



FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

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26 May 2004

INITIAL ASSESSMENT REPORT

PROPOSAL P288

FOOD SAFETY PROGRAMS FOR FOOD SERVICE TO VULNERABLE POPULATIONS

DEADLINE FOR PUBLIC SUBMISSIONS to FSANZ in relation to this matter:

21 July 2004

(See 'Invitation for Public Submissions' for details)

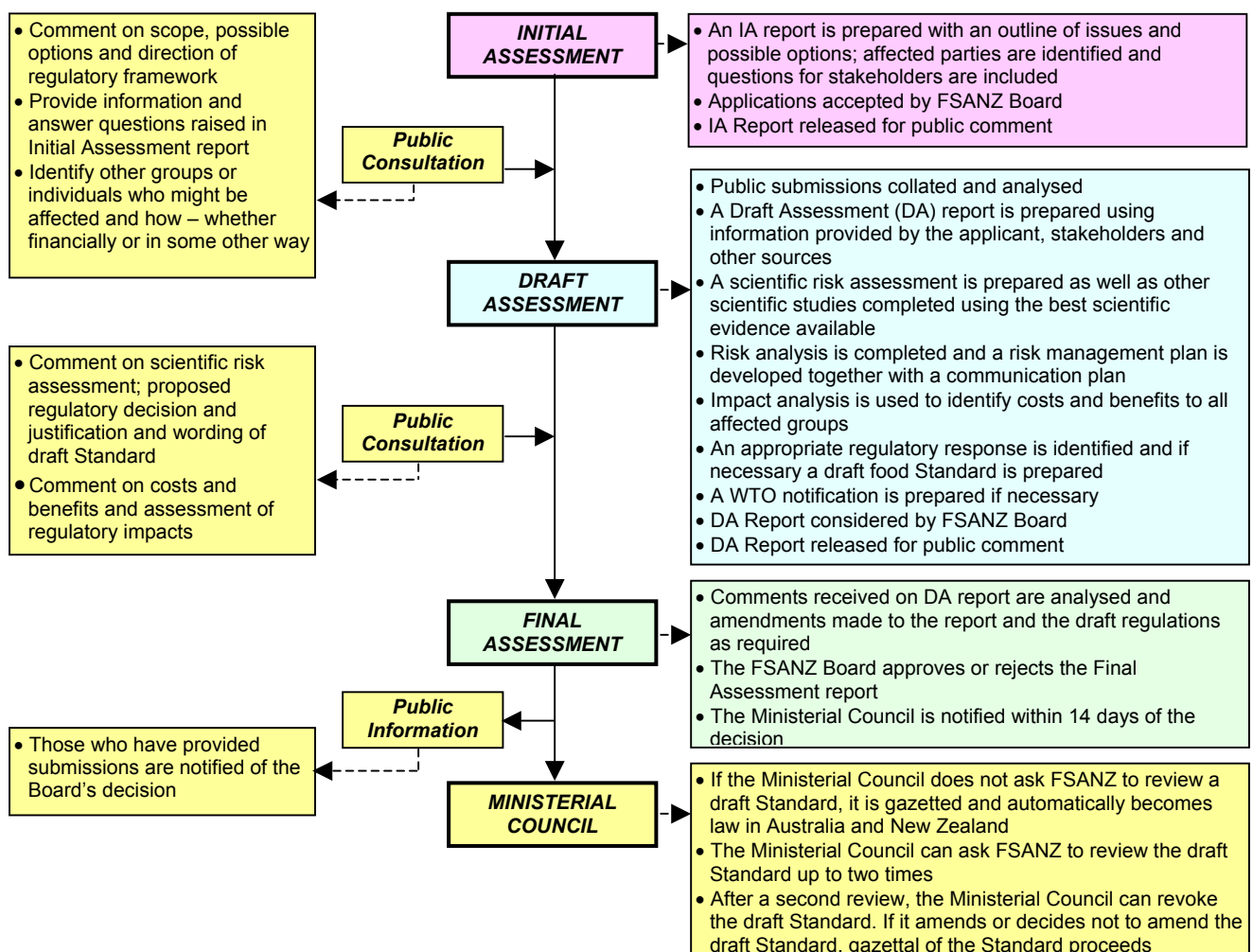
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten Governments: the Commonwealth; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing Standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food Standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new Standards or variations to food Standards in accordance with policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Commonwealth, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved Standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing Standard. If the Ministerial Council does not request that FSANZ review the draft Standard, or amends a draft Standard, the Standard is adopted by reference under the food laws of the Commonwealth, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a Standard.

The process for amending the *Australia New Zealand Food Standards Code* is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared an Initial Assessment Report of Proposal P288, which includes the identification and discussion of the key issues.

FSANZ invites public comment on this Initial Assessment Report for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the draft assessment for this Proposal. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
www.foodstandards.govt.nz

Submissions should be received by FSANZ **by 21 July 2004**.

Submissions received after this date may not be considered, unless the Project Manager has given prior agreement for an extension.

