ANAO *recommends* that, in the interests of more comprehensive stakeholder input, ANZFA includes:

- a) local government as an important group of stakeholders in their own right in its future Consultation and Communication strategies; and
- b) local government representation on the Australia New Zealand Food Authority Advisory Committee and the Senior Food Officers working group.

ANZFA response

3.36 Agree. ANZFA recognises the importance of consultation with, and participation by our stakeholders in its decision making processes. ANZFA has already recognised the need to facilitate more effective involvement by local government and has been discussing options with the Australian Local Government Association (ALGA) and the Australia New Zealand Food Authority Advisory Committee (ANZFAAC) who have both agreed that it would not be appropriate for ALGA to sit on ANZFAAC. However, ANZFAAC recently agreed to ANZFA initiating a range of strategies such as having regular discussions between the Managing Director of ANZFA and the CEO of ALGA as well as inviting officers from ALGA and the Australian Institute of Environmental Health to attend meetings of the Board and Senior Food Officer's meeting where appropriate.

3.37 ANZFA already provides its consultation documents to ALGA and the AIEH and, where appropriate, to each local government jurisdiction.

²⁶ ANZFA (1999) ANZFA News 9—February 1999, p. 3.

4. Surveillance and enforcement of food safety regulations

Voluntary recalls

Recommendation No.5 from the 1995 Audit: The ANAO recommends regulators:

- improve monitoring of voluntary product recalls and adherence to recall codes;
- improve the effectiveness of voluntary product recalls by continually evaluating the recall process;
- take a leadership role to ensure that a national approach to product recalls is implemented;
- ensure recall notices clearly identify the hazard involved and possible consequences; and
- conduct recall audits and follow up corrective action by suppliers to prevent recurrence.

NFA Response: Agreed.

ANZFA Context: The ANAO found that:

- contrary to what was reported in the then NFA's 1993–94 Annual Report, companies did not comply with the procedures for voluntary recalls (particularly in relation to the submission of interim and final recall reports from companies);
- the then NFA did not assess recall effectiveness in terms of the amount of product successfully recalled as a percentage of the product that left the manufacturer, as required by the NFA Recall Protocol;
- Australian consumers received varying levels of protection due to the then NFA's preference for the State to initiate and coordinate recalls;
- Commonwealth consumer product safety regulators, including the then NFA, sometimes failed to communicate product hazards in plain language; and
- the then NFA did not conduct recall audits.

4.1 ANZFA has overall responsibility for coordinating voluntary or State-initiated mandatory food recalls in Australia.²⁷ Under current arrangements, the Consumer Affairs Division of the Treasury is responsible for coordinating mandatory recalls initiated by the Commonwealth. ANZFA's coordinating role in voluntary/State-mandated food recalls is 'hands on' as ANZFA:

- is advised of all voluntary food recalls;
- provides advice and assistance to the sponsor(s) (ie. the entity(s) primarily responsible for the supply of the product in Australia) conducting the recall—including the appropriate recall level²⁸;
- informs the relevant state/territory health authorities; and
- assesses the effectiveness of each food recall.

4.2 Sponsors have the prime responsibility for implementing the recall and for ensuring compliance with the recall procedures. Figure 4 summarises the procedure for a food recall.

Initiating and coordinating recalls

4.3 The 1995 Audit considered that there was no uniform national approach to State-initiated mandatory food recalls as each State and Territory operates under their own legislation and the then NFA was not active in facilitating and coordinating a national approach to recalls. At the time of the current audit, the States and Territories still do not have uniform mandatory food recall powers and, according to the FRR Committee, the food industry still has some concerns that 'on occasions food recalls have not been adequately coordinated and that there is potential for costly incorrect decisions'.²⁹ The FRR Committee, however, notes a number of initiatives underway to improve uniform approach to coordinating food recalls including the development of:

- food safety (hygiene) standards (that will require food businesses to have a satisfactory system for recalling food);
- uniform 'model' State and Territory Food Acts; and
- a Government Health Authorities Recall Protocol [that ANZFA introduced in 1998].³⁰

²⁷ For the purposes of this report, 'voluntary and State-initiated mandatory food recalls' are collectively called 'voluntary/State-mandated food recalls'.

²⁸ There are three broad levels of recalls—wholesale, retail and consumer. Each recall level progressively increases the recall intensity and effort for sponsors and government. For additional information on recall levels, refer to the Food Industry Recall Protocol.

²⁹ Op. cit., Food Regulation Review Committee (1998), p. 63.

³⁰ *Ibid.*, pp. 63,64

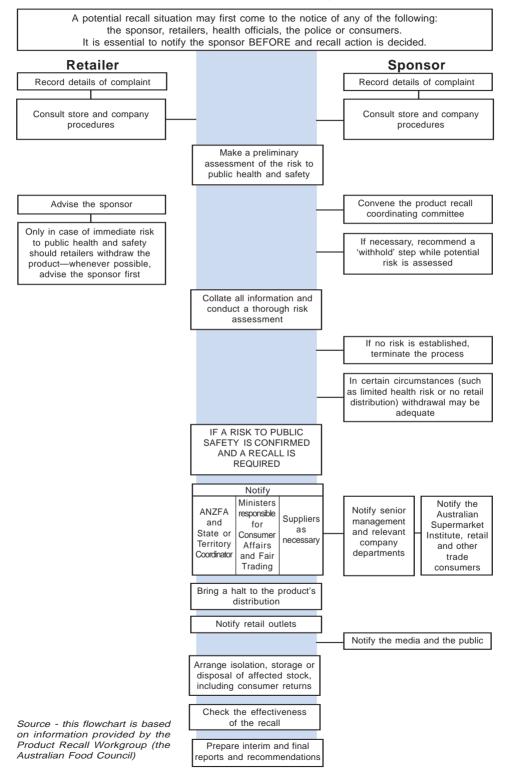


Figure 4 Procedure for a food recall (ANZFA's Food Industry Recall Protocol)

4.4 The Government Health Authorities Recall Protocol clearly sets out the roles, actions and responsibilities of Commonwealth, State/ Territory and local governments in the event of a voluntary food recall. The Protocol also identifies ANZFA as the government agency responsible for notifying all affected State/Territory health authorities of recall actions initiated in other State/Territory jurisdictions. The ANAO did not examine the extent to which ANZFA and other government authorities adhered to the food recall protocols as this is outside the scope of the audit.

Compliance with voluntary/State-mandated food recall procedures

4.5 The ANAO considers that ANZFA has improved sponsor compliance with voluntary/State-mandated food recall procedures, particularly in relation to the provision of interim and final recall reports, since the 1995 Audit. The ANAO found that of the more recent voluntary/State-mandated food recalls (from July 1997 to November 1998), 37 of the 44 recalls (84.9 per cent) had been finalised adequately by the sponsor's provision of interim and final reports. This represents a 72 and 24 percentage point increase in the provision of interim and final reports respectively, since the 1995 Audit. In addition, the timeliness of receiving interim and final reports has improved markedly since the 1995 Audit. Final recall reports from sponsors for recalls conducted between July 1997 and November 1998 were received, on average, 1.75 months after the due date. At the time of the 1995 Audit, final recall reports were received, on average, three months after the due date.

Assessing recall effectiveness

4.6 As noted in the Food Industry Recall Protocol, 'the effectiveness of the recall is assessed on the basis of the amount of product received as a proportion of the amount of product that left the sponsor, while taking into account the retail turnover of the product'. A similar clause was in the former Recall Protocol in force at the time of the 1995 Audit.

4.7 ANZFA collects data on the percentage of affected product recalled, where provided by sponsors. Although ANZFA were only able to obtain the recalled product return rates in 73 per cent of recalls, where provided, the rates ranged from two to 100 percent (median - 57.5 per cent). This data, however, on its own does not indicate the effectiveness of recalls. Factors such as product distribution patterns, production/ consumption turnover rates and the product's shelf life need to be considered on a case-by-case basis, in conjunction with recalled product return rates, to determine recall effectiveness.

4.8 The ANAO considers that ANZFA is not taking full advantage of the information provided by industry to assess the effectiveness of voluntary food recalls. Like the findings of the 1995 Audit , the only indication of ANZFA's satisfaction or otherwise with the amount of product recalled is ANZFA's decision to close the recall file on receipt of the final report from the sponsor. The ANAO considers that the food recall process would be improved by some form of explicit assessment of recall effectiveness by ANZFA. ANZFA indicated that the success of a system to assess recall effectiveness depends upon sponsor cooperation, without which, recall data would probably not be complete. The ANAO considers that ANZFA should encourage sponsors to provide sufficient data in the interim and final recall reports to make such an assessment possible. Recall audits (see below) are another means of obtaining data on the amount of product recalled.

4.9 The ANAO also considers that the method of assessing food recall effectiveness could be improved by focussing on the appropriateness of the proportion of recalled product <u>that has not been returned</u> rather than the amount of recalled product <u>received</u>. For example, for a consumer-level food recall (the most intensive) the appropriate recall target would be 100 per cent of recalled product less any product consumed or thrown out by consumers. Therefore ANZFA would assess consumer level recalls as effective when ANZFA was satisfied that the proportion of recalled product that was not returned represented recalled product that had been consumed or thrown out by the consumer.

