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DRAFT ASSESSMENT REPORT

PROPOSAL P288

FOOD SAFETY PROGRAMS FOR FOOD SERVICE TO VULNERABLE POPULATIONS

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 20 July 2005
SUBMISSIONS RECEIVED AFTER THIS DEADLINE
WILL NOT BE CONSIDERED
(See 'Invitation for Public Submissions' for details)

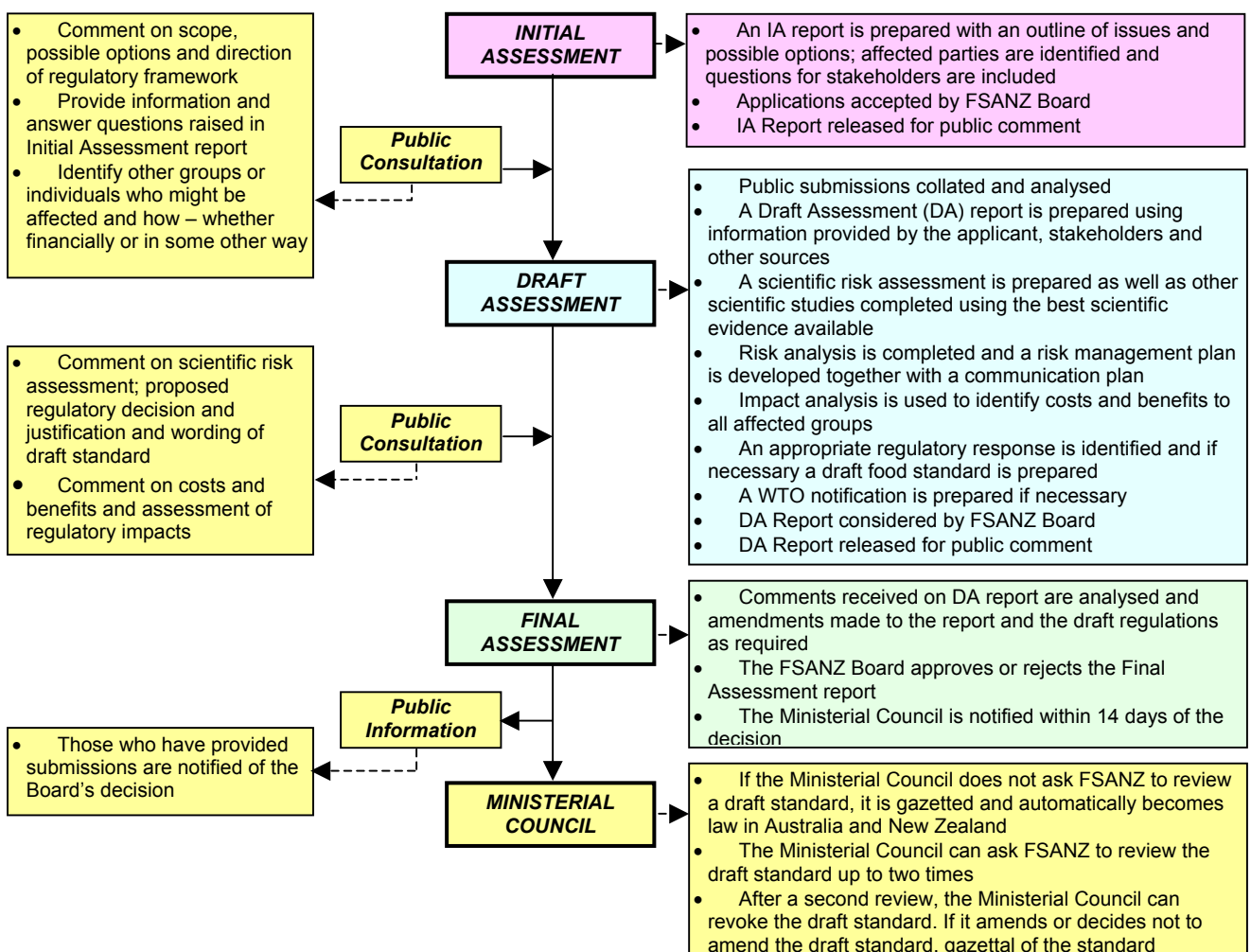
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 Australian Government; 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 Australian Government, 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 Australian Government, 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 a Draft Assessment Report for Proposal P288; and prepared a draft variation to the *Australia New Zealand Food Standards Code* (the Code).

FSANZ invites public comment on this Draft Assessment Report based on regulation impact principles and the draft variation to the Code 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/Final 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
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Submissions need to be received by FSANZ by 6pm (Canberra time) 20 July 2005.

Submissions received after this date will not be considered, unless agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ Website and will apply to all submitters.

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 and Statement of Reasons

In response to a decision of the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) FSANZ is proposing to mandate food safety management systems for food businesses that process potentially hazardous food for service to vulnerable populations. The relevant Ministerial Policy Guidelines is at Attachment 6.

The proposed Standard will apply to food businesses in Australia only, as New Zealand has its own legislation in regard to the application of food safety programs and food safety standards are outside the terms of the agreement between Australia and New Zealand on a joint food standards system.

An Advisory Group with representatives from industry, the Australian, State and Territory Governments and from consumer groups has assisted with the development of this Proposal.

In accordance with the Ministerial Policy Guidelines the proposed Standard (3.3.1) requires mandatory food safety management systems for ‘food businesses that process potentially hazardous food specifically intended to be supplied to six or more vulnerable persons.’ A vulnerable person is defined as someone who is:

- (a) four years of age or less; or
- (b) pregnant; or
- (c) 70 years of age or more; or
- (d) immuno-compromised.

Food businesses that would be covered by this requirement include those that specifically supply potentially hazardous food within hospitals, childcare centres, aged care facilities, delivered meals organisations and other similar food businesses. In accordance with the Ministerial Policy Guidelines FSANZ proposes to exempt smaller businesses that supply five or less vulnerable persons, as the cost of implementing a food safety program is greater than the benefit. The exclusion of food businesses of this size will also exclude family day care type organisations (see Attachment 4 for a summary in table form of who is included and who is not included).

Two regulatory options were identified:

- Option 1 to maintain the status quo and not adopt Standard 3.3.1 to apply food safety management systems to potentially hazardous food supplied to vulnerable persons.
- Option 2 to adopt Standard 3.3.1 to mandate food safety management systems to food businesses that process potentially hazardous food specifically intended to be supplied to vulnerable persons.