While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the [Standards Development](#) tab and then through [Documents for Public Comment](#). Questions relating to making submissions or the application process can be directed to the Standards Management Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au.

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Executive Summary

The Food Regulation Standing Committee (FRSC) has developed Ministerial Policy Guidelines on Food Safety Management in Australia that were endorsed by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) in December 2003. These guidelines propose that food safety programs be mandatory for four high risk food industry sectors:

- food service, whereby potentially hazardous food is served to vulnerable populations;
- harvesting, processing and distributing raw oysters and other bivalves;
- catering operations serving food to the general public; and
- producing manufactured and fermented meat.

The Australian Government Department of Health and Ageing (DoHA) undertook key projects to determine the incidence and causes of food-borne illness in Australia and to assess the costs, benefits and justification for food safety programs. The findings of these projects were published in two reports, the *National Risk Validation Project* report and the *Food Safety Management Systems – Costs, Benefits and Alternatives* report. The evidence presented in these reports supported the recommendation that food safety programs be made mandatory for the high risk food industry sectors identified. This Initial Assessment Report is concerned with proposing food safety programs for food service, whereby potentially hazardous food is served to vulnerable populations. Food safety programs for the other sectors are being addressed through separate processes.

A national requirement for businesses engaged in food service to vulnerable populations; to have documented food safety programs, will require an amendment to Standard 3.2.1– Food Safety Programs of the Code. FSANZ is responsible for implementing the decision of the Ministerial Council through the amendment of Standard 3.2.1 in the Code and has raised Proposal P288 for this purpose.

The definition of ‘food service, whereby potentially hazardous food is served to vulnerable populations’ will be an important issue to resolve in the development of this Standard. The Standard will not apply to non-government funded family day care or to businesses that have a clientele of five persons or less. Comment is specifically sought on the definition to be included in the Standard as well as on implementation issues such as audit, interpretive guides, tools and other support material.

This Initial Assessment Report provides the first opportunity for stakeholders to comment on and supply information and data to FSANZ regarding the mandatory application of Standard 3.2.1 to food service to vulnerable populations. In addition, an advisory group will be formed which will comprise representatives from industry, the Australian Government, each State and Territory Government, and from consumer groups. The comments, information and data provided during this consultation will be considered during the development of the Draft Assessment Report.

1. Introduction

In response to the decision in December 2003 by the Ministerial Council, FSANZ is proposing to amend Standard 3.2.1– Food Safety Programs in Chapter 3 of the Code. The Proposal is to make mandatory the requirements of the Standard to food service, whereby potentially hazardous food is served to vulnerable populations. This Standard will apply in Australia only and does not apply in New Zealand.

Consistent with the Ministerial decision, amendments to the Standard will require businesses to develop and implement audited food safety programs as defined in the Standard.

The purpose of the Initial Assessment Report is to inform the food industry, governments, consumers and other stakeholders of the Proposal to apply Standard 3.2.1– Food Safety Programs to food service serving potentially hazardous food to vulnerable populations, to present the reasons for the Proposal and to raise issues that FSANZ will need to address during its assessment of the Proposal. Through this report, FSANZ invites stakeholders to comment on these issues and asks whether there are additional issues that need to be considered.

2. Background

2.1 Regulatory framework for mandating Standard 3.2.1

2.1.1 Introduction of food safety Standards

In August 2000 the Code was amended to include a new chapter of food safety Standards, for application in Australia only. This new chapter covers the safe production of food, the structure of food premises, and equipment and vehicles used by food businesses. The Standards introduced a notification system for food businesses and a requirement that food handlers and their supervisors have food safety skills and knowledge. These Standards have been progressively introduced into State and Territory legislation and provide a nationally consistent set of food safety requirements for food businesses. They replace inconsistent, outdated and unduly prescriptive State and Territory hygiene regulations. These Standards are:

- Standard 3.1.1 Interpretation and Application;
- Standard 3.2.2 Food Safety Practices and General Requirements; and
- Standard 3.2.3 Food Premises and Equipment¹.

State and Territory Governments also agreed to the introduction of a model Standard, Standard 3.2.1– Food Safety Programs, which was included in the Code in December 2000. This Standard requires food businesses, as determined by State and Territory Governments, to demonstrate that they are controlling food safety hazards in their businesses by developing and complying with a food safety program. The Ministerial Council made the application of Standard 3.2.1 to food businesses voluntary until sound data on food-borne illness in Australia and more information on costs and efficacy of food safety programs were available.

¹ The Standards and a guide to their interpretation are available on www.foodstandards.gov.au.

The intention of including the Standard in the Code was to promote national consistency by providing a model for States such as Victoria, which was introducing food safety programs ahead of a national requirement.

DoHA and State and Territory Governments, in cooperation with the food industry and other interested parties, undertook a range of studies to provide Governments with data on food-borne illness and an analysis of the costs and benefits of introducing mandatory food safety programs.

The results of three projects, in particular, have been important in assisting the Food Regulation Standing Committee to develop options for managing food safety in Australia. These projects are:

- a study into the costs and efficacy of introducing food safety programs in Australia, prepared by The Allen Consulting Group;
- the National Risk Validation Project which identified the highest risk sectors of the food industry and undertook specific cost and benefit analysis of these sectors; and
- the establishment of OzFoodNet to provide data on the incidence and causes of food-borne illness in Australia.