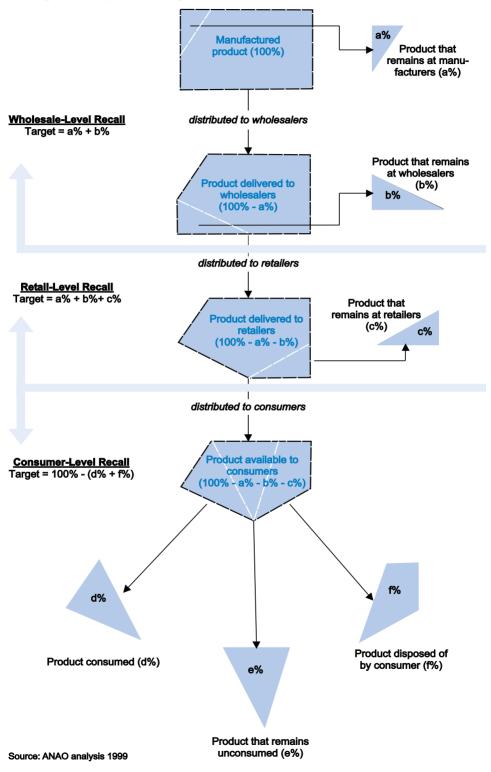
4.10 Figure 5 illustrates the process for determining the appropriate food recall target for each wholesale, retail and consumer level recall.

Communication of hazard in plain language

4.11 To ensure consumers respond to recalls, recall notices and advertisements should alert the consumer to the potential hazard, the possible consequences and how to avoid these. In the 1995 Audit the ANAO found that recall notices of Commonwealth consumer product safety regulators generally were sometimes too technical or simply indicated that there might be some risk in using the product, without providing consumers with suitable information to assess the hazard in language they could immediately understand.

4.12 The current 1998 Food Industry Recall Protocol more clearly illustrates the format (including presentation and message requirements) of food recall advertisements than did the superseded Protocol. ANZFA also provide assistance to sponsors when they are developing the wording of advertisements (eg. sending approved wording of a similar recall from the past). ANZFA ultimately must approve the wording of voluntary food recall advertisements before they are placed in the media.

Figure 5 Setting recalled product targets for the three levels of food recalls



Recall audits

4.13 The 1995 Audit considered that recall audits provide a mechanism for making voluntary recalls more effective. Such audits would also contribute to an improvement in the effectiveness of all food recalls. They can also provide a valuable insight into why a recall is necessary and the reasons underlying the recalled product return rate, and possibly prevent re-occurrence. Recall audits can involve visiting the site of the sponsor; inspecting recalled product; examining recall documentation and procedures put in place to avoid the need for future recalls; and making recommendations to improve the success of the recall process.

4.14 The ANAO found, however, that no food recall audits have been undertaken since the 1995 Audit. At ANZFA there seems to be some confusion as to which government agency-Consumer Affairs Division or ANZFA—has the power and responsibility for conducting food recall audits. ANZFA's two Food Recall Protocols illustrate its confusion in relation to this issue. The 1998 Food Industry Recall Protocol states that 'in order to advise the Minister [for Financial Services and Regulation] that a recall has been completed satisfactorily, the Consumer Affairs Division, in consultation with the Australia New Zealand Food Authority, may conduct a food recall audit³¹ However, this statement differs substantially from the one contained in the Government Health Authorities Food Recall Protocol stating that 'ANZFA will conduct an audit, on behalf of the Consumer Affairs Division, [Department of the Treasury], to ensure recalls have been completed satisfactorily'.³² Irrespective of the differences in wording between the Protocols, the Commonwealth and the States/Territories are clearly committed to the Commonwealth conducting food recall audits.

4.15 ANZFA is of the view that only the Consumer Affairs Division has the power to conduct food recall audits because of the provisions of the *Trade Practices Act 1974*. The Consumer Affairs Division indicated that it has been using a risk-based recall audit program (for recalls for which it has <u>direct</u> responsibility) since 1996 although the *Trade Practices Act 1974* does not specifically provide Commonwealth officers the power to conduct recall audits.³³ Recall audits are a means by which the Consumer Affairs Division satisfies its Minister that satisfactory action has been taken by recall sponsors.

³¹ ANZFA (1998) Food Industry Recall Protocol, p.9.

³² ANZFA (1998) *Government Health Authorities Food Recall Protocol*, p. 5.

³³ Although the Consumer Affairs Division considers that this power is implied by the requirement for the Minister to order a compulsory recall if it appears that the sponsor has not taken satisfactory voluntary recall action.

4.16 Recall audits conducted by the Consumer Affairs Division rely on cooperation from recall sponsors (which it has had no problems in gaining) to access sponsors' premises or recall documentation. The Consumer Affairs Division cannot see any barriers for ANZFA setting up its own audit program for food recalls and is willing to assist ANZFA in this regard.

4.17 Given that ANZFA has subject matter expertise in food regulation, the ANAO considers that ANZFA should establish a risk-based audit program similar to the one used currently by the Consumer Affairs Division. As a consequence of establishing a risk-based audit program, the Food Recall Protocols would need to be clarified to reflect the revised recall audit arrangements.

Recommendation No.2

4.18 The ANAO *recommends* that, to enhance the food recall framework agreed between the Commonwealth and the States/Territories, ANZFA:

- a) explicitly assess the effectiveness of each food recall by focussing on the proportion of recalled product (which is commensurate with the recall level) that has not been returned; and
- b) pursue the establishment of a risk-based audit program for food recalls, similar to the one used currently by the Consumer Affairs Division of the Department of the Treasury.

ANZFA response

4.19 a) and b) Agrees with qualification. ANZFA agrees that postrecall assessments and audits are useful exercises in identifying problems and improvements in the food recall arrangements coordinated by ANZFA. However, in order for ANZFA to fully assess the effectiveness of each recall or routinely carry out a risk-based audit, we would need detailed information from each of the companies conducting the food recalls. In most cases, sufficiently detailed information is not submitted as part of the post recall reporting arrangements, despite companies being encouraged to provide this information in accordance with the *Food Industry Recall Protocol.* ANZFA does not have the statutory powers, to require this information but would welcome further powers in this respect.

ANAO comment on ANZFA response

4.20 The ANAO considers that through recall audits, such as those conducted by the Consumer Affairs Division of Treasury, ANZFA should be able to obtain any missing information from the sponsor's recall reports. As noted above, when the Consumer Affairs Division conducts

recall audits, it has had no problems gaining the cooperation of sponsors to access their premises or recall documentation.

Commonwealth-initiated mandatory recalls

Recommendation No.6 from the 1995 Audit: The ANAO recommends the Federal Bureau of Consumer Affairs [now Consumer Affairs Division of the Treasury] promote to all regulators the use of mandatory recalls by:

- informing them of the procedures and kind of evidence needed for the Federal Bureau of Consumer Affairs to recommend that the Minister of Consumer Affairs order a mandatory recall;
- encouraging the regulators to use mandatory recalls where suppliers have not taken satisfactory action to prevent a product causing injury; and
- examining ways to improve their timeliness.

NFA Response: Agreed.

4.21 The power for ordering a mandatory recall for all consumer products (including food) at the Commonwealth level rests with the Minister responsible for sections 65E and 65L of the *Trade Practices Act 1974*—currently the Minister for Financial Services and Regulation (in the Treasury portfolio). In the 1995 Audit, the ANAO considered the complex arrangements for initiating a mandatory recall inhibited their effectiveness because of the time critical nature of mandatory food recalls. Mandatory recall arrangements in existence at the time required the then Minister for Small Business and Consumer Affairs (now the Minister for Financial Services and Regulation) to be convinced of the need for a mandatory food recall after:

- attempts to obtain a voluntary food recall in the first instance would have failed (meaning that the public would already be at risk); and
- convincing the Minister for Health that a mandatory food recall was needed.

The arrangements in place in the 1995 Audit are still in place today.

4.22 In response to Recommendation No.6 from the 1995 Audit, the Consumer Affairs Division issued a guide to Commonwealth consumer product safety regulators in November 1996 on using the mandatory recall provisions of the *Trade Practices Act 1974*. The Consumer Affairs Division acknowledged, in the Guide, that the current system for mandatory recalls has 'inherent delays built into it' and recommended that

agencies considering a mandatory recall liaise early with the Consumer Affairs division to avoid unnecessary delays.³⁴

4.23 This guidance has not changed ANZFA's attitude to Commonwealth-instituted mandatory recalls. ANZFA is reluctant to undertake any mandatory food recalls as it considers these arrangements are '*cumbersome and could put lives at risk*'. ANZFA further indicated that:

[its] preferred response, in case of an urgent food safety risk which was not being adequately addressed through voluntary means, would be to work with the States and Territories to ensure mandatory recalls in each State and Territory, using State and Territory powers.

4.24 The ANAO considers that a situation where ANZFA has to rely on the mandatory food recall powers of the States and Territories to obtain a prompt response is unsatisfactory, given the Commonwealth has its own mandatory recall legislation.