In order to implement the Ministerial Policy Guidelines, Option 2 is the only acceptable outcome. The draft proposed Standard 3.3.1 – Food Safety Programs for food supplied to vulnerable persons is provided at Attachment 1. As this Standard refers to Standard 3.2.1, a copy is provided at Attachment 2. If the Code is amended as proposed, compliance with Standard 3.3.1 will be no later than required two years after gazettal.

An Initial Assessment Report was available for public comment for eight weeks in May-June 2004. A total of ten submissions were received in response to the Initial Assessment Report and identified a number of issues. These issues included auditing, the interpretive guide, duplication with existing accreditation systems, the scope of the Proposal, definition of potentially hazardous food, the exclusion of family day care, hospital cafes, application to delivered meals organisations (DMOs) and the provision of support material. These issues have been addressed in this report.

FSANZ is now seeking public comment in order to progress this Proposal to Final Assessment.

Statement of Reasons

At Draft Assessment FSANZ recommends that the Code be amended to mandate food safety management systems for food businesses that process potentially hazardous food specifically intended to be supplied to vulnerable persons for the following reasons:

- The Ministerial Council, on 12 December 2003, made a decision that food safety programs should be mandated for specific high-risk sectors of the food industry, as set out in the Ministerial Policy Guidelines (see Attachment 6).
- The National Risk Validation Project concluded that food service to vulnerable (sensitive) populations was the highest risk sector of the food industry.
- The Allen Report on the costs and efficacy of introducing food safety programs concludes that the benefits for high-risk businesses outweigh the costs of implementing, utilising and auditing a food safety program.
- The proposed amendments to the Code are consistent with the section 10 objectives of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act).
- Victoria currently requires food safety programs for food service to vulnerable populations; the proposed amendments to the Code would promote national consistency by providing a national requirement.
- Compliance with the proposed amendments to the Code should reduce the number of food poisoning incidents in vulnerable population groups.
- The proposed amendment is an improvement on the current regulatory requirements, as it requires a system that is initiated by the food business and provides a preventative approach to food safety management that allows enforcement agencies to see, through audit, compliance with the program and hazard control measures.

1. Introduction

In December 2003, the Ministerial Council made a decision to require specific high-risk sectors of the food industry to have audited food safety programs. In response to this decision FSANZ has prepared Proposal P288 to address the identified high-risk area of ‘Food service whereby potentially hazardous food is served to vulnerable populations’. As part of this process FSANZ is proposing to amend the Code to include Standard 3.3.1 – Food Safety Programs for Food Supplied to Vulnerable Persons.

The proposed Standard will apply in Australia only and does not apply in New Zealand, as New Zealand has its own legislation in regard to the application of food safety programs and food safety standards are outside the terms of the agreement between Australia and New Zealand on a joint food standards system. Therefore, this Proposal will not affect food businesses serving food to vulnerable populations or consumers in New Zealand.

FSANZ has established an advisory group to assist with this Proposal. The group comprises representatives from industry, relevant Australian Government and State and Territory Government Departments and consumers. A list of organisations that are members of the advisory group can be found in Attachment 5.

The Initial Assessment Report for Proposal P288 was released for public comment in May 2004 for eight weeks. Ten submissions were received. The purpose of this Draft Assessment Report is to inform the food industry, governments, consumers and other stakeholders of the results of the initial public consultation and provide further detail on the Proposal including the proposed draft amendments to the Code. This report provides a formal opportunity for stakeholders to comment on this Proposal, including the draft Standard.

2. Regulatory problem

All food businesses in Australia (except Western Australia) are currently required to comply with the Food Safety Standards in Chapter 3 of the Code, with the exception of the voluntary Standard, Standard 3.2.1 – Food Safety Programs.

The *Ministerial Policy Guidelines on Food Safety Management in Australia: Food Safety Programs* (Ministerial Guidelines) state that there are identified benefits to public health that result from the implementation of food safety programs for food businesses that are identified as high risk. One of the high-risk sectors that is identified in these guidelines is ‘food service, whereby potentially hazardous food is served to vulnerable populations’. These guidelines were based on the research findings into food-borne illness and cost and benefits of food safety programs in Australia. The Ministerial Council has directed FSANZ to implement food safety management systems for vulnerable populations as defined in the Ministerial Policy Guidelines.

The National Risk Validation 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. It concluded that food service to vulnerable populations was the highest risk sector based on the sensitivity of the populations it serves. This sector includes hospitals, aged care, childcare centres and organisations delivering to housebound people.

These population groups are more vulnerable to food-borne illness compared with the general population. This vulnerability is a combination of the susceptibility of the population groups to food-borne illness and the severity of illness experienced once infected. The food-borne illness data collected by the National Risk Validation Project indicated that hospitals, nursing homes and childcare centres were responsible for approximately 18% of outbreaks of food-borne illness.

All State and Territory Governments with the exception of Western Australia have now adopted the Food Safety Standards, Standards 3.1.1 – Interpretation and Application, 3.2.2 – Food Safety Practises and General and 3.2.3 – Food Premises and Equipment, of the Code into their State and Territory food legislation. This requires all food businesses to comply with the food safety measures including requirements for 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.

Compliance with these Food Safety Standards should reduce the number of food poisoning incidents. However, they do not require food businesses to identify and monitor the control of potential hazards in their business or document a food safety program and have the program audited, as required by Standard 3.2.1. The requirements of Standard 3.2.1 place the responsibility for maintaining food safety on the food business rather than expecting the enforcement agency to identify hazards and their appropriate controls. As a food safety program is a documented, preventative food safety management system, it can provide greater assurance that appropriate food safety controls are in place. This is an improvement on the current regulatory requirements.

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 1 food businesses¹ and as such are required to have audited food safety programs that are consistent with Standard 3.2.1. There is evidence from Victoria that food safety programs have helped to improve food safety and food safety knowledge. Other jurisdictions are also looking to mandate food safety programs for high-risk sectors. Thus the proposed amendment to the Code will allow for increased national consistency in this area.

2.1 Regulatory framework for mandating food safety programs

In order to provide support for the implementation of food safety programs, the Australian Government Department of Health and Ageing and State and Territory Governments, in cooperation with the food industry and other interested parties, undertook a range of studies. These studies provided 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, were used by the Food Regulation Standing Committee (FRSC) to develop Ministerial Guidelines for managing food safety in Australia. These projects are:

¹ 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.

- 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 lead to the development of the Ministerial Guidelines.