OzFoodNet reports and Final Reports of the other two studies are available from DoHA².

Evidence from these projects has supported the development of Policy Guidelines on Management of Food Safety in Australia.

2.1.2 Ministerial Policy Guidelines on Food Safety Management in Australia

FRSC established a sub-committee in 2002 to develop options for food safety management in Australia. An objective of the sub-committee was to seek an ‘all of government’ position on managing food safety risks in Australia. On 12 December 2003, the Ministerial Council approved the Ministerial Policy Guidelines on *Food Safety Management in Australia: Food Safety Programs*³ for national application. These guidelines include overarching principles and recommendations on which food business sectors should develop and implement mandatory food safety programs.

The Ministerial Policy Guidelines specify five overarching principles to apply when addressing particular policy issues of food safety management in Australia:

1. That regulations covering food safety management in Australia be based on risk, where the level of legislative requirements and their verification is commensurate with the level of risk;

² OzFoodNet website: www.ozfoodnet.org.au

The two reports are The National Risk Validation Project - Final Report (2002) which can be accessed at the following link: www.health.gov.au/pubhlth/strateg/foodpolicy/pdf/validation.htm and

The Final Report of *Food Safety Management Systems - Costs, Benefits and Alternatives* is available at: www.health.gov.au/pubhlth/strateg/foodpolicy/pdf/alternatives.htm

³ The Ministerial Policy Guidelines on *Food Safety Management in Australia: Food Safety Programs* can be viewed at www.foodsecretariat.health.gov.au/pdf/food_safety.pdf

2. That risk profiling be used to classify food businesses or food industry sectors in Australia on the basis of risk;
3. At a minimum, Standard 3.2.1 Food Safety Programs should be implemented in those businesses/sectors involved in operations identified as high risk **and** where the benefit to cost ratio justifies the implementation of food safety programs;
4. That the risk classification of a business or an industry sector may change when new data on the causes and incidence of food-borne illness become available for updating the risk profile, or when the specific circumstances of an individual business can be considered and such change is justified; and
5. That support is made available to community groups and small businesses to assist them meet their legislative requirements.

On the basis of evidence that, for the highest risk sectors of the food industry, the benefits of food safety programs outweighed the costs, the Ministerial Council recommended that Standard 3.2.1 Food Safety Programs be mandatory for the four highest risk industries identified by the National Risk Validation Project:

- food service, in which potentially hazardous food is served to vulnerable populations;
- producing, harvesting, processing and distributing raw oysters and other bivalves;
- catering operations serving food to the general public; and
- producing manufactured and fermented meat.

The Ministerial Policy Guidelines identify, where appropriate, specific issues for each of these industries including definitional matters and areas of exclusion from the requirement for particular sectors based on a low benefit to cost ratio. They have also specified a timeframe for mandating Standard 3.2.1 for the highest risk sectors, which is two years after the amendment to the Code is gazetted.

This Initial Assessment Report applies to only the first of these industries - food service, in which potentially hazardous food is served to vulnerable populations.

2.1.3 Food Safety Programs

A food safety program is a documented food safety management system. It is defined by Standard 3.2.1 as a written document which:

- (a) systematically identifies the potential hazards that may be reasonably expected to occur in all food handling operations of the food business;
- (b) identifies where, in a food handling operation, each hazard identified under paragraph (a) can be controlled and the means of control;
- (c) provides for the systematic monitoring of those controls;
- (d) provides for appropriate corrective action when that hazard, or each of those hazards, is found not to be under control;

- (e) provides for the regular review of the program by the food business to ensure its adequacy; and
- (f) provides for appropriate records to be made and kept by the food business demonstrating action in relation to, or in compliances with, the food safety program.

In a food safety program, the business is demonstrating how it is complying with Standard 3.2.2 – Food Safety Practices and General Requirements and Standard 3.2.3 – Premises and Equipment. The amount of information needed in a food business’ food safety program will depend on the type and complexity of the food business.

2.1.4 Projects to support the introduction of food safety programs

DoHA has funded projects to develop ‘tools’ to assist food business in the highest risk sectors to implement their own, customized food safety programs at minimal cost and time to businesses. In regard to vulnerable groups of the population, a tool to assist the children’s services sector develop and implement food safety programs is currently under development and is being managed by Queensland Health on behalf of the Australian Government. Development is guided by a reference group consisting of representatives from childcare associations and government⁴. DoHA is responsible for distributing this tool and will provide details on its availability when the project is finalised.

In addition, DoHA is developing a tool to assist small /medium hospitals and nursing homes to develop and implement food safety programs. This project is managed by the Western Australia Department of Health with guidance from a steering committee comprising industry and government representatives⁵.

DoHA is also developing resources as part of the National Delivered Meals Organisations Food Safety Strategy to assist organisations that deliver meals to housebound, and other people that are unable to prepare their own meals, to improve the organisations’ food safety practices over time. When resources are finalised, expected in 2005, DoHA will provide details on availability.