4.25 Since the 1995 Audit ANZFA has made representations at officer and Ministerial level for ANZFA to obtain mandatory food recall powers. However, consideration of changes to mandatory food recall powers has been suspended pending the result of a multi-stage review into the efficiency and effectiveness of the mandatory recall provisions of the *Trade Practices Act 1974*. One of the options for change being considered in the review is the delegation of mandatory recall powers from the Minister for Financial Services and Regulation to, in the case of food, the Minister for Health. Such a change was recommended recently by the FRR Committee and supported by nearly 90 per cent of respondents to the Review's draft report.³⁵ ANZFA and the ANAO also support such a change as it would invariably hasten Commonwealth-initiated mandatory food recall decisions.

Other treatment options

Recommendation No.8 from the 1995 Audit: The ANAO recommends that Department of Human Services and Health [now the Department of Health and Aged Care] and the regulators cooperate and collaborate in reducing risks by greater promotion of product safety through the use of more cooperative approaches such as targeted education campaigns, voluntary codes of practice and encouraging the teaching of safe design.

NFA response: Agreed

³⁴ Federal Bureau of Consumer Affairs (1996) *Product Safety Provisions of the* Trade Practices Act 1974: A Guidenote, p. 4.

³⁵ Op. cit., Food Regulation Review Committee (1998), pp. 64, 168.

4.26 In its 1995 Audit, the ANAO considered that a comprehensive food safety framework should include proactive approaches such as education programs and the adoption of codes of practice as well as reactive processes such as recalls and prosecutions where warranted. The ANAO did not examine these proactive approaches in the 1995 Audit but has now done so as part of the current follow-up audit.

4.27 The ANAO notes that the comprehensive review of the food product standards and the development of the food safety (hygiene) standards—both of which are scheduled for completion within a year—has reduced the scope for codes of practice³⁶ at the moment. ANZFA has, however, developed one interim code of practice³⁷ since the 1995 Audit but it is unrelated to food safety.

4.28 Since 1995 ANZFA has been considering the role that treatment options other than setting standards has to address food regulatory issues. In December 1997 ANZFA developed a framework to guide the development, role and use of future codes of practice, guidelines and ancillary documents in the food regulatory environment.

4.29 Apart from codes of practice, the Regulatory Impact Statements that accompany the development of each proposed new or varied food standard ensures that ANZFA considers treatment options other than regulation (such as no regulation and codes of practice) to achieve the object of the proposed new or varied standard. The Office of Regulation Review in Treasury oversights ANZFA's development of Regulatory Impact Statements.

4.30 The FRR noted that ANZFA and other food regulation agencies use various methods to communicate food safety information to consumers and industry. However, the FRR considered that

efforts to collate and disseminate information [by food regulation agencies] have been constrained by available resources and the priority assigned to these functions [and] as a result, published information is patchy and incomplete.³⁸

4.31 The ANAO considers that efforts put into reviewing ANZFA's 'whole of organisation' stakeholder communication approaches has the potential to substantially address previous shortcomings in this area.

³⁶ As distinct from guidelines that accompany the food safety (hygiene) standards developed by ANZFA for use by the food industry and government.

³⁷ The Interim Code of Practice is title *An Interim Code of Practice for the communication of the health benefits of food products* that ANZFA produced in conjunction with a pilot for health claims relating to folate/neural tube defects.

³⁸ Op. cit., Food Regulation Review Committee (1998), p. 101.

ANZFA's Communications Strategy developed in 1998 (but not yet implemented) critically analysed the various mediums of communication that ANZFA uses generally, and the specific communication strategies in place for all of ANZFA's important current issues.

4.32 At an individual project level, the ANAO found that ANZFA integrates its new and revised standards with the environment that will surround them. This was particularly evident in the development of the food safety (hygiene) standards where ANZFA has directed effort towards preparing and educating the food industry—particularly small business—for their expected introduction from 2000.

Integrated national food safety strategy

Recommendation No.13 from the 1995 Audit: The ANAO recommends the NFA involve AQIS, the States/Territories and local government in the development of an integrated national food safety strategy.

NFA response: Agreed.

ANZFA context: The ANAO found that:

- food surveillance was not effectively coordinated by the then NFA;
- the then NFA did not seek advice from the States, Territories and local government on the resources they employ on food surveillance, their enforcement priorities or methods;
- the then NFA was developing a national strategy for food surveillance and enforcement; and
- the then NFA planned to develop the Australian Food Safety Information Network (AFSIN) to assist in the national coordination of monitoring of food-borne health risks and enforcement of food standards.

Progress towards an Integrated National Food Safety Strategy

4.33 In July 1997, the Department of Primary Industries and Energy (now AFFA) and ANZFA finalised a report into Australia's National Safe Food System. The report described a model for a National Safe Food System designed to encompass the entire food supply chain and integrate and commit all food stakeholders, including industry and government, to the goal of producing safe food. ANZFA and AFFA recommended its adoption and implementation by all stakeholders. The objectives and principles underpinning the National Food Safety System proposed by ANZFA and AFFA are outlined in Table 1.

Objectives	Principles
 Safeguard consumer health by protecting the safety of Australia's food supply Strengthen Australia's competitive position as a reliable producer and exporter of safe food Implement a fully integrated approach to food safety across all steps and processes of the food supply chain Recognise that industry has prime responsibility for ensuring food safety with policy and program support from government including consumer education Ensure that the safe food system is driven by market requirements and meets Australia's international obligations Provides a cohesive framework for a national approach to risk based food safety management that includes government, industry and the community 	 The shared vision that all Australian food will fully satisfy consumer and export market expectations for a safe product The joint commitment and responsibility of all stakeholders along the food supply chain to contribute to the supply of safe food The management of risks to safe food production and handling through preventative strategies and activities The continuous improvement of the National Safe Food System through ongoing monitoring, evaluation, correction, review The integrated management of all food hazards including, for example, persistence of chemical residues, those linked to animal husbandry practices and animal disease management, safeguards against physical hazards and control of the microbiological contamination of foods

Table 1

National Food Safety System: objectives and principles

Source: ANZFA & AFFA (1997) Australia's National Safe Food System, p. 5.

4.34 The Australia's National Safe Food System report also recommended that mechanisms be explored to ensure that the national food safety (hygiene) standards and associated monitoring and compliance arrangements are uniformly adopted and applied. The report also noted that successful implementation of the system would require the full commitment of all stakeholders.³⁹

4.35 In ANZFA's view, the report did not go far enough to resolve some of its key concerns about the abundance of government stakeholders at both the Commonwealth and State/Territory level involved in the food safety process. The need for a National Safe Food System was more recently considered by the FRR and ANZFA considers that the FFR took on board ANZFA's concerns. However, according to ANZFA any form of Commonwealth and State/Territory government endorsement of the FRR is some way off. Further progress towards endorsing/

³⁹ National Food Safe Working Group (1997) *Australia's National Safe Food System*, pp. 1,2.

developing and implementing a National Safe Food System is, understandably, unlikely until Commonwealth and State/Territory endorsement of the FRR is received.

Coordination of food surveillance and enforcement

4.36 ANZFA does not have the power to directly monitor and enforce food product or food safety (hygiene) standards. This power rests with the States/Territories and/or local government (through its on-site inspections of food products and premises) and, in the case of imported food, AQIS (through its inspection of shipments entering Australia). Nevertheless, one of ANZFA's statutory functions is 'to coordinate the surveillance by the States, the Territories and any other bodies or persons of food available in Australia'.⁴⁰

4.37 ANZFA's food coordination role can be seen as adding a <u>national</u> perspective to food monitoring and surveillance and provides a basis for greater consistency of food safety outcomes between jurisdictions. In this context, the ANAO considers that for ANZFA to better fulfil its food coordination role it should:

- aggregate results of State/Territory and local government food monitoring and surveillance activities and identify food safety trends/ risks (that, without ANZFA's involvement, could be overlooked);
- influence the food monitoring and surveillance priorities of the States/ Territories and local government, taking into account any identified food safety trends; and
- identify and disseminate food monitoring and surveillance better practice.

4.38 Figure 6 illustrates a model food inspection framework for domestic and imported foods that could be adopted by ANZFA.

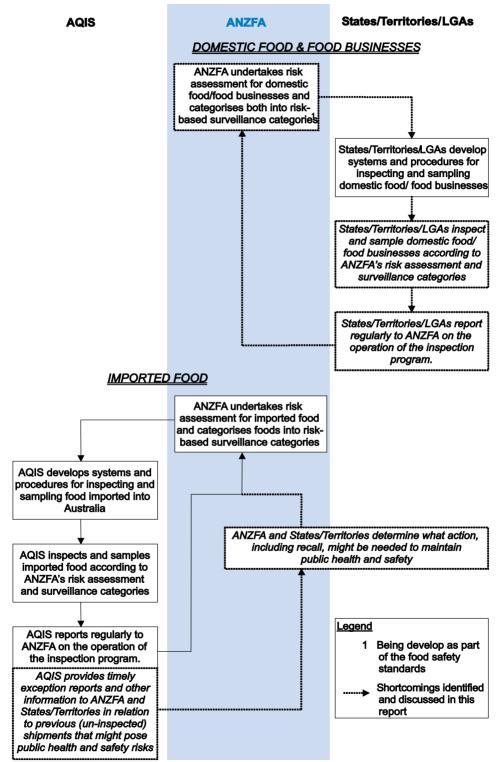
4.39 At the national level, an effective national food monitoring and surveillance system would also allow ANZFA to better manage public health and safety by determining:

- the extent of industry compliance with food product/safety standards;
- whether risks to public health and safety are occurring despite food product/safety standards being complied with;
- whether there are gaps in food regulation that might need addressing; and
- the incidence of food-borne illness with greater precision than would otherwise be the case.