2.1.1 Ministerial Policy Guidelines on Food Safety Management in Australia

On 12 December 2003, the Ministerial Council approved the *Ministerial Policy Guidelines on Food Safety Management in Australia: Food Safety Programs* (Attachment 6) 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 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. 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 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.

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* (Allen report) is available at: www.health.gov.au/pubhlth/strateg/foodpolicy/pdf/alternatives.htm

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
- producers of manufactured and fermented meat.

The Ministerial Guidelines identify 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.

This Draft Assessment Report applies to only the first of these industries, food service, in which potentially hazardous food is served to vulnerable populations. The other business sectors identified are being addressed through separate processes.

2.1.2 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 compliance with, the food safety program.

A food safety program demonstrates how a business will produce safe food. The amount of information needed in a food business' food safety program will depend on the type and complexity of the food business.

3. Objectives

In developing or varying a food Standard, FSANZ, is required by its legislation, to meet three primary objectives that 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 food safety programs 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.

4. Background

The sector addressed by this Proposal is characterised by vulnerable population groups that are provided with meals by commercial organisations. These population groups are more vulnerable to food-borne illness compared with the general population. The definition of vulnerable persons in the proposed Standard is based on the groups identified in the Ministerial Guidelines. The proposed definition is:

Vulnerable person means a person who is:

- four years of age or less;
- pregnant;
- 70 years of age or more; or
- immuno-compromised;

This would include food businesses that process potentially hazardous food for service in or provided to:

- hospitals;
- aged care facilities;
- clients of organisations that provide delivered meals;
- childcare centres; and
- other organisations that specifically cater for vulnerable persons.

Process is defined in Standard 3.2.2 as *an activity conducted to prepare food for sale including chopping, cooking, drying, fermenting, heating, pasteurising, thawing and washing, or a combination of these activities.*

4.1. Rationale for Mandating Standard 3.2.1 for vulnerable populations

The National Risk Validation Project was undertaken in 2001, in Part 1, to 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.

4.1.1 Scientific assessment

The National Risk Validation 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 project concluded that food service to vulnerable populations was the highest risk sector; based on the sensitivity of the populations they serve. The sectors included hospitals, aged care, childcare centres and organisations delivering to housebound people.

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. Specific information on each sector is found below.

4.1.1.1 Hospitals

Hospitals were identified as a high-risk business on the basis of the clients they treat. In a paper by Jardine (2003) he suggests that hospitalised patients are a group that is more vulnerable to food-borne disease as *it is logical to expect that hospitalised patients are more likely to be comprised of a significant percentage of neonates, immuno-suppressed and elderly individuals.*

4.1.1.2 Aged Care and Delivered Meal Organisations

Aged care and DMOs have been identified as high risk on the basis of the clients they serve. Jardine (2003) states that *Nursing home residents or home delivered meal recipients are more likely to have other risk factors such as underlying immuno-suppressive conditions, inactivity and poor nutrition and will therefore be vulnerable biologically and also behaviourally, as 'mass catered' food is a risky practice in itself.* The report concludes *The elderly can be considered an 'at-risk' population due mainly to the greater severity of food-borne disease in this population. The increasing prevalence of underlying risk factors that independently increase vulnerability indicate that those aged 70 and over are in need of extra protection. Home delivered meal recipients, residents of nursing homes and the hospitalised elderly are particularly high-risk populations among the elderly and clearly in need of strong protection.*

4.1.1.3 Childcare

Children aged four or less have a significantly higher number of gastroenteritis cases than the rest of the population (Jardine, 2003). Due to this susceptibility children aged four or less have been identified as a high-risk group.

However, the proportion of gastrointestinal disease in children that is food-borne is unclear as poor hygiene and frequent hand to mouth behaviour means that environmental exposure to pathogens is increased via sources other than food (Jardine A, 2003).

The 0-4 age group appear to be significantly susceptible to food-borne illness. Jardine further states *No convincing evidence exists to suggest that foodborne illness is more common in childcare facilities. However, as the evidence suggests that the very young are more susceptible to some foodborne pathogens, particular care must still be taken when mass catering to this age group.*

4.1.2 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), the ongoing costs of record keeping, 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 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 for the Australian population, based on a 15% reduction in food-borne illness.

The National Risk Validation Report, which included a cost benefit analysis of implementing food safety programs, specifically for high-risk food industries, further built on data from the Allen Report. 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 outbreaks³) and 6.8 (class 1 and 2 outbreaks). This cost benefit analysis strongly supports the mandating of food safety programs for the vulnerable populations.

³ 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.

4.2 Overview of the sector

This section will provide an overview of the facilities covered within this Proposal; specific issues such as exclusions will be discussed in section 5.

4.2.1 Hospitals

The Ministerial Guidelines have identified hospitals as routinely serving potentially hazardous food to vulnerable populations and as facilities where food safety programs would provide a benefit in reducing the incidence of food-borne illness.

In 2001-2 Australia had a total of 1,306 hospitals (both public and private) (AIHW, 2003) providing 78,868 hospital beds. Public hospitals provide about 65% of the hospital service nationally (AIHW, 2003).

The National Risk Validation Project describes the food operation of hospitals. The report states that most hospitals manage their own catering with less than 20 percent using contract caterers, that there is a trend towards merging kitchens and a move to cook/chill from a central kitchen. Cook/chill involves processing food in advance. Once cooked food is then rapidly chilled and then stored until it is required. It is then reheated and served. Cook-chill has the advantage of allowing a large quantity of meals to be prepared and then delivered to a number of different sites for reheating and serving.

The requirement for a food safety management system would apply to any food business that processes potentially hazardous food specifically intended to be served in a hospital.

4.2.2 Aged Care

The Ministerial Guidelines have identified the elderly (aged 70 and over) as a vulnerable population. The Guidelines specifically identify aged care facilities and nursing homes as services where food safety programs would provide a benefit in reducing the amount of food-borne illness.

This Proposal covers both private and government funded residential aged care and day care programs/centres that provide meals.

In 2001 approximately 23,042 clients, aged over 65, used centre-based day care as part of the Home and Community Care program (AIHW, 2002).

In June 2003 there were 151,181 places available in residential aged care provided by 2,927 mainstream facilities, 90 multi-purpose services⁴ and 26 services receiving flexible funding for Aboriginal and Torres Strait Islander care (AIHW, 2004).

The breakdown of the age of residents in residential aged care is shown in the Table 1. This data identifies that 92% of clients in residential aged care are 70 years or older. Hence these type of facilities provide services for people within the vulnerable population definition.