FSANZ has commenced work on an interpretative guide to Standard 3.2.1 in consultation with State and Territory enforcement agencies. This guide is primarily for enforcement officers and will promote a nationally consistent interpretation of the requirements of Standard 3.2.1. The guide, and additional material produced by FSANZ for food businesses, will aid State and Territory Departments in their role of assisting food businesses understand their legal obligations.

⁴ Representatives from the Australian Government Department of Health and Ageing, Australian Government Department of Family and Community Services, FSANZ, Queensland Health, Redland Shire Council, Australian Institute of Science and Technology and representatives from child care associations including the Crèche and Kindergarten Association of Qld, Child Care Centres Association of Victoria, Australian Federation of Child Care Association and Child Care Industry Association of Qld.

⁵ Representatives from Australian Government Department of Health and Ageing, FSANZ, WA Department of Health, Queensland Health, Geraldton Health Service, Armadale Hospital, Infection Control-Western Diagnostics, Institute of Hospitality in Health Care and the Nursing Homes and Extended Care Association of WA.

2.2 Overview of the sector

2.2.1 *Size of the sector*

The sector addressed by this Proposal is characterised by the population groups that are provided with meals by commercial organisations. These are the groups more vulnerable or sensitive to food-borne illness compared with the general population. The reason for this vulnerability is a combination of the susceptibility of the groups to food-borne illness and the severity of illness once infected. Vulnerable populations have been identified as:

- pregnant women;
- the immunocompromised;
- children aged four years or less; and
- the elderly aged 70 and over.

The organisations that provide food to these groups on a commercial basis (i.e. other than for preparing by the persons in their own homes) are:

- hospitals;
- nursing homes;
- aged care facilities;
- organisations delivering meals to housebound persons and others who cannot provide their own meals at home; and
- childcare centres that provide meals to young children.

The size of the sector affected by this Proposal will be examined in detail as part of the draft assessment of the Proposal. However, the National Risk Validation Project has provided some indication of the numbers of businesses that may be affected by the Proposal. Quoting BIS Shrapnel 2001⁶, the Project Report states that nursing homes/ aged care facilities forms the largest institutional provider of meals in Australia, serving in 1999, 200 million meals from 3037 establishments. Hospitals are reported to have served 140 million meals from 1190 hospitals in 1999.

The National Risk Validation Project considered only formal types of child care such as long day care centres, family day care, occasional care and preschools and provided an estimate of over 600,000 children in this type of care. The mix includes providers in private ownership, community organisations, local government, religious organisations, employers and cooperatives.

Organisations delivering meals to housebound people are estimated to number 235, which delivered 4 million meals to housebound people per year in NSW alone.

2.2.2 *Existing food safety management strategies*

All State and Territory Governments have now adopted Standards 3.1.1, 3.2.1 and 3.2.2 of the Code into their State food legislation, requiring all food businesses to comply with the food safety measures specified.

⁶ BIS Shrapnel, Australian Food Service Market 1998-2000, 6th Edn, BIS Shrapnel, Sydney

Standard 3.2.2 – Food Safety Practices and General Requirements sets out specific requirements for food businesses and food handlers including food handling controls; health and hygiene requirements; cleaning, sanitising and maintenance of premises and equipment, and requirements relating to skills and knowledge of food handlers. Standard 3.2.3– Food Premises and Equipment sets out the requirements for food premises and equipment that, if complied with, will facilitate compliance by food businesses with the food safety requirements of Standard 3.2.2. While compliance with these food safety Standards should have an effect in reducing the number of food poisoning incidents, they do not require food businesses to identify and monitor the control of potential hazards in the business, document the food safety program and have the program audited, as required by Standard 3.2.1 – Food Safety Programs.

The Victorian Government already requires all, except minimal risk, food businesses to have food safety programs under the Victorian Food Act. The sectors included in this Proposal operating in Victoria are classified as Class 1⁷ food premises and as such are required to have audited food safety programs that are consistent with Standard 3.2.1.

Many Australian public and private hospitals, other health care organisations and children’s services providers participate in accreditation or certification programs for example, providers of aged care services are required by Commonwealth legislation, as a condition of funding, to maintain accreditation through the Aged Care Standards and Accreditation Agency. These accreditation programs usually contain food safety components. At draft assessment of the Proposal, the relationship between the existing accreditation systems and the application of Standard 3.2.1 will be examined particularly in relation to equivalence of auditing.

3. Rationale for Mandating Standard 3.2.1

The National Risk Validation Project was undertaken in 2001 to, in Part 1, identify potentially high risk food industry sectors and to use risk assessment principles to validate the categorisation of selected sectors as high risk. Part 2 of the project had two objectives; to determine the potential cost to the food industry, public and Government of food-borne illness associated with high risk businesses and to determine the costs and benefits of implementing food safety programs in high risk food industry sectors.

3.1 Scientific assessment

The project identified potentially high risk food businesses through a review of both Australian and overseas data on food-borne disease outbreaks and examined the factors contributing to these outbreaks.