⁴⁰ Australia New Zealand Food Authority Act 1991, s7(d).

Figure 6

Model food inspection framework



Source: ANAO analysis 1999

4.40 Public health and safety risks can be considered at two levels. At one level, the Australian Food Standards Code administered by ANZFA addresses public health and (primarily longer-term) safety risks associated with <u>food products</u>. At the other level, public health and (shorter term) safety risks are addressed through <u>food safety (hygiene)</u> regulations (currently State/Territory-based but uniform food safety (hygiene) standards are under development and are expected to be introduced from 2000).

4.41 The ANAO considers that ANZFA continues to manage the longerterm public health and safety risks associated with food products reasonably well through the work it undertakes directly or work performed by other Commonwealth departments (including its regular use of food and diet surveys; nutritional modeling; and food contamination exposure assessments for proposed food standard reviews and foods generally).⁴¹ However, ANAO considers that, as was the case at the time of the 1995 Audit, ANZFA's ability to address shorter-term public health and safety risks associated with food hygiene (safety) issues are still hampered somewhat by the lack of:

- a risk-based national surveillance and monitoring strategy (that outlines, *inter alia*, the agreed roles and responsibilities of all levels of government, national priorities, audit/inspection coverage and approach, and timely reporting mechanisms); and
- appropriate and sufficient information on the current food monitoring and surveillance activities and outcomes of the States/Territories and local government.

4.42 The ANAO's view is supported by the FRR Committee which considered that:

the current monitoring and surveillance 'system' does not provide timely, comprehensive, systematic and integrating information to governments, industry and consumers in a manner that enables appropriate public health and safety action to be taken.⁴²

National Surveillance and Monitoring Strategy

4.43 The 1995 Audit noted that then NFA was developing a national strategy for surveillance and enforcement. This strategy and the National Surveillance and Monitoring Strategy promoted by ANZFA in its 1996–97 Annual Report did not progress far as ANZFA contends that the States and Territories were, and are still, hesitant to allow ANZFA a substantial role in food surveillance and monitoring. Nevertheless, the States and

⁴¹ See paragraph 3.5 for more information on ANZFA's nutritional modeling.

⁴² Op. Cit., Food Regulation Review Committee (1998), p. 97.

Territories expressed support for better sharing of surveillance information at a stakeholder workshop on surveillance issues in late 1998. The ANAO also notes that the State and Territories expressed such support at the time of the 1995 Audit.

4.44 The need for a better coordinated approach to food surveillance and monitoring was considered by the FRR which found that

although most States and Territories use risk assessment protocols, there are no nationally consistent practices for assessing food safety risks and determining product inspection and analysis priorities.⁴³

4.45 The FRR Committee recommended, as a matter of priority, the establishment of a national integrated surveillance and monitoring system and around 90 per cent of respondents to the FRR draft report agreed.⁴⁴ The ANAO considers that given this recent overwhelming support, there is an opportunity for ANZFA to implement a national surveillance and monitoring strategy with the States/Territories and local government. ANZFA indicated that a working group involving itself and the States/Territories was established in March 1999 to develop a national surveillance and enforcement strategy for consideration by ANZFAAC at some (unspecified) future date. A detailed plan for its development would be drafted in 1999–2000.

4.46 From information provided recently to the ANAO, it appears that ANZFA does not intend to involve local government in developing a national surveillance and enforcement strategy. ANZFA considers that issues such as resourcing at the local government level, the extent of information aggregation and sensitivities between some States/Territories and local governments would need careful consideration before local government can become involved. The ANAO notes that a large proportion of food surveillance and enforcement activities is undertaken by local government (particularly in Victoria where these activities have been delegated to local government). Therefore the ANAO considers that local government should be involved in the development of a national surveillance and enforcement strategy (say, through local government associations or the Australian Institute of Environmental Health) and any supporting infrastructure projects (see Australian Food Safety Information Network sub-section in this Chapter).

4.47 A national surveillance and enforcement strategy is a key element in improving the protection of public health and safety and its introduction is considered to be a high priority by key stakeholders. The roles and responsibilities for all parties in its development; funding

⁴³ *Ibid.*, p. 55.

⁴⁴ *Ibid.*, pp. 98-100, 168.

allocated by each party towards its development; and timetables for its introduction and trialing, are matters for consideration as part of the strategy.

Obtaining food surveillance and enforcement information

4.48 The ANAO found that ANZFA's knowledge of State/Territory food surveillance is limited primarily to ad-hoc information provided orally at Commonwealth-State forums, mainly the monthly Senior Food Officers meetings/teleconferences. Although information exchanged at these meetings canvasses important current issues, it could not be considered comprehensive.

4.49 ANZFA does not have any regular fora to consider food monitoring and surveillance issues at the local government level and the States and Territories cannot always be relied on to have a good understanding of these issues. Information exchange between local and State/Territory governments does not work well in all cases. A particular risk is jurisdictions such as Victoria where the surveillance and monitoring of food production processes and premises have been delegated by its Parliament to the local government authorities.

4.50 ANZFA receives very little written information on State/Territory and local government surveillance activities, although at times ANZFA receives issues-specific reports, if requested and available. ANZFA was not able to provide the ANAO with any recent general-purpose monitoring and surveillance strategies, plans or activity reports from any State/Territory or local government authority. Neither could ANZFA provide evidence to the ANAO indicating that ANZFA has attempted to obtain such reports in recent times. Annual reports from these bodies rarely contain qualitative or quantitative information of substance on their food surveillance and enforcement activities.

4.51 The ANAO acknowledges that it can be difficult for ANZFA to obtain relevant and succinct information on food monitoring and surveillance activities because:

- the food regulatory frameworks in the States and Territories vary greatly⁴⁵ making it difficult to obtain and collate comparable information;
- the working relationships between States and Territories and their local governments, in some cases, are not good, lessening the likelihood of information exchange;

⁴⁵ Food regulatory frameworks in Australia range from: fully-centralised frameworks (ACT and most of NT) to a mixture of State/Territory and local government (NSW, Qld, WA, SA and Tasmania) to decentralised frameworks (Vic). (Source: Quarantine and Inspection Resources Pty Ltd (1997) *Report to the Review of Food Regulation (Part A)—Mapping Food Regulation in Australia*, p. 22.)

- the Commonwealth does not provide any incentives to the States/ Territories and local government as an inducement for improving food surveillance and enforcement coordination and information exchange;
- the States Territories and local government might not wish to provide ANZFA with information that will allow direct comparison with other States/Territories on matters such as resourcing (human and financial); food inspection strategies and practices; regulatory effectiveness (eg. number of inspections versus number of failures); and the incidence of food-borne illness;
- the States/Territories and local government might consider that better coordinated surveillance and enforcement will require more resources than it currently allocates; and
- until recently, food hygiene regulation (against which most food surveillance and enforcement effort is directed) was the exclusive domain of the States and Territories, reducing the State's recognition of a role for ANZFA in this area.

4.52 A significant step forward would be achieved if ANZFA was to gain access to information recorded on State/Territory food management information systems (or summaries thereof). For example, the Victorian food data base, VicFood (administered by the Victorian Department of Human Services), records results of all food testing performed by government and private laboratories on food samples taken by local government. VicFood is updated quarterly and information is relayed back to local government in quarterly reports for follow-up where appropriate.⁴⁶

4.53 Initiatives associated with the development of the food safety (hygiene) standards might also facilitate a flow of necessary information from the States/Territories to ANZFA (see the Improving ANZFA's coordination of food surveillance section).

4.54 Another means to progress ANZFA's knowledge of State/Territory food surveillance and enforcement activities is the Australian Food Safety Information Network (AFSIN).

Australian Food Safety Information Network

4.55 In 1995, the then NFA proposed to develop the Australian Food Safety Information Network (AFSIN) to share information on State/ Territory food surveillance and monitoring activities. Original plans for ANZFA were to have most of AFSIN implemented before 1999. However, to date AFSIN has not progressed far. ANZFA indicated that the States

⁴⁶ Department of Human Services (1997) A Fresh Approach—Victoria's Food Hygiene Strategy.

and Territories are committed to the AFSIN concept⁴⁷ and that a lack of funds stalled the original plans for AFSIN (using as it would a network of dedicated personal computers across Australia). The States and Territories were also keen to avoid entering food surveillance and enforcement data more than once onto management databases.

4.56 The software component of AFSIN is being progressed through the development of a series of modules. ANZFA indicated that its first module (a decision history database designed to aid consistent State/ Territory decision-making where a 'precedent' has been set in the State/ Territory or in another jurisdiction) will be introduced later in 1999 (ie. over four years after the development of AFSIN was first mooted). ANZFA hopes that increased support for AFSIN will result and other modules introduced over time using lower-cost Internet technology. ANZFA advised that ANZFA's information technology infrastructure needs would be considered during the development of a national monitoring and enforcement strategy (see the National Surveillance and Monitoring Strategy sub-section of this chapter).