⁴ Multipurpose services operate in rural and remote locations that are too small to support the standard systems of aged care provision. They bring together a range of local health and aged care services and often include residential care.

Table 1: Source: AIHW 2004 *Residential Aged Care in Australia 2002-03, A statistical overview, Page 28*

Age	Percent of residents	Number of residents
Under 65	4.3	6208
65-69	3.1	4491
70-74	6.3	9010
75-79	13.2	18900
80-84	22.3	31816
85-89	25.7	36762
90-94	18.3	26142
95+	6.7	9517

Only a small number of food businesses that process potentially hazardous food for aged care facilities currently have food safety programs. Ninety-five percent of aged care facilities do not have a food safety program (The Allen Consulting Group, 2002a).

The requirement to have a food safety management system would apply to any food business that processes potentially hazardous food specifically intended to be served in an aged care setting.

4.2.3 *Delivered Meals Organisations*

A delivered meal organisation (DMO), such as Meals on Wheels, provides meals that are delivered to individuals' homes. Recipients of delivered meals are likely to be immuno-compromised or elderly and therefore more vulnerable to food-borne illness.

In 2003-04, DMOs delivered 11,707,325 meals to 147,207 clients (Australian Government Department of Health and Ageing, 2004). Eighty-one per cent of recipients of delivered meals are aged 70 years or older (Australian Government Department of Health and Ageing, 2004). This indicates that the main customer of delivered meals services are those aged 70 years and older or individuals who may be otherwise sensitive to food-borne illness and thus a vulnerable population. The eligibility for receiving meals also includes housebound, ill and disabled persons.

There is a wide variation in the source of meals for DMOs according to the National Risk Validation Project. Meals can be supplied hot, frozen, or chilled and may be supplied by an external caterer, hospital or prepared in the DMOs kitchen.

This requirement to have a food safety management system would apply to any food business that processes potentially hazardous food specifically intended to be served to vulnerable persons by a DMO.

4.2.4 *Childcare Centres*

The Ministerial Guidelines have identified children aged four years or less as a vulnerable population. The Guidelines specifically identify childcare centres providing meals as facilities where food safety programs would provide a benefit in reducing the amount of food-borne illness. The guidelines specifically exclude family day care from the Proposal based on a low cost-benefit ratio.

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.

In May 2002, it was estimated that 732,100 children attended government funded childcare services (Facs, 2003). The use of formal childcare increases with the age of the children with 7% of all children under 1 year, 27% at 1 year and 83% of four year olds attending childcare in 2002 (Australian Bureau of Statistics, 2003). The higher attendance of three and four year olds reflects preschool attendance, with many childcare centres providing preschool or preschoolers also attending childcare. Ninety per cent of long day care centres opened for 10 hours a day or more (Facs, 2003) and thus providing meals is an important part of their service.

This requirement to have a food safety management system would apply to any food business that processes potentially hazardous food specifically intended to be served in a childcare setting.

4.2.5 *Other facilities*

The proposed amendments to the Code allow for other food businesses that process potentially hazardous food specifically intended for vulnerable populations in addition to childcare, aged care, hospitals and DMOs to be required to have food safety programs.

Jardine (2003) identifies AIDS, HIV, cancer, diabetes, kidney or liver disease, haemochromatosis, stomach problems and low stomach acid as disease states that predispose individuals to food-borne illness⁵. Facilities that process potentially hazardous food to these vulnerable persons with these types of diseases will be required to have a food safety program.

The requirement to have a food safety management system would apply to any food business that processes potentially hazardous food specifically intended to be served in facilities that specifically provide services to vulnerable persons, for example, food businesses that process potentially hazardous food for service at facilities such as chemotherapy centres, day surgery or some rehabilitation centres.

5. **Relevant Issues**

5.1 **Defining the food businesses for implementation of food safety management systems**

Consistent with the Ministerial Guidelines, two key issues were considered in developing this Proposal: that the Standard is both **enforceable** and that it **captures** those businesses that are processing potentially hazardous food specifically intended to be provided to vulnerable populations.

⁵ Data provided by Jardine show that ‘of the 225 non-pregnant cases of listeriosis recorded in France in 1992, 71% had either severe immuno-suppression or immuno-suppressive risk factors such as diabetes, alcoholism or hepatic failure’.

The proposed Standard 3.3.1 ‘applies to food businesses that process potentially hazardous food specifically intended to be supplied to six or more vulnerable persons’. This definition will exclude food businesses that process potentially hazardous food for five or less vulnerable persons.

Process is defined in Standard 3.2.2 as *an activity conducted to prepare food for sale including chopping, cooking, drying, fermenting, heating, pasteurising, thawing and washing or a combination of these activities*⁶. Those businesses that transport or serve food only are not covered in the scope of the definition of *process* and hence are not required to have a food safety management system. The cost to these businesses of developing a system and auditing their system is not justified. These businesses are covered by the transport requirements of Standard 3.2.2.

A vulnerable person in this Proposal is defined as ‘a person who is –

- four years of age or less; or
- pregnant; or
- 70 years of age or more; or
- immuno-compromised.’

This Proposal only covers food businesses, therefore where the client supplies food and not by the business it would not be required to have a food safety program.

5.1.1 Definition of immuno-compromised

Immuno-compromised person is defined in the proposed Standard as *a person whose immune system is functioning in an abnormal or incomplete manner.*

Including immuno-compromised individuals in the definition of vulnerable persons potentially allows for other type of food businesses to be included within this Proposal. These will include food businesses that process potentially hazardous food specifically intended to be supplied to patients at some day surgery units, chemotherapy centres and some drug and alcohol rehabilitation centres as well as other businesses that cater for the immuno-compromised. The inclusion of these types of businesses is within the intention of the Ministerial Guidelines.

FSANZ would welcome submissions on both the proposed definition of **immuno-compromised** and the types of businesses that serve immuno-compromised persons that may fall within the scope of this Standard.

5.1.2 Exclusion for milk in definition of potentially hazardous food

This Proposal only applies to food businesses that are processing **potentially hazardous foods**. ‘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.*

⁶ Note this list is not exhaustive, other similar activities would also be included for example: portioning.

Food businesses that serve only non-potentially hazardous foods will not be required to comply with Standard 3.2.1. Clause 2 of the proposed Standard clarifies the definition of potentially hazardous food by stating *To avoid doubt, in this Standard, 'potentially hazardous food' does not include pasteurised milk or soymilk.* The aim of this exclusion is to allow facilities that would only serve tea/coffee or child care centres that may serve only milk to be excluded from the requirement to have a food safety program.