The National Risk Validation Project concluded that food service to vulnerable populations was the highest risk sector based on the sensitivity of the populations they serve. The populations are described as including the aged, those who are ill or immunocompromised, and preschool children.

⁷ In Victoria Class 1 businesses are food businesses where food handled or sold is-
- high risk and ready to eat;
- handled prior to sale; and
- to be consumed predominantly by at-risk/vulnerable populations. Class 1 food businesses will generally include Hospitals, Nursing Homes, Child Care Centres, Meals on Wheels operations etc.

The businesses serving these populations operate aged care facilities, hospitals or childcare centres providing meals. They also include businesses (voluntary or otherwise) that deliver meals to housebound people or others who require meals provided at home. These operations may include both catering and direct cook-serve operations.

The food-borne illness data collected by the National Risk Validation Project indicated that hospitals, nursing homes and childcare centres were responsible for around 18% of outbreaks of food-borne illness.

3.2 Cost/Benefit Rationale

DoHA engaged The Allen Consulting Group to undertake a review of the costs and efficacy of introducing food safety programs, as proposed by Standard 3.2.1, across all food businesses. The Final Report of this project, *Food Safety Management Systems – Costs, Benefits and Alternatives* (the Allen Report), found that the benefits of introducing Standard 3.2.1 outweighed the cost for all but ‘low risk’ businesses.

The Allen Report considered that the requirements of Standard 3.2.1 involve a fundamentally different approach to food safety management, requiring a proactive evaluation of specific risks compared to a ‘rote learning’ reactive approach to general risk categories. The costs associated with this approach are largely time-based, though businesses would feel the burden of extra hours of work and related stress. The main cost drivers include implementation costs (training and development) and the ongoing costs of record keeping and review, and audit costs.

The Report concludes that the benefits for high risk businesses outweigh the costs of implementing, utilising and auditing a food safety program.

The main benefits of food safety programs reported by the Allen Report would arise from the reductions in food-borne illness. The extent of this benefit is hard to quantify and relates to judgements around:

- the size of current incidence and associated costs; and
- the size of any decrease in food-borne illness attributable to food safety programs.

The Allen Report calculated a median benefit of \$339 million per annum, based on a 15% reduction in food-borne illness.

Data from the Allen Report was further built on by *The National Risk Validation Report* which included a cost benefit analysis of implementing food safety programs, specifically for high risk food industries. The total cost of food-borne illness associated with vulnerable populations was estimated to be \$75 million per year or 21 cents per meal. A benefit cost ratio was calculated at 6.5 (for class 1 outbreaks⁸) and 6.8 (class 1 and 2 outbreaks). This cost benefit analysis strongly supports the mandating of food safety programs for the vulnerable populations.

⁸ Class 1 outbreaks are those where it is reasonable to assume that the cause of illness would have been detected and remedied by measures put in place under a food safety program. Class 2 outbreaks are those where the information on the source of the outbreak is insufficient to make a judgement on the likely effectiveness of a food safety program.

4. Objectives

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 10 of the FSANZ Act. These are:

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

In developing and varying Standards, FSANZ must also have regard to:

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

The main objective in mandating Standard 3.2.1 for food service to vulnerable populations is to protect the public health and safety of vulnerable populations by reducing the incidence of food-borne illness in this sector.

5. Relevant Issues

5.1 Scientific justification

The National Risk Validation Project has provided the scientific basis for the Ministers' policy decision to require food safety programs for food service, whereby potentially hazardous food is served to vulnerable populations. This Project will be an important source of information underpinning the assessment of this Proposal. However, there may be additional information relating to health and safety risks available that updates the National Risk Validation Report or may not have been addressed in this Project.

Stakeholders may provide any additional information relevant to the scientific justification to require food safety programs for food service, whereby potentially hazardous food is served to vulnerable populations.

5.2 Defining the food businesses for application of Standard 3.2.1

The wording to be used in Standard 3.2.1– Food Safety Programs to describe the term ‘Food service, whereby potentially hazardous food is served to vulnerable populations’ will define the specific types of food service operations to which Standard 3.2.1 applies. It is important, therefore, that the scope of this definition is clear and easily understood by all stakeholders.

The Ministerial Policy Guidelines proposes a term that was developed in consultation with government and industry representatives; ‘Food service, whereby potentially hazardous food is served to vulnerable populations’. In developing the current description, two considerations were taken into consideration; that the definition is both **enforceable** and captures those businesses that are providing food to vulnerable populations operations that are of **highest risk** (those associated with outbreaks in the National Risk Validation Project). Additionally, the definition should not unfairly impinge on small business.

5.2.1 Definition of food service

The term ‘food service’ is used to encompass both catering as defined by the National Risk Validation Project and direct cook - serve operations to vulnerable populations. Catering is defined as any method of food service of potentially hazardous foods which utilises an intended delay during preparation and service; cook chill operations in a hospital would be included in this type of catering. It is also when food is served to a large number of people simultaneously; again the hospital situation is an example. Cook-serve refers to meals that are prepared and then served without deliberate delay and therefore usually would have no chilling, reheating, holding or transport steps.