4.57 From information provided recently to the ANAO, it appears that ANZFA does not intend to involve local government in the supporting IT infrastructure. As was mentioned earlier in this chapter, the ANAO considers that local government should be invited to become involved in developing the national surveillance and enforcement strategy and its supporting infrastructure projects.

Improving ANZFA's coordination of food surveillance

4.58 The ANAO also considers that the food safety (hygiene) standards,⁴⁸ currently under development by ANZFA, provide an ideal mechanism and opportunity for ANZFA to improve its national coordination of food surveillance. In addition to the standards, ANZFA is developing sets of guidelines and criteria for industry, the States/ Territories and local government to aid them in implementing the food safety (hygiene) standards. The soon-to-be-released auditing framework guidelines, for use in food safety monitoring and enforcement by the States/Territories and local government, provides an opportunity for ANZFA to recommend systems that will:

• allow ANZFA to coordinate food surveillance and influence national priorities;

⁴⁷ The ANAO also received confirmation of support for the AFSIN concept from the Queensland and Western Australian Health Departments, although the latter agency thought that AFSIN had been disbanded.

⁴⁸ The matters subject to the food safety (hygiene) standards will comprise the overwhelming majority of what the States/Territories and local government will be monitoring in the future.

- use a common risk-based approach to food monitoring and surveillance; and
- ensure ANZFA receives information necessary to fulfil its national food surveillance role.

4.59 The ANAO notes that ANZFA has already developed and promoted a risk-based priority classification system for food businesses that takes into account the inherent risks for different food types (eg. fruit and vegetables versus seafood), risk factors of potential food consumers (eg. hospital patients) and confidence in the suppliers' food safety systems. The frequency of audit coverage and the timetable for developing food safety programs⁴⁹ would then be linked to the resulting 'food risk' score.

4.60 The ANAO acknowledges that the auditing framework guidelines are recommendations only and the States/Territories and local government may choose to follow or not follow them. The ANAO also recognises that the development of effective frameworks require a cooperative approach by all levels of government.

ANZFA's comments on food surveillance and monitoring

4.61 ANZFA considers that its ability to coordinate State and Territory monitoring and surveillance activity is based on an 'invitation' of the States and Territories through their decision for the Commonwealth to develop uniform standards on domestic food safety which then become law by being adopted into State and Territory food laws. As a result, ANZFA considers that a sensitive approach to the coordination work of the Authority needs to be taken. ANZFA also cites a lack of resources as a constraining factor for achieving improvement. ANZFA also indicated that its budget in coming years is to be reduced significantly, coinciding with the completion of the Food Product Standards review and food safety (hygiene) standards.

4.62 The ANAO considers that ANZFA has taken rather a restricted view of its functions. The ANAO acknowledges that work on the national food safety (hygiene) standards commenced only after State/Territory agreement but notes that ANZFA's food surveillance coordination role is a separate statutory function that operates independently of its standard-setting role. In addition, ANZFA's functions state that its coordination of food surveillance can be conducted on its own initiative or in consultation with the States and Territories. The ANAO considers that obtaining more comprehensive information on the food surveillance

⁴⁹ It is intended that Food Safety Programs for all food businesses will be introduced progressively over six years. Food businesses that handle foods that pose the greatest risk will be required to develop their Food Safety Programs first.

activities and outcomes of the States/Territories and local government is essential for ANZFA to better fulfil its role of protecting national public health and safety. Information on the enforcement activities of the States/ Territories is also important so that the Commonwealth can more appropriately target legal action under Part VA of the *Trade Practices Act 1974* (see Commonwealth enforcement section in this Chapter).

4.63 In relation ANZFA's resourcing, the ANAO notes that ANZFA's annual level of funding will reduce by some 30 per cent from 2000-01 to coincide with a reduction in workload on the expected completion of the food product standards review and food safety (hygiene) standards. However, the ANAO also notes that ANZFA's forward estimates have been reduced as a result of anticipated cost-recovery arrangements with the food industry that did not eventuate. ANZFA indicated that an earlier attempt to obtain amendments to ANZFA's enabling legislation to allow the introduction of cost-recovery arrangements, was not successful. As a result, the ANAO estimates that ANZFA has 15–20 per cent less financial resources than would otherwise be the case had the cost-recovery arrangements been in place. ANZFA has recently proposed amendments to its legislation (to be considered in the Autumn 1999 session of the Parliament) that, inter alia, will allow for the introduction of cost-recovery arrangements at some future date.

4.64 The ANAO acknowledges that improving the coordination of the food surveillance activities of the States and Territories and local government comes at a cost. However, the ANAO considers that this cost is outweighed by the benefits of better protecting public health and safety. The ANAO also considers that the expected completion of the food product standards review and the food safety (hygiene) standards (which will reduce ANZFA's workload and change the balance of its responsibilities) gives ANZFA an opportunity to re-evaluate the proportion of its resources it devotes to monitoring and surveillance issues. ANZFA estimates that it currently spends about 15 per cent of its resources on monitoring and surveillance activities.

Recommendation No.3

4.65 The ANAO *recommends* that, in the interests of nationally consistent protection of public health and safety, ANZFA improve its national coordination of food surveillance by:

- a) seeking access to appropriately summarised State/Territory-based information on the food surveillance, monitoring and enforcement activities and outcomes of the States/Territories and local government;
- b) developing, as a matter of priority, a national surveillance and enforcement strategy and supporting information technology

infrastructure that involves the Commonwealth, States and Territories and local government and determining the roles and responsibilities of each party; funding allocated by each party towards its development; and timetables for its introduction and trialing with all parties; and

- c) including, as part of the proposed auditing framework guidelines for the food safety (hygiene) standards, mechanisms and processes that:
 - (i) will allow ANZFA to coordinate food surveillance effectively and influence national priorities;
 - (ii) are based on sound risk-based methodology; and
 - (iii) will allow ANZFA to receive sufficient, relevant and timely information on the implementation of, and compliance with, the food safety (hygiene) standards.

ANZFA response

4.66 a) Agrees. ANZFA has started to investigate and identify sources of data available at State and Territory level with a view to improving national coordination of those activities.

4.67 b) Agrees. ANZFA has taken a role in development of the communicable diseases network national strategy and wishes to build upon this experience to develop a wider national surveillance and enforcement strategy. ANZFA has also moved to establish a Commonwealth/State/Territory working group to develop a national surveillance and enforcement strategy. Full implementation of the recommendation would require additional budget resources.

4.68 c) Agrees. ANZFA is currently examining the mechanisms and processes listed in the context of the proposed auditing framework guidelines for the food safety (hygiene) standards.

Assess to customs data—imported foods

Recommendation No.14 from the 1995 Audit: The ANAO recommends the regulators work with Customs to gain access to Customs imports data to improve surveillance of imports.

NFA response: Agreed.

ANZFA context: The ANAO noted that the Imported Foods Inspection Program exemplified the successful use of Customs data to target surveillance of high risk products as well as to randomly sample others. However, the ANAO considered that the then NFA did not take a sufficiently active coordinating role to ensure unsafe imported food was recalled.

4.69 In 1997–98, the total value of food and beverage imports was estimated to be some \$3.6 billion. The Imported Foods Inspection Program (IFIP) is the primary means through which ANZFA gains assurance that imported food is safe and complies with the food standards. This represents over 10 per cent of the Australian food market.⁵⁰ IFIP is conducted jointly by ANZFA and the Australian Quarantine and Inspection Service (AQIS) and a memorandum of understanding outlines the respective roles and responsibilities of both parties (ANZFA/AQIS MOU). ANZFA conducts food risk assessments that assist AQIS to develop and maintain appropriate systems and procedures, including imported food inspection and sampling procedures as required by the Imported Food Control Act 1992 (IFCA). In 1998, the IFCA was reviewed against National Competition Policy (see chapter 2). Figure 6 in the previous section of this Chapter illustrates the model imported food inspection framework.

4.70 Risk assessments for foods and food groups determines the amount and type of inspections and testing done on imported foods by AQIS. For 'risk' assessed foods, shipment inspection rates range from 100 per cent to 5 per cent for those foods with a good compliance history. Shipment inspection rates for other categories of food range from 10 per cent to 5 per cent for those foods with a good compliance history. Shipments that fail an inspection test are temporarily reclassified into a greater risk category and subsequent shipments of that food are inspected more frequently until a good compliance history is re-established. In the case of non-'risk' categorised foods, AQIS adopts a 'sample and release' approach to testing food shipments. If testing identifies problems, AQIS advises the relevant State Health official(s) and ANZFA (as required under the ANZFA/AQIS MOU) of the nature of the failure and that some of the released product might need to be recalled.

4.71 Overall, IFIP still exemplifies the successful use of data, in this case Customs data, to target surveillance of high risk products as well as randomly sample others. However, there are testing and recall issues not covered by the IFCA Review.

4.72 Between July 1997 and mid-November 1998 ANZFA received notice from AQIS of some 20 non-complying imported foods that were inspected and released by AQIS. Although both the IFCA Review

⁵⁰ Australian Bureau of Statistics 1998a, International Merchandise Trade, Cat. No. 5422.0, June Quarter 1998, Canberra; and Australian Bureau of Statistics 1998b, Manufacturing Industry 1996-97, Cat. No. 8221.0, Canberra.