Milk is traditionally seen to be a potentially hazardous food, however, it is likely that pasteurised milk that is in a sealed package may spoil under non-refrigerated conditions or poor handling before it becomes a health risk.

FSANZ would welcome comment on the exclusion of pasteurised milk and pasteurised soymilk from the definition of potentially hazardous food for this proposed Standard.

5.1.3 Exclusion of businesses which provide food to 5 vulnerable persons or less

The Ministerial 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 (and this exclusion would pick up other home-based care services).

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 or hospital that had the capacity to provide meals to five or less residents.

These businesses are excluded in clause 1 of the proposed Standard 3.3.1 by the application of the Standard to food businesses that supply six or more vulnerable persons. This would exclude family day care on the basis that they do not process potentially hazardous food for more than five children aged four or less.

Comment was received in the submissions about the exclusion of family day care and any food businesses with 5 clients or less on the basis that all food businesses that are serving vulnerable populations should be required to have a food safety program and size should not be considered.

The reasons for maintaining the exclusion of these premises are:

- The costs of the self-regulation imposed by food safety programs are too onerous for such small businesses (whatever their source of funding) and the cost outweighs the benefit of such a move.
- The cost (both of time and money) of implementing food safety programs for these businesses may provide an incentive to cease providing food for the children/clients in their care or to cease operation. The social/nutritional and economic impact of this has not been accounted for in the cost-benefit analysis.

- It is not the intention of this Proposal to provide an incentive for essential services to the community to close.
- These businesses are currently required to meet the requirements of Standards 3.1.1, 3.2.2, and 3.2.3; these cover food handling and safety requirements and compliance with these should ensure safe food.
- The cost of auditing a food safety program for these very small businesses would have a significant impact.

An example of the number of residential aged care facilities that this proposal would include is shown in Table 2. This Table shows the size of these type of facilities. The majority of residential aged care facilities (>90%) will be required to implement food safety programs⁷.

Table 2: Source: AIHW 2004 Residential Aged Care in Australia 2002-03, A statistical overview, Page 22

Number of Places	Percent of facilities	Number of facilities
1-20	9.7	284
21-40	34.1	999
41-60	30.2	885
61-80	13.8	403
81-100	6.4	188
101-120	3.0	87
121+	2.8	81

FSANZ would welcome comment on whether the proposed Standard will exclude all family day care type organisations and adequately exclude small businesses.

5.1.4 Exclusion of Hospital cafes/kiosks

An issue raised in one submission was whether cafes and kiosks that operate in hospitals or aged care facilities are included within the scope of this Proposal. As the main customers of these facilities are staff and visitors to the hospitals, they will not be required to have a food safety program. However, as a consequence of the proposed requirements they may operate under a food safety program (as the food safety program may operate across the facility).

5.1.5 Exclusion of Delivered Meals Organisations that Deliver only

A submission was received to clarify whether an organisation that only delivers meals and does not produce, prepare or change the state of the meal (defrost, heat, or chill) would be covered by this Proposal. An organisation that delivers meals only would be excluded from the requirement to have a food safety program. These organisations are not included in the application of the proposed Standard 3.3.1, as they do not **process** food.

The cost of auditing and implementing a food safety management system in these facilities is not justified by the benefit received by the requirement. In this instance the current Food Safety Standards 3.2.2 and 3.2.3, specifically the transport requirements in Standard 3.2.2, would be sufficient to manage food safety.

⁷ Information on the number of facilities with 5 places or less was not available

5.1.6 Exclusion of Fundraising Events

Clause 6 of Standard 3.2.1 states *A food business does not have to prepare a food safety program in accordance with this Standard in relation to fundraising events conducted by the food business, that is, events that raise funds solely for community or charitable causes and not for personal financial gain.* This exemption of fundraising events is carried over into Standard 3.3.1. This exemption means that fundraising events, for community or charitable causes that are staffed exclusively by volunteers are excluded from the requirement to have a food safety management system.

The reason for this exemption is that a successful food safety program depends on continual understanding of compliance and food safety outcomes. This is not achievable unless there is staff with a responsibility for food safety as an integral part of their work. The use of volunteers may provide staff on one occasion only and hence provides no continuity of food safety knowledge and it would not be feasible, therefore, for the requirements of a food safety program to be complied with. These food businesses, although exempt from the requirement to have a food safety program, are required to comply with the food safety requirements of Standard 3.2.2 (They are not required to comply with the skills and knowledge component).

5.2 Implementation issues

5.2.1 Existing accreditation arrangements

The existing accreditation arrangements, whether they duplicate the proposed requirement and the possibility of combining audits for accreditation and food safety programs was raised in a number of submissions. Many Australian public and private hospitals, other health care organisations, aged care 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.

5.2.1.1 Child care

The National Childcare Accreditation Council inc. (NCAC) administers a Quality Improvement and Accreditation System (QIAS) nationally. To remain eligible for continued Childcare Benefit approved by the Australian Government Department of Family and Community Services (FACS) all childcare centres must participate in the program and receive a rating of Satisfactory or higher on all 10 quality areas.

The QIAS currently has two principles childcare providers must meet which concern the safety of food. These are Principle 8.2: *Staff implement effective and current food-handling standards and hygiene practices* and Principle 8.4: *The centre acts to control the spread of infectious diseases and maintains records of immunisations* (National Childcare Accreditation Council, 2001). To comply with these principles the centre must demonstrate compliance with the requirements of the relevant authority. Compliance may be checked during the audit through viewing inspection or audit reports from the relevant authority but the audit does not check to see that the centre is complying with the requirements at the time of the audit. These two principles are only a small part of a large accreditation system consisting of 35 principles.

QIAS auditors are not required to hold specific food safety auditing qualifications and as such are not currently appropriately qualified to conduct a food safety audit or to audit a food safety program.

5.2.1.2 Aged care

The Aged Care Accreditation Agency Limited is an accreditation body established by the Australian Government to operate an accreditation system for aged care. In order to receive funding aged care services must demonstrate they comply with the accreditation standards.

In the accreditation standards there is no specific standard that applies to food safety. Aged care facilities are required to comply with relevant legislative requirements and have an effective infection control program.

Aged care assessors are not required to be qualified for food safety auditing. During an accreditation audit the assessment team reviews documents to ensure that the facility is complying with statutory requirements, however, it does not examine the details of hazard control as it relates to food safety.