5.2.2 Definition of vulnerable populations

The National Risk Validation Report referred to food service for ‘sensitive’ populations and by ‘sensitive populations’ was referring to pregnant women, the immunocompromised, children aged four years or less and the elderly aged 70 and over. Public consultation on the DoHA draft document *Food Safety Management in Australia – Risk profiling and food safety programs* (March 2003) highlighted some confusion over the sector of the population referred to as the sensitive population. Several respondents thought that a business that served food to a pregnant customer would be required to implement Standard 3.2.1. This is not the intent and changes have been made to the definition of vulnerable populations to clarify that ‘populations’ are targeted by the food service rather than individuals.

The Ministerial Policy Guidelines have stated that children cared for in non-government funded family day care are not included in the ‘vulnerable population’ for the purposes of this Proposal due to the low benefit to cost ratio, as determined in the National Risk Validation Project. Family day care is the term used to describe care for a small number of children (usually four or less) in a private home.

The Guidelines also state that businesses that serve potentially hazardous food to vulnerable populations and have a clientele of five people or less should be excluded from the requirements of Standard 3.2.1, as they would suffer an unwarranted cost and administrative burden. An example of such a business would be an aged care facility that had the capacity to provide meals to five or less residents.

5.2.3 *Definition of potentially hazardous food*

‘Potentially hazardous food’ is defined in Standard 3.2.2 and means ‘food that has to be kept at certain temperatures to minimise the growth of any pathogenic micro-organisms that may be present in the food or to prevent the formation of toxins in the food’. This definition includes all the types of foods that are likely to be included in meals served at institutions such as hospitals, childcare etc. There are some exclusions for example, canned and bottled food, dried fruit, yoghurts, hard cheeses, bread and raw whole fruit and vegetables⁹. Business that served only non-potentially hazardous foods would not be included in the businesses required to comply with Standard 3.2.1.

Comment is sought on a definition of ‘food service, whereby potentially hazardous food is served to vulnerable populations’ to be included in Standard 3.2.1.

Comment should consider:

- enforceability of the definition; and
- that the definition does not extend to family day care, to businesses that serve food to five or less persons or to business that do not serve any potentially hazardous food.

5.3 **Implementation**

5.3.1 *Existing accreditation arrangements*

Due to the large variation in size and type of organisations that are included in the sector, flexibility in auditing application and frequency is required. Where accreditation systems already exist for sectors such as child and aged care, work will be undertaken as part of the Standard development process to explore the merging of requirements for Standard 3.2.1 (including auditing) with the existing accreditation framework.

Comment is sought on whether the requirements for auditing food safety programs will fit within existing accreditation systems.

5.3.2 *Audit*

Standard 3.2.1 requires a food business to ensure that its food safety program is audited by a food safety auditor at the auditing frequency applicable to the food business. The editorial note to the Standard states that the former Australia New Zealand Food Authority (ANZFA) now FSANZ has developed food safety auditor approval criteria for food safety auditors in conjunction with States and Territories. Where auditing arrangements exist for food service to vulnerable populations all effort should be made to ensure this is not duplicated by the amendments made in this Proposal.

⁹ For more information on potentially hazardous foods within the meaning of Chapter 3 of the Food Standards Code see *Safe Food Australia* or *Food safety: temperature control of potentially hazardous foods*. Both publications are available on the FSANZ website www.foodstandards.gov.au

5.3.2.1 Auditor competency and approval

Competency of auditors will be assessed as part of the auditor approval process. Approval of auditors is the responsibility of States and Territories who may maintain publicly available lists of approved auditors as part of their overall management of the audit process.

In the consultation process for the development of the Ministerial Policy Guidelines, the need for suitable, qualified auditors was raised. As part of the Australian Government's National Food Industry Strategy¹⁰, the Australian Government Department of Agriculture, Fisheries and Forestry established the National Food Safety Auditor Framework Strategy, which, in 2003, initiated a project to improve the integrity of Australia's food safety auditor infrastructure. Work is currently underway to assess existing auditing arrangements within the food industry and make recommendations for national food safety auditor competency criteria. In addition, this project will develop options for the adoption of these criteria and for the ongoing management and administration of food safety auditors. This work builds on earlier work by ANZFA (now FSANZ) on the food safety auditor approval process, the audit process and audit management systems described in *Food Safety: An Audit System*¹¹. An outcome of the project will be to ensure that good training and on-going professional development, assessment and accreditation underpin competency of food safety auditors.

5.3.2.2 Type of audits

States and Territories determine whether the audit system for food businesses in the particular jurisdiction will be second-party or third-party. Second party auditors are auditors employed by the government and third party auditors are private and independent of the government. First-party audits are internal audits carried out by staff of the business and outcomes of such audits would not be recognized by the enforcement agency for the purpose of compliance with Standard 3.2.1. However, they are essential for the business to assess for itself whether it is complying with its food safety program and would form an important part of the business's review of its food safety program as required by Standard 3.2.1.