Committee and ANZFA consider that decisions to recall non-complying imported foods lie with the States and Territories, neither of the Food Recall Protocols reflects this State/Territory responsibility. The ANAO considers that the Food Recall Protocols should reflect that the States and Territories are responsible for deciding whether to recall noncomplying imported foods that are tested and released by AQIS.

4.73 The IFCA Review Committee found in 1997–98 that in total some 40 imported food failures detected by AQIS were a 'high risk to human health' and another 52 or so had 'longer term health risks'.⁵¹ There should be concern about the lack of action that is needed to determine whether previous shipments of (not inspected) imported food should be examined/ recalled when a later shipment of that food (or food from that supplier) fails inspection and that failure poses a 'high risk to human health' or 'longer term health risks'. The ANZFA/AQIS MOU indicates that AQIS will assist in providing information to ANZFA about other food from the same supplier that might be available for sale in Australia and for which a food recall or enforcement action might be necessary. The ANAO did not sight any evidence to indicate that ANZFA has received or sought any such assistance from AQIS.

4.74 The ANAO considers that for each inspection failure that poses a 'high risk to human health', AQIS should <u>immediately</u> notify ANZFA and the relevant State Health officials of the failure and provide them with a report on any recent previous (not inspected) shipments of that food and/or other foods from that supplier that might pose the same risks. (The quarterly reports provided to ANZFA by AQIS on the results of imported food testing are not sufficient for this purpose as any action needed is time critical.) Responsibility for deciding whether to recall non-complying foods should be clearly outlined between ANZFA and the States and Territories. The ANAO acknowledges that AQIS might need initial and ongoing assistance from ANZFA to determine those inspection failures that, *prima facie*, constitute a 'high risk to human health'.

⁵¹ Op. cit., Imported Food Control Act Review Committee (1998), pp. 26, 27. The IFCA Review committee defined **high risk to human health** as *microbiological failures with the potential to pose high risk to human health, and extraneous failures with the same potential* and **longer term health risks** as *failures with the potential of longer term health risks including: heavy metal, chemical residues, aflatoxins, histamines and ethylene oxide residues.* (Source: Ibid, p. 24).

Recommendation No.4

4.75 The ANAO *recommends* that ANZFA improve its coordination of imported food by seeking amendments to its memorandum of understanding with AQIS, in the case of imported food inspection failures that pose 'high risks to human health', to provide for AQIS to:

- a) notify ANZFA and the relevant State/Territory Health official(s) immediately of such events; and
- b) provide ANZFA and the relevant State/Territory Health official(s) with a timely report on any recent previous (not inspected) shipments of that food and/or other foods from that supplier that might pose the same risks.

ANZFA response

4.76 Agrees with qualifications. Foods that have the potential to pose a high or medium risk to public health are placed in the 'risk' food surveillance category and a high proportion of the risk food is being testing (up to 100 per cent). The inspection rate may be reduced where compliance is very high. Since all imported high risk food subject to analysis is retained on a test and hold basis, food posing a high risk to human health would not normally reach retail or consumer levels. However, occasionally previous shipments may not have been inspected for foods later identified as being of a high risk to human health. In these cases ANZFA agrees that AQIS should notify ANZFA. Discussions are taking place.

Commonwealth enforcement

Recommendation No.15 from the 1995 Audit: The ANAO recommends all regulators improve their approach to enforcement by: ...

- reporting the level of compliance with requirements;
- setting target levels of compliance; and
- reporting activities undertaken to monitor and enforce compliance.

NFA Response: None.

ANZFA context: Although the then NFA did not respond to this recommendation, the ANAO considered that then NFA should encourage State/Territory and local government food law enforcement agencies to adopt the above recommendation within their own jurisdictions. (This being consistent with the then NFA's food surveillance role).

Recommendation No.16 from the 1995 Audit: The ANAO recommends all regulators use the full range of powers the Parliament has provided where circumstances demand and, where limitations are identified, seek to have the legislation amended.

NFA Response: Agreed.

ANZFA context: The ANAO considered that the then NFA had not undertaken substantive steps to facilitate and encourage improved enforcement by States/Territories and local government. (This being consistent with the then NFA's food surveillance role).

Recommendation No.17 from the 1995 Audit: The ANAO recommends the TPC [now ACCC]:

- evaluate the effectiveness of its education programs;
- work with the other Commonwealth regulators to identify possible product liability actions and breaches of the Trade Practices Act. The TPC should then educate consumers on the product liability provisions of the Trade Practices Act and undertake representative actions where appropriate; and
- work with the legal profession to facilitate use of the product liability provisions of the Trade Practices Act in appropriate circumstances.

NFA response: None.

ANZFA context: The ANAO considered there would be benefit for the then NFA if it were to seek to maximise the use of the Part VA provisions of the *Trade Practices Act 1974*.

4.77 ANZFA has no statutory powers to directly enforce food standards. This power rests with the States/Territories and local government. However, Commonwealth legislation (Part VA of the *Trade Practices Act 1974*) imposes strict liability on manufacturers and importers for injuries caused by defective products (including food). Part VA defines products to be defective if they do not provide the degree of safety that persons are generally entitled to expect, taking into account all the circumstances including the way the product was marketed and the likely uses to which the product will be put. In the Commonwealth, Part VA is administered by the Australian Competition and Consumer Commission (ACCC). As well as facilitating private actions, Part VA allows the Commonwealth (through the ACCC) to undertake representative actions on behalf of one or more persons who have suffered loss.

4.78 ANZFA indicated, and ACCC confirmed, that the ACCC has not undertaken any representative actions under Part VA in respect of

defective food products. However, as the front-line Commonwealth agency responsible for coordinating food surveillance, the ANAO considers that ANZFA has a role to play in assisting those who suffer loss caused by defective food products. In any event, the ANAO doubts whether any Part VA representative action would be considered by ACCC without a recommendation from, or at the very least, consulting with, ANZFA.

4.79 The ANAO did not sight any evidence to suggest that ANZFA has attempted to encourage State/Territory and local government food law enforcement agencies to adopt Recommendation No.15 from the 1995 Audit. In addition, the lack of a national surveillance and monitoring strategy (as noted earlier in this Chapter) has meant that little, if any, progress has been made to facilitate and encourage improved enforcement bv States/Territories and local government (Recommendation No.16 from the 1995 Audit). The ANAO notes that ANZFA is starting to develop an MOU between itself. ACCC. State/ Territory health authorities and State/Territory fair trading agencies in relation to uniform interpretation and enforcement of misleading and deceptive advertising and labelling. However, this MOU will cover trade practice issues that are different to the food safety issues targeted when the ANAO made Recommendation No.16 in the 1995 Audit.

4.80 ANZFA considers that the States/Territories are better placed to take enforcement action under their own Food Acts instead of the Commonwealth taking enforcement action under Part VA of the *Trade Practices Act 1974*. ANZFA maintains that a greater role in Commonwealth enforcement would require ANZFA to collect a significant amount of information. In addition, ANZFA considers that it does not have the resources (referred to earlier in this Chapter) nor expertise to fulfil such a role. While accepting these points, the ANAO considers that a State/ Territory decision to prosecute (or not) under its own food legislation will not necessarily meet the objectives or purposes of Part VA of the *Trade Practices Act 1974*.⁵² A State/Territory prosecution is but one factor that should be considered when determining whether an action under Part VA should proceed.

⁵² The Trade Practices Act 1974 'recognises that in many consumer protection matters there is a need for a national approach, and that the effectiveness of State [consumer protection] laws is necessarily limited' (Source: Senator Murphy, Attorney-General and Minister for Customs and Excise, Trade Practices Bill 1974, Second Reading Speech, 30 July 1974, p. 547). The key features of Part VA of the Trade Practices Act 1974 include, inter alia, that 'a manufacturer or importer of goods is to be strictly liable for defects in those goods... The claimant will not have to prove negligence. The difficulty in proving negligence is one of the factors identified in existing law which can lead to injustice.' (Source: Ms J. McHugh MP, Minister for Consumer Affairs, Trade Practices Amendment Bill 1992, Second Reading Speech, 4 June 1992, p. 3667).

4.81 The ACCC is aware of a number of cases taken by private law firms that effectively litigated using Part VA for defective food products, including peanut butter and uncooked fermented smallgoods. The ACCC indicated that it closely monitored such cases and conducted its own investigations and negotiations with key parties to ensure that redress for consumers was available. The ACCC considers that in cases that receive major publicity, representative actions are undertaken by private law firms ensuring consumers received appropriate redress.

4.82 The ANAO considers that actions under Part VA should not be limited to, or triggered by, those ad-hoc cases that receive major publicity and that a better risk management approach is needed. Comments received by the FRR from food industry and consumer groups indicated that they were also concerned about ineffective and inconsistent enforcement of the Trade Practices Act (and State and Territory Food Acts) caused by, *inter alia*, a lack of, or uncoordinated, risk assessment practices for enforcement programs.⁵³ The FFR also noted that '*there are no nationally agreed enforcement strategies based on food safety risk assessment*'.⁵⁴

4.83 To date ANZFA has not received any information or guidance from the ACCC on using or assisting the ACCC in using, Part VA of the *Trade Practices Act 1974* (as recommended in the 1995 Audit). However, in response to Recommendation No.17 from the 1995 Audit, ACCC indicated that it is currently developing a set of guidelines for all consumer product safety regulators on assessing appropriate cases for ACCC representative action. These guidelines include recommendations about the course of investigations by the investigating authority (ANZFA, in relation to food products) and the ACCC and make clear cooperation is essential to allow effective enforcement and consumer benefit. Appropriate training would most likely accompany the introduction of these guidelines. The ANAO supports initiatives such as the guidelines proposed by ACCC.