5.2.1.3 Hospitals

The major accreditation body in Australia for Hospitals and other healthcare establishments is the Australian Council on Healthcare Standards (ACHS). There are no specific accreditation standards for food safety; however, there is a relevant criterion in the 'Safe Practice and Environment' function of the accreditation standards. The survey team does not audit food safety as such but through a verification process will review evidence of compliance with Australian Standard, State/Territory standards/legislation, codes of practice and industry guidelines presented by the organisation.

There are no requirements for auditors to have any specific food safety qualifications. A food safety audit would be complimentary to the accreditation process in that it would provide evidence to demonstrate compliance with relevant legislation.

5.2.1.4 Conclusion

Investigation into accreditation arrangements for aged care; hospitals and childcare established that the requirements of Standard 3.2.1 do not duplicate any of the requirements of the accreditation arrangements for childcare, aged care and hospitals. This is consistent with the findings of a report by Food Safety Victoria (Liu and Strickland, 2002).

The possibility of limiting the number of audits by combining an accreditation audit with the audit of the food safety program was also investigated by FSANZ. Given the scope of the accreditation audit and the qualifications of the auditor, however, this was not considered to be feasible.

5.2.2 Audit

The accreditation of auditors for the purposes of this proposed Standard, as well as the implementation of the audit system, is a matter for the State and Territory implementation authorities.

The proposed amendments to the Code require 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’. Auditing frequency, auditor competency and approval and the type of audit were raised in submissions. These issues and other auditing related issues are matters for the States and Territories.

6. Regulatory Options

At Initial Assessment two regulatory options were posed for this Proposal;

- 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 as defined by Standard 3.2.1 for food service, whereby potentially hazardous food is served to vulnerable populations as defined by Standard 3.2.1

These two options have been amended to reflect the adoption of the proposed Standard 3.3.1 rather than providing an amendment to the existing Standard 3.2.1. The new options read as follows:

- Option 1 to maintain the status quo and not adopt Standard 3.3.1 to apply food safety management systems to potentially hazardous food supplied to vulnerable persons.
- Option 2 to adopt Standard 3.3.1 to mandate food safety management systems to food businesses that process potentially hazardous food specifically intended to be supplied to vulnerable persons.

Nine of the submissions received to the Initial Assessment Report supported Option 2 and one submission supported Option 1.

6.1 Option 1 – maintain the status quo

Option 1 means that no amendment is made to the *Code* to apply a requirement for food safety program to food businesses that process potentially hazardous food specifically intended 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 Guidelines to require food safety programs for food service, in which potentially hazardous food is served to vulnerable populations.

6.2 Option 2 – adopt Standard 3.3.1

Adoption of Standard 3.3.1 would mean that a food safety program would be a national requirement for food businesses that process potentially hazardous food specifically intended to be supplied to vulnerable persons.

This option would exclude food businesses that supply potentially hazardous food to less than six vulnerable persons. It also exempts fundraising events from the requirement for a food safety management system.

A food safety management system includes a food safety program as defined by Standard 3.2.1, or a food safety management system recognised by the relevant authority.

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 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.

The Office of Regulation Review (ORR) has assessed the regulatory impact analysis for 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 addressed⁹.

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.

⁹ ORR reference number 3339

7.1 Affected Parties

Only a small number of food businesses that process potentially hazardous food for aged care facilities currently have food safety programs. Ninety-five per cent of aged care facilities do not have a food safety program (The Allen Consulting Group, 2002b). The situation is expected to be similar in both childcare centres, DMOs and hospitals (except in Victoria where food safety programs are already mandatory in these type of food businesses).

8. Consultation

8.1 Written Submissions

A total of ten submissions were received in response to the Initial Assessment Report from industry, government regulators and consumers. Nine of the submissions support the Proposal. Submissions were received from the following:

- Correct Food Systems
- Queensland Public Health Services
- South Australian Department of Health
- New South Wales Food Authority
- Meals on Wheels South Australia
- New Zealand Food Safety Authority
- Food Technology Victoria
- Australian Food and Grocery Council
- ACT Health Protection Services
- Western Australian Food Advisory Committee

A summary of the issues raised in these submissions is provided at Attachment 3.

8.2 Other Consultations

In addition to the call for written submissions, FSANZ established a stakeholder advisory group to assist in collecting information and analysing issues. The organisations involved in this process are listed in Attachment 5.

8.3 Issues raised in submissions

The submission process raised issues included auditing, the interpretive guide, duplication with existing accreditation systems, the scope of the Proposal, definition of potentially hazardous food, the exclusion of family day care, hospital cafes, application to DMOs and the provision of support material. These issues have been addressed earlier in this report under section 5 and section 9.

8.4 Broad consultation

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

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 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, State and Territory Governments, the food industry and industry sectors affected by this Proposal.

8.5 World Trade Organization (WTO)

As member of the World Trade Organization (WTO), Australia is 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.

A WTO notification is not necessary for this Proposal due to its nature, as the services do not extend beyond Australia's borders.

9. Implementation

Following approval of the Final Assessment Report by the FSANZ Board, and if agreed to by the Ministerial Council, the proposed Standard 3.3.1 will be gazetted. Food businesses will be required to comply with the Standard within two years from the date of gazettal.

9.1 Tools and other support

In order to minimise costs associated with the initial preparation of a food safety program, particularly for smaller businesses, a number of tools (e.g. templates) have been developed or are under development by DoHA and States and Territories, to assist businesses that may be required to have food safety programs under this Proposal.

A template to assist the children's services sector develop and implement food safety programs has been developed and finalised. A reference group consisting of representatives from childcare associations and government guided the development of this template¹⁰. This project was funded by DoHA.

In addition, DoHA is funding a project to develop 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 representatives¹¹.

¹⁰ 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.

¹¹ 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.

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. This project currently includes the development of a template for food safety programs, and a video and poster set.

The template is being developed in modular form to allow DMOs that provide different services, such as those that prepare meals only or reheat meals and deliver only to develop a tailored food safety program using the modules that apply to their operation. Queensland Health is managing the project with guidance from a steering committee¹².

The video and poster set aim to provide guidance on complying with Standard 3.2.2 and 3.2.3 in a form that is easy to understand. When these resources are finalised, expected in 2005, DoHA will provide details on availability. Copies of the video and poster set will be distributed to all DMOs in Australia.

9.2 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.

FSANZ also intends to develop an appendix to the guide that will outline details that will be specific for food businesses that provide potentially hazardous food to vulnerable populations.