5.3.2.3 Auditing frequency

Determining the frequency of auditing food safety programs is also the responsibility of States and Territories. To assist national consistency in this regard, ANZFA (FSANZ), in conjunction with States and Territories provided guidance on auditing frequency in *Food Safety: An audit system*. Frequency is dependant on the priority rating of the type of business based on the risk posed to public health and safety. A risk-based system to classify food businesses into priority ratings has been developed by FSANZ and is described in *Food Safety: The priority classification for food businesses*¹². Businesses classified as 'high risk' under this system, which includes catering operations, are assigned an initial audit frequency of one audit every six months with an increase or reduction in frequency dependant on compliance.

¹⁰ Information on the National Food Industry Strategy is available on the website of the Australian Government Department of Agriculture, Forestry and Fisheries www.daff.gov.au

¹¹ *Food Safety: An audit system* is available on the FSANZ website www.foodstandards.gov.au

¹² *Food Safety: The priority classification for food businesses* is available on the FSANZ website www.foodstandards.gov.au

Since the development of the priority classification system for food businesses, the concept of risk profiling is being developed to provide a foundation for food safety management in Australia. Risk profiling is a process of initially evaluating a food safety problem and its context to identify the potential for the problem to impact on public health. Risk profiling was used by the National Risk Validation Project to identify the highest risk food business types and further work is currently being undertaken, funded by DoHA, to identify a nationally applicable, valid process to classify all businesses on the basis of risk.¹³ This will support decisions on audit frequency for various classifications of businesses and may affect the frequency of auditing of caterers indicated by the priority classification system.

Other matters relevant to auditing are addressed by the State and Territory Food Acts for example, duties of food safety auditors and reporting requirements¹⁴.

5.3.2.4 Auditing costs

Studies into costs and impacts of mandatory food safety programs considered ongoing costs to businesses of second or third party audits and concluded that there is a strong case for mandatory food safety programs in the commercial catering industry. FSANZ in *Food Safety: An audit system* indicated that these costs could be reduced for businesses that have a good compliance history by proposing that the audit frequency be reduced.

5.3.3 Tools and other support material

In order to minimise costs associated with the initial preparation of a food safety program, particularly for small businesses, a number of tools (e.g. templates) have been developed or are under development for the various sectors covered by the vulnerable populations definition. These tools include:

- Food Safety Program Tool for Children's Services Operations; and
- Food Safety Program Tool for Small / Medium Hospitals and Nursing Homes.

The project for delivered meals organisations, discussed above, may also result in the preparation of additional support materials including a food safety program tool.

Generic versions of tools will be available from the DoHA and FSANZ websites. Additionally, DoHA will distribute the tools to State and Territory jurisdictions so that they can make any modifications that may be necessary to reflect specific jurisdictional requirements. The tools will then be made available to food businesses via local enforcement authorities.

During the implementation of Standards 3.1.1, 3.2.2 and 3.2.3, a number of fact sheets were developed to assist industry with compliance with various requirements within these Standards (for example, on health and hygiene responsibilities, temperature control requirements and food receipt). States and Territories also produced supporting material for food businesses.

¹³ Information on risk profiling is available on the website of the Department of Health and Ageing e.g. www.foodsecretariat.health.gov.au

¹⁴ Information and copies of State and Territory food legislation is available on the government websites of the States and Territories.

Comment is sought on the need for additional tools, fact sheets or other support material to assist food service to vulnerable populations to prepare and implement food safety programs.

5.3.4 Interpretive guide

FSANZ, in consultation with jurisdictions and other stakeholders, has commenced work to develop a guide to Standard 3.2.1 to explain the intent of the provisions in the Standard on a clause-by-clause basis. The primary purpose of the guide is to promote nationally consistent interpretation of Standard 3.2.1 by State and Territory enforcement officers and thereby assist them in assessing whether the objectives of the legislation are being met. However, industry associations and training organizations may find the guide useful to prepare information to assist businesses to comply with Standard 3.2.1. The interpretive guide may also be of direct use to food businesses.

The guide is likely to be similar to *Safe Food Australia* (the guide to Standards 3.1.1, 3.2.2 and 3.2.3), which was first released in 2000 and, like *Safe Food Australia*, is unlikely to be specific to any particular type of food business. However, the precise format, style and content will be based on the results of a national consultation undertaken in March 2004. A draft guide will be trialled later in 2004.

Comment on the format, style and content or other issues related to the interpretive guide may be made in response to this Initial Assessment Report.

6. Regulatory Options

In developing food Standards, FSANZ must identify two or more regulatory options and consider the pros and cons (including impacts and implications) of each. For this Proposal two options are considered:

- Option 1 to maintain the status quo and not amend Standard 3.2.1 to apply to food service, whereby potentially hazardous food is served to vulnerable populations as defined by Standard 3.2.1
- Option 2 to amend Standard 3.2.1 to mandate food safety programs for food service, whereby potentially hazardous food is served to vulnerable populations as defined by Standard 3.2.1

6.1 Option 1 – maintain the status quo

Option 1 means that no amendment is made to Standard 3.2.1 to apply the requirements to food service for vulnerable populations as a national requirement. States and Territories could mandate food safety programs for this sector within their jurisdictions. This option would not be consistent with the Ministerial Policy Guidelines to require food safety programs for food service, in which potentially hazardous food is served to vulnerable populations.