4.84 For ANZFA to viably fulfil an investigating and advising role with the ACCC, ANZFA must have access to management information relevant to defective food products. As ANZFA relies on the States and Territories for 'on-the-ground' food surveillance, most of this information will come from the States/Territories and local government. However, the ANAO noted earlier in this Chapter that ANZFA receives very little information from States/Territories and local government on their food monitoring and surveillance activities and ANZFA does not currently have systems in place that could manage this information.

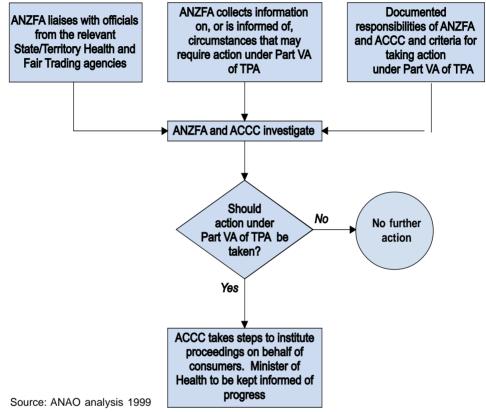
⁵³ Op. cit., Food Regulation Review Committee (1998), p. 54.

⁵⁴ *Ibid.*, p. 55.

4.85 Figure 7 illustrates a desirable process for managing Commonwealth enforcement action under Part VA of the *Trade Practices Act 1974* in relation to food.

Figure 7

Desirable process for representative actions under *Trade Practices Act* 1974 in relation to food



4.86 The ANAO considers that a memorandum of understanding (MOU) between ANZFA and ACCC should be developed setting out:

- the roles and responsibilities of both parties;
- the *prima facie* circumstances that would need to be met before a legal action under Part VA would be considered; and
- the procedure to be followed with respect to the concurrent operation of any other law (eg. as Part VA does not limit the concurrent operation of any law, it may be prudent in some circumstances to allow the States/Territories the opportunity to prosecute under their legislation first).

ACCC would be expected to provide ANZFA with any initial and ongoing training and support that it requires to most effectively assist ACCC in its legal actions under Part VA. **4.87** Such an MOU would strengthen the guidelines proposed by ACCC and would declare to the food industry and consumers when and how the Commonwealth intends to apply Part VA trade practices legislation in respect of defective food.

4.88 The ANAO acknowledges that its proposed active food monitoring and enforcement role for ANZFA to support ACCC legal actions comes at a cost. However, as mentioned earlier in this Chapter, the expected completion of the food product standards review and food safety (hygiene) standards also gives ANZFA an opportunity to re-evaluate the proportion of its resources it devotes to monitoring and surveillance issues.

Recommendation No.5

4.89 The ANAO recommends that ANZFA develop a memorandum of understanding with ACCC in relation to legal actions under Part VA of the Trade Practices Act 1974 setting out:

- a) the roles and responsibilities of both parties;
- b) the prima facie circumstances that would need to be met before a legal action under Part VA would be considered by the ACCC; and
- c) the approach to be adopted with respect to the concurrent operation of any other food law in another jurisdiction.

ANZFA Response

4.90 Agree. ANZFA has met with the ACCC and the State and Territory Fair Trading Departments and Health Departments to develop a Memorandum of Understanding addressing cooperative arrangements to facilitate consistent enforcement of the provisions relating to false, misleading and deceptive conduct in the Food Acts, the Fair Trade and Consumer Affairs legislation, the Trade Practices Act and relevant New Zealand legislation. The State and Territory Fair Trading Departments have declined to participate in future work as they do not currently enforce their legislation in relation to food. ANZFA is now proceeding to draft an MOU with the ACCC and the NZ Commerce Commission addressing these issues.

5. Performance reporting

Recommendation No.18 from the 1995 Audit: The ANAO recommends that all regulators and the Department of Human Services and Health [now Department of Health and Aged Care] improve their performance reporting by:

- reporting on outcomes and impacts;
- providing clear links between reported strategies, outcomes and program objectives. This would include:
 - reporting priorities;
 - developing a range of measurable performance indicators which address economy, efficiency and effectiveness and are derived from program objectives. The range of indicators should also address the timeliness of the outputs and outcomes of the agency; and
 - setting targets for performance indicators and reporting against those targets; and
- reporting concise, understandable and balanced performance information.

NFA response: Agreed.

5.1 The 1995 Audit found that performance reporting by Commonwealth consumer product safety regulators (including the then NFA) described activities undertaken or outputs produced rather than outcomes. The ANAO found that the same can be said of ANZFA's performance reporting in relation to 1997–98.

5.2 ANZFA's reporting of its performance to the Parliament has slightly improved since the 1995 Audit. Organisational restructures in ANZFA between 1995 and 1997 have better aligned its structure to its outputs. There has also been some improvement by the inclusion of measurable performance indicators and preset performance targets in ANZFA's Annual Report—particularly in the Food Product Standards program, and to a lesser extent, the food safety (hygiene) standards. However, these indicators and targets still focus on processes and outputs rather than outcomes.

5.3 ANZFA's reporting on compliance with standards, likelihood of detection breaches and reports on prosecutions/administrative actions taken has not improved since the 1995 Audit. Although ANZFA has no

direct powers of enforcement, the ANAO considers that aggregate reporting at the Commonwealth level would demonstrate the effectiveness of ANZFA's standard setting and the state of food regulation in Australia generally.

5.4 Table 2 summarises some of the public health and safety outcomes that may assist Parliament in determining the effectiveness of ANZFA.

Table 2

Public health and safety outcomes for food

Food product standards

- · extent that food products meet/do not meet food product standards
- extent that food products meet food product standards but still pose risks to public health and safety
- extent that public health and safety is at risk from food products not covered by food product standards

Food safety (hygiene) standards^(a)

- extent that food and food businesses meet/do not meet food safety (hygiene) standards
- extent that food and food businesses meet food safety (hygiene) standards but food-borne illness occurs
- incidence of food-borne illness in Australia
- (a) Until uniform food safety (hygiene) standards have been developed and implemented, the food safety (hygiene) standards referred to here are the current State/Territory food hygiene regulations (and local government by-laws).

5.5 The ANAO considers the greatest hindrances to improving ANZFA's reporting of outcomes are the lack of:

- reliable data on the incidence of food-borne illness in Australia (discussed in Chapter 3);
- a coordinated national surveillance and monitoring strategy (discussed in Chapter 4); and
- food surveillance and enforcement information from the States/ Territories and local government (also discussed in Chapter 4).

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P.J. Barrett Auditor-General

Canberra ACT 2 June 1999

Appendices

Appendix 1

1995 Audit recommendations and summarised responses

The ANAO considered recommendations 1, 2, 3, 4, 15, 16 and 18 to have the highest priority.

Consumer Product Safety (Chapter 2)

RecommendationThe ANAO recommends Commonwealth consumer
product safety regulators adopt and use a structuredNo.1product safety regulators adopt and use a structuredPara.2.24'whole of agency' strategically-based risk
management approach, involving a systematic, data-
driven approach to identifying, analysing and ranking
risks, and assessing treatment options.

Agency responses

DHSH, the FBCA, NISU, FORS, TGA, NFA and the TPC agreed.

Risk identification and analysis (Chapter 3)

RecommendationThe ANAO recommends that the Department of
Human Services and Health provide the leadership
and coordination necessary to achieve and implement
the national goals, targets and strategies for injury
prevention and control specified in the Better Health
policy statement endorsed by the Minister for Human
Services and Health.

Agency responses

Recommendation No.3 Para.3.45	DHSH, NISU and the FBCA agreed. FORS did not agree. The ANAO recommends that consumer product safety risk management be improved by:
	• the Department of Human Services and Health, in consultation with the regulators, evaluating the costs and benefits of establishing a function for risk identification to improve the collection, collation and analysis of relevant injury, death and illness data;
	 regulators and the Department collaborating to set priorities and performance targets;

- regulators reporting to the Parliament on achievement against targets; and
- DHSH chairing a forum of regulators to discuss common issues, such as standard-setting approaches and compliance activities, and to improve the level of cooperation and collaboration.

Agency responses

The FBCA, NISU and the TPC agreed in principle. DHSH, FORS, NFA and TGA did not agree.

Treatment of risk (Chapter 4)

RecommendationThe ANAO recommends that the FBCA and the NFANo.4develop product performance standards using aPara.4.42structured risk-based strategic approach.

Agency responses

The FBCA, NFA and TPC agreed.

Recommendation The ANAO recommends regulators:

- No.5 improve monitoring of voluntary product recalls and adherence to recall codes;
 - improve the effectiveness of voluntary product recalls by continually evaluating the recall process;
 - take a leadership role to ensure that a national approach to product recalls is implemented;
 - ensure recall notices clearly identify the hazard involved and possible consequences; and
 - conduct recall audits and follow up corrective action by suppliers to prevent recurrence.