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. A draft guide will be trialled with enforcement agencies in mid 2005.

10. Conclusion and Recommendations

Food safety programs are calculated in the Allen Report to have a median benefit of \$339 million per annum for the Australian population, based on a 15% reduction in food-borne illness.

¹² Representatives from the City of Melville (Western Australia), Banyule City Council MOW (Victoria), MOW (SA) Incorporated (Southern Australia), Australian Red Cross MOW (Tasmania), New South Wales & Bathurst MOW (New South Wales), Queensland MOW (Queensland), Department of Health South Australia, Redland Shire Council, Australian Institute of Environmental Health, Australian Institute of Food Science and Technology, Statewide Health and Community Services Branch, Food Standards Australia New Zealand, Australian Government Department of Health and Ageing, Queensland Health – Brisbane Northside Public Health Unit

This Proposal is specifically targeted at food businesses that process potentially hazardous food that is specifically intended to be served to vulnerable persons. These vulnerable persons are generally at a higher risk of contracting food-borne illness as well as suffering from prolonged illness and more severe consequences than the general population. The total cost of food-borne illness associated with vulnerable populations is estimated to be \$75 million per annum (Food Science Australia and Minter Ellison Consulting, 2002).

Small food businesses that process potentially hazardous food for five or less people and family day care are proposed to be excluded from these requirements.

FSANZ recommends the amendment of the Code to include Standard 3.3.1. This Proposal is consistent with the research conducted by DoHA and with the Ministerial Guidelines.

10.1 Statement of Reasons

At Draft Assessment FSANZ recommends that the *Food Standards Code* be amended to mandate food safety management systems for food businesses that process potentially hazardous food specifically intended to be supplied to vulnerable persons for the following reasons:

- The Ministerial Council, on 12 December 2003, made a decision that food safety programs should be mandated for specific high-risk sectors of the food industry, as set out in the Ministerial Policy Guidelines (see Attachment 6).
- The National Risk Validation Project concluded that food service to vulnerable (sensitive) populations was the highest risk sector of the food industry.
- The Allen Report on the costs and efficacy of introducing food safety programs concludes that the benefits for high-risk businesses outweigh the costs of implementing, utilising and auditing a food safety program.
- The proposed amendments to the Code are consistent with the section 10 objectives of the FSANZ Act.
- Victoria currently requires food safety programs for food service to vulnerable populations; the proposed amendments to the Code would promote national consistency by providing a national requirement.
- Compliance with the proposed amendments to the Code should reduce the number of food poisoning incidents in vulnerable population groups.
- The proposed amendment is an improvement on the current regulatory requirements, as it requires a system that is initiated by the food business and provides a preventative approach to food safety management that allows enforcement agencies to see, through audit, compliance with the program and hazard control measures.

11. Closing Remarks

This Draft Assessment Report provides a second and final formal opportunity for stakeholders to comment to FSANZ on the information, data and proposed Standard 3.3.1 to FSANZ regarding the mandatory application food safety management systems to food businesses that process potentially hazardous food specifically intended to be supplied to vulnerable persons. FSANZ welcomes and encourages stakeholder input.

The comments, information and data provided during consultation will be considered during the development of the Final Assessment Report.

Attachments

1. Draft variation to the *Australia New Zealand Food Standards Code*
2. Standard 3.2.1 – *Food Safety Programs*
3. Summary of submissions
4. Scope of Proposal
5. Advisory Group members
6. Ministerial Policy Guidelines of Food Safety Management in Australia
7. References

Draft variation to the *Australia New Zealand Food Standards Code*

The Australia New Zealand Food Standards Code is varied by inserting after Standard 3.2.3

STANDARD 3.3.1

**FOOD SAFETY PROGRAMS FOR FOOD SUPPLIED TO VULNERABLE PERSONS
(AUSTRALIA ONLY)**

Purpose and commentary

This Standard requires food businesses that process certain types of food specifically for supply to vulnerable persons (children of four years of age or less, persons of seventy years of age or more, pregnant persons and those who are immuno – compromised) to implement a documented and audited food safety management system.

Food businesses that specifically process potentially hazardous food for hospital patients, aged care recipients, children in child care centres and vulnerable people receiving other services or delivered meals will generally fall within the requirements of this Standard, provided they process food intended for six or more vulnerable persons.

Table of Provisions

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Clauses

1 Application

(1) This Standard applies to food businesses that process potentially hazardous food specifically intended to be supplied to six or more vulnerable persons.

(2) To avoid doubt, in this Standard, ‘potentially hazardous food’ does not include pasteurised milk or soymilk.

Editorial note:

‘Process’ in relation to food is defined in Standard 3.2.2 as an activity conducted to prepare food for sale including chopping, cooking, drying, fermenting, heating, pasteurising, thawing and washing, or a combination of these activities.

‘Potentially hazardous food’ is defined in Standard 3.2.2 as 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.

2 Interpretation

(1) Unless the contrary intention appears, the definitions in Parts 3.1 and 3.2 of this Code apply in Standard.

(2) In this Standard -

vulnerable person means a person who is –

- (a) four years of age or less; or
- (b) pregnant; or
- (c) 70 years of age or more; or
- (d) immuno-compromised.

immuno-compromised person means a person whose immune system is functioning in an abnormal or incomplete manner.

3. Food safety management system

(1) A food business to which this Standard applies must implement a documented food safety management system.

(2) A food business is taken to comply with subclause (1) if it implements –

- (a) Standard 3.2.1; or
- (b) any other equivalent food safety management system recognised by the relevant authority.

(3) Clause 6 of Standard 3.2.1 (exemption for fund raising events) applies for the purposes of this clause.

Editorial note:

‘Relevant authority’ is defined in Standard 1.1.1 and means the authority responsible for the enforcement of the Code.

Standard 3.2.1 – Food Safety Programs

STANDARD 3.2.1

FOOD SAFETY PROGRAMS

(Australia only)

Purpose

This Standard is based upon the principle that food safety is best ensured through the identification and control of hazards in the production, manufacturing and handling of food as described in the Hazard Analysis and Critical Control Point (HACCP) system, adopted by the joint WHO/FAO Codex Alimentarius Commission, rather than relying on end product standards alone. This standard enables States and Territories to require food businesses to implement a food safety program based upon the HACCP concepts. The food safety program is to be implemented and reviewed by the food business, and is subject to periodic audit by a suitably qualified food safety auditor.