6.2 Option 2 – amend Standard 3.2.1

An amendment to Standard 3.2.1 would mean that food service to vulnerable populations, as defined by Standard 3.2.1, would be required to have documented food safety programs as prescribed in Standard 3.2.1.

7. Impact Analysis

The Allen Consulting Group Report *Food Safety Management Systems, Costs, Benefits and Alternatives* made an assessment of:

- the costs and benefits of meeting previous State and Territory food safety regulations;
- the incremental costs and benefits of meeting Standards 3.1.1, 3.2.2 and 3.2.3 given current practices (at that time);
- the incremental costs and benefits of meeting Standard 3.2.1 given achievement of Standards 3.1.1, 3.2.2 and 3.2.3;
- the advantages and disadvantages of alternatives to a requirement for food safety programs; and
- ways in which compliance costs of meeting the Standards could be minimised.

The Allen Report found that while the implementation of Standard 3.2.1 includes significant costs, the benefits outweigh these costs for all but “low risk” businesses.

Data from the Allen Report was further built on by *The National Risk Validation Report* which included a cost benefit analysis of implementing food safety programs, specifically for high risk food industries. The total cost of food-borne illness associated with vulnerable populations was estimated to be \$75 million per year or 21 cents per meal. A benefit/cost ratio was calculated at 6.5 (for class 1 outbreaks¹⁵) and 6.8 (class 1 and 2 outbreaks). This cost benefit analysis strongly supports the mandating of food safety programs for the vulnerable populations.

The Office of Regulation Review (ORR) has assessed the *Ministerial Policy Guidelines on Food Safety Management in Australia: Food Safety Programs* taking into account:

- whether the regulatory Impact Statement guidelines have been followed;
- whether the type and level of analysis are adequate and commensurate with the potential economic and social impact of the Proposal; and
- whether alternatives to regulation have been adequately considered.

The ORR considered that these matters have been adequately addressed.

¹⁵ Class 1 outbreaks are those where it is reasonable to assume that the cause of illness would have been detected and remedied by measures put in place under a food safety program. Class 2 outbreaks are those where the information on the source of the outbreak is insufficient to make a judgement on the likely effectiveness of a food safety program.

Information and comments is sought on any other issues relevant to mandating Standard 3.2.1 for the sector. In particular, comment is sought on the impact of Standard 3.2.1 on small businesses within the food service sector that is providing food to vulnerable groups and suggestions are sought on how imposts on this sector could be minimised.

8. Consultation

8.1 Broad consultation

The preamble to this Initial Assessment Report explains the consultation that FSANZ undertakes as part of its obligations under the *FSANZ Act 1991*. FSANZ provides details of consultation documents on its website which are available electronically from the website or from FSANZ as paper copy.

FSANZ will also consult with stakeholders through stakeholder forums and industry events in order to engage stakeholders in feedback on the Proposal. Stakeholders are invited to advise FSANZ where such participation may be timely and useful.

The development of the food safety Standards in Chapter 3 of the Code has already required extensive consultation with all industry and government stakeholders, and other interested parties. In addition, the projects that DoHA have undertaken to inform the Ministerial Policy Guidelines have involved the formation of Steering Committees and/or project management groups to oversee and contribute to the work program. These committees have had representatives from the Australian and State and Territory Governments, the food industry and industry sectors affected by this Proposal. Additionally the public consultation process during the preparation of ministerial Policy Guidelines, referred to in 5.1.2 above, identified issues highlighted in this Initial Assessment Report and which will be considered further at draft assessment.

FSANZ will continue to consult with stakeholders in the development of the Standard through its normal processes. In addition, the development of this Proposal will involve the formation of a specific advisory group.

8.2 Advisory Groups

FSANZ will establish an advisory group in May 2004 to assist with amending Standard 3.2.1 for application to food service for vulnerable populations. The group will comprise representatives from industry, from relevant Australian Government and each State and Territory Government Departments, and from consumers. Industry representatives will include specific bodies/organisations identified as representing the interests of institutions and organisations that serve food to vulnerable groups.

8.3 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

This issue will be fully considered at Draft Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia's and New Zealand's obligations under the WTO Technical Barrier to Trade and Sanitary and Phytosanitary Measure Agreements. This will enable other WTO member countries to comment on proposed changes to Standards where they may have a significant impact on them.

9. Closing Remarks

This Initial Assessment Report provides the first formal opportunity for stakeholders to comment on and supply information and data to FSANZ regarding the mandatory application of Standard 3.2.1 to food service, whereby potentially hazardous food is served to vulnerable populations. There will be additional opportunities to comment at stakeholder forums and other events. FSANZ welcomes and encourages stakeholder input.

The comments, information and data provided during consultation will be considered during the development of the Draft Assessment Report, which will provide the next formal opportunity for stakeholders to comment.