Agency responses

FORS, TGA, NFA and the TPC agreed. The FBCA agreed in principle.

RecommendationThe ANAO recommends the FBCA promote to all
regulators the use of mandatory recalls by:

Para.4.77

- informing them of the procedures and kind of evidence needed for the FBCA to recommend that the Minister of Consumer Affairs order a mandatory recall;
- encouraging the regulators to use mandatory recalls where suppliers have not taken satisfactory action to prevent a product causing injury; and
- examining ways to improve their timeliness.

Agency responses

The FBCA, the TPC, the NFA and FORS agreed.

RecommendationThe ANAO recommends that the FBCA be moreNo.7proactive in providing advice to encourage regulatorsPara.4.86to use powers such as warning notices, bans and
litigation under the Trade Practices Act, that is, where
the Trade Practices Act powers are more effective than
remedies available under other legislation.

Agency responses

The FBCA and FORS agreed. The TPC agreed in principle.

RecommendationThe ANAO recommends that DHSH and the
regulators cooperate and collaborate in reducing risksNo.8by greater promotion of product safety through the
use of more cooperative approaches such as targeted
education campaigns, voluntary codes of practice and
encouraging the teaching of safe design.

Agency responses

The FBCA, NFA, the TPC and FORS agreed. The DHSH and TGA agreed in principle.

Enforcement (Chapter 5)

Recommendation The ANAO recommends the TGA:

No.9 Para.5.30

- (a) adopt a risk-based approach to scheduling audits of manufacturers;
- (b) re-audit manufacturers in accordance with its current re-audit frequency objectives;
- (c) rate manufacturers as not complying with the manufacturing principles if they are found to have major deficiencies in complying with the Codes of Good Manufacturing Practice;
- (d) consider making greater use of legislative remedies where non-compliance with the manufacturing principles is detected; and
- (e) better coordinate its post-market regulatory activities. This could include the adoption of guidelines which facilitate prompt and consistent decision making, with use of regulatory powers where appropriate. The TGA may also benefit from seeking to develop and implement information systems that facilitate a coordinated regulatory approach.

Agency response

TGA agreed in principle with part (a), agreed in principle with parts (b) and (e), and disagreed with parts (c) and (d).

Recommendation The ANAO recommends FORS:

No.10 Para.5.37 (a) adopt a rigorous, risk-based approach to scheduling audits of test facilities and manufacturers;

(b) implement a scheme to rate the acceptability of manufacturer control systems;

(c) report:

- targets and the actual level of compliance detected by audits of manufacturers and test facilities;
- action taken where audits found unacceptable controls; and

targets and the actual period of time between audits;

- (d) ensure audits are 'closed out' efficiently and effectively;
- (e) seek regulatory powers which will enable it to strengthen its enforcement response by withdrawing approval to affix compliance plates where an audit indicates a manufacturer cannot demonstrate it has controls in place to ensure compliance with standards: and
- (f) seek to discontinue production where manufacturers cannot demonstrate to FORS' satisfaction that they have controls in place to ensure compliance with the standards. The action taken should be commensurate with the level of non-compliance and the consequential risk to public health and safety.

Agency response

FORS agreed.

Recommendation	The ANAO recommends the TPC request Customs to
No.11	include banned products in the Prohibited Imports
Para.5.49	Regulations enforced by Customs.
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Agency responses

FORS agreed. The FBCA and the TPC agreed in principle. Customs did not agree.

RecommendationThe ANAO recommends the TPC adopt a risk-based
approach to enforcement following the transfer of
enforcement responsibilities from the FBCA, using the
full range of remedies provided by the Trade Practices
Act.

Agency responses

The TPC agreed.

Recommendation No.13 Para.5.79	The ANAO recommends the NFA involve AQIS, the States/Territories and local government in the development of an integrated national food safety strategy. <i>Agency responses</i> NFA and AQIS agreed.
Recommendation No.14 Para.5.84	The ANAO recommends the regulators work with Customs to gain access to Customs imports data to improve surveillance of imports. <i>Agency responses</i> The FBCA, NFA and TGA agreed. The TPC and Customs agreed in principle.
Recommendation No.15 Para.5.88	 The ANAO recommends all regulators improve their approach to enforcement by: adopting a pyramid of enforcement and committing resources to monitoring and enforcing compliance; making greater use of available remedies; reporting the level of compliance with requirements; setting target levels of compliance; and reporting activities undertaken to monitor and enforce compliance. <i>Agency responses</i> The TPC agreed. The FBCA, TGA and FORS agreed in principle.

Exercising and testing the law (Chapter 6)

RecommendationThe ANAO recommends all regulators use the full
range of powers the Parliament has provided where
circumstances demand and, where limitations are
identified, seek to have the legislation amended.

Agency responses

The FBCA, NFA, TPC and TGA agreed. FORS agreed in principle.

Recommendation The ANAO recommends the TPC:

No.17 • evaluate the effectiveness of its education programs;

- work with the other Commonwealth regulators to identify possible product liability actions and breaches of the Trade Practices Act. The TPC should then educate consumers on the product liability provisions of the Trade Practices Act and undertake representative actions where appropriate; and
- work with the legal profession to facilitate use of the product liability provisions of the Trade Practices Act in appropriate circumstances.

Agency responses

FORS agreed. The TPC agreed in principle.

Performance reporting (Chapter 7)

RecommendationThe ANAO recommends that all regulators and theNo.18Department of Human Services and Health improvePara.7.14their performance reporting by:

- reporting on outcomes and impacts;
- providing clear links between reported strategies, outcomes and program objectives. This would include:
 - reporting priorities;
 - developing a range of measurable performance indicators which address economy, efficiency and effectiveness and are derived from program objectives. The range of indicators should also address the timeliness of the outputs and outcomes of the agency; and
 - setting targets for performance indicators and reporting against those targets; and
- reporting concise, understandable and balanced performance information.

Agency responses

DHSH, the FBCA, TGA, NFA and the TPC agreed. FORS agreed in principle.

Index

Α

Audit Report No.12 1995-96 Risk Management by Commonwealth **Consumer Product Safety** Regulators (1995 Audit), 5, 6, 9-16, 18, 19, 25, 26, 29-33, 36-38, 41-43, 46-49, 51, 52, 55, 57, 59-62, 66, 73, 76-79, 82, 87 Recommendation No.1, 36, 87 Recommendation No.3, 41, 87 Recommendation No.4, 42, 88 Recommendation No.5, 51, 88 Recommendation No.6, 59, 89 Recommendation No.8, 60, 89 Recommendation No.13, 62, 92 Recommendation No.14, 73, 92 Recommendation No.15, 76, 78, 92 Recommendation No.16, 77, 78, 93 Recommendation No.17, 77, 79. 93 Recommendation No.18, 82, 94 Australia New Zealand Food Authority Act 1991 (ANZFA Act), 29, 34, 49.64 Australia New Zealand Food Authority Advisory Committee (ANZFAAC), 6, 14, 20, 37, 49, 50, 67 Australia New Zealand Food Standards Council (ANZFSC), 6, 10, 29, 30-32, 44, 45, 50 Australian Competition and Consumer Commission (ACCC), 6, 10, 19, 22, 25, 31, 42, 77-81 Australian Food Safety Information Network (AFSIN), 6, 18, 62, 67, 69, 70 Australian Institute of

Environmental Health (AIEH), 6, 14, 48, 49, 67 Australian Local Government Association (ALGA), 6, 14, 48-50 Australian Quarantine and Inspection Service (AQIS), 6, 10, 21, 30-32, 35, 62, 64, 65, 74-76, 92

С

Codex Alimentarius Commission, 6, 32, 38, 40, 43

Consumer Affairs Division of the Department of the Treasury, 10, 11, 15, 20, 25, 42, 52, 57-59

D

Department of Agriculture, Fisheries and Forestry - Australia (AFFA), 6, 15, 35, 62, 63

F

food product standards, 10-12, 14, 17, 30, 32, 33, 36, 38, 43, 46, 49, 61, 72, 81, 83

Food Regulation Review (FRR), 6, 10, 13, 15, 16, 27, 33, 34, 36, 39, 46, 47, 52, 60, 61, 63, 66, 67, 79

food safety (hygiene) standards, 10, 12-14, 16, 17, 21, 30-32, 35, 36, 43, 46, 49, 50, 52, 61, 64, 66, 69-73, 81, 83

food surveillance, 11, 12, 16-18, 20, 21, 39, 62, 64, 67-73, 76-79

food-borne illness, 17, 18, 28, 39, 40, 64, 69, 83

L

Imported Food Control Act 1992 (IFCA), 6, 10, 28, 32, 35, 74, 75 Imported Food Inspection Program (IFIP), 6, 10, 18, 30, 35, 74

J

Joint Committee of Public Accounts (JCPA) now Joint Committee of Public Accounts and Audit, 6, 9, 26, 41

Μ

Minister for Financial Services and Regulation, 15, 59, 60 Minister for Health, 15, 40, 59, 60

S

Senior Food Officers working group, 14, 20, 37, 49, 50, 68

т

Trade Practices Act 1974 (TPA), 10, 15, 19, 22, 29, 42, 57, 59, 60, 72, 77-81, 89, 91, 93

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