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- 1 Interpretation
- 2 Application

Division 2 — Food safety programs

- 3 General food safety program requirements
- 4 Auditing of food safety programs
- 5 Content of food safety programs
- 6 Fund raising events

Division 1 — Interpretation and application

1 Interpretation

In this Standard -

auditing frequency means the most recently determined frequency of auditing determined by the appropriate enforcement agency, or a food safety auditor, in accordance with the Act.

food safety program means a food safety program that satisfies the requirements of clause 5.

food safety auditor means a person approved as a food safety auditor under the Act as a person competent to audit the relevant class of food business.

Editorial note:

Jurisdictions may approve environmental health officers, private contractors, or a mixture of the two as food safety auditors.

monitoring includes checking, observing or supervising in order to maintain control.

2 Application of this Standard

(1) This Standard applies to food businesses in Australia in accordance with Standard 3.1.1 - Interpretation and Application and subclause (2).

(2) This Standard applies to all food businesses that are determined by the appropriate enforcement agency under the Act to be within a priority classification of food business from the commencement date for that priority classification of food business.

Editorial note:

Under the Act, the appropriate enforcement agency must determine the priority classification of individual food businesses.

Jurisdictions may determine the mechanism by which a priority classification system and date of commencement is established, i.e. by regulation or declaration.

Division 2 — Food safety programs

3 General food safety program requirements

A food business must:

- (a) systematically examine all of its food handling operations in order to identify the potential hazards that may reasonably be expected to occur;
- (b) if one or more hazards are identified in accordance with paragraph (a), develop and implement a food safety program to control the hazard or hazards;
- (c) set out the food safety program in a written document and retain that document at the food premises;
- (d) comply with the food safety program; and
- (e) conduct a review of the food safety program at least annually to ensure its adequacy.

4 Auditing of food safety programs

A food business must:

- (a) ensure that the food safety program is audited by a food safety auditor at the auditing frequency applicable to the food business;

- (b) make the written document that sets out the food safety program, and the appropriate records referred to in paragraph 5(f), available to any food safety auditor who has been requested to conduct an audit of the food safety program; and
- (c) retain copies of all written reports of the results of all audits of the food safety program conducted by a food safety auditor within the last four years, for inspection upon request by a food safety auditor who audits the food safety program or an authorised officer.

Editorial note:

ANZFA has developed food safety auditor approval criteria for food safety auditors in conjunction with the States and Territories.

5 Content of food safety programs

A food safety program must:

- (a) systematically identify the potential hazards that may be reasonably expected to occur in all food handling operations of the food business;
- (b) identify where, in a food handling operation, each hazard identified under paragraph (a) can be controlled and the means of control;
- (c) provide for the systematic monitoring of those controls;
- (d) provide for appropriate corrective action when that hazard, or each of those hazards, is found not to be under control;
- (e) provide for the regular review of the program by the food business to ensure its adequacy; and
- (f) provide for appropriate records to be made and kept by the food business demonstrating action taken in relation to, or in compliance with, the food safety program.

6 Fund raising events

A food business does not have to prepare a food safety program in accordance with this Standard in relation to fundraising events conducted by the food business, that is, events that raise funds solely for community or charitable causes and not for personal financial gain.

Summary of Submissions

Initial Assessment Report: P288 Vulnerable Populations.

- A Total of ten submissions were received. Nine of the submissions support the Proposal.

Submitter	Issue
Gary Kennedy Correct Food Systems	Supports amending Standard States that only qualified auditors should be able to audit food safety programs.
Queensland Public Health Services	Support amending Standard 1. Suggest the following need to be risk assessed: <ul style="list-style-type: none"> • Baby bottles prepared at home compared to prepared at facility compared to supplied breast milk. • Fruit and vegetables – whole or pre-cut at home compared to those being prepared at the facility. Supplied on a platter – risk may be shared. • Food supplied by family/ facility – leftovers as compared to pre-packaged goods as compared to food prepared at the facility. Concern that day care is more interested in preventing burns then reheating food to correct temperatures. • Cooking classes in day care 2. The interpretive guide to 3.2.1 needs to be in plain English. 3. Support an initial auditing frequency of one every six months and that the frequency be performance based 4. Duplication of auditing requirements needs to be addressed where possible existing certification and accreditation should be recognised.

SA Department of Health	<p>Supports the Proposal</p> <p>Definition needs to clarify whether the following are included:</p> <ol style="list-style-type: none"> 1. Cafes and kiosks that operate in hospitals and aged care facilities. 2. Delivered meals organisations that do not prepare food but deliver food prepared by others to clients. <p>Suggest that both of these are not warranted to be included within the definition.</p> <ol style="list-style-type: none"> 3. Supports the potential for combining audits with existing accreditation arrangements. 4. Concerned about the impact of auditing on volunteer organisations both by cost and volunteers not comfortable with the process. Suggest that FSANZ develops a fact sheet that explains how audits are conducted and how staff may be involved.
NSW Food Authority	<p>Supports the Proposal</p> <p>Supports an activity based definition of vulnerable populations.</p> <ol style="list-style-type: none"> 1. Clarification of the scope of vulnerable is needed – does it include specialist medical and other treatment centres such as day procedure centres, drug and alcohol rehabilitation centres. 2. Need to clarify the exemption for family day care, all family day care is government funded (current definition excludes non-government funded family day care) – In NSW there is a similar home based care service that should be included in the definition of family day care. 3. The definition of ‘potentially hazardous foods’ can lead to some problems in implementation with child care centres only providing milk and snacks such as fruit potentially falling within the definition. 4. Investigation of existing accreditation system is essential.
Meals on Wheels SA	<ul style="list-style-type: none"> • Do not support the Proposal for DMOs. • Support the role of government as third party auditors, combined with second party auditing. • Increase in compliance and auditing costs would have to be met by government.
NZFSA	<ul style="list-style-type: none"> • The Proposals apply to Australia only. This should be made clear in the executive summary not only in the body of the report.
Food Technology Victoria	<ul style="list-style-type: none"> • Supports the Proposal.

Australian Food and Grocery Council	<ul style="list-style-type: none"> • Support the Proposal <ol style="list-style-type: none"> 1. Considers that all high risk businesses should be required to have a food safety program and the cost benefit ratio should not be a consideration. A FSP should be required irrespective of size. 2. Suggests that a way to minimise costs is for enforcement authorities to conduct audits at no cost to the business.
ACT Health Protection Services	<p>Issues associated with the definition include:</p> <ol style="list-style-type: none"> 1. Enforceability 2. What is a vulnerable population - how large or small does a group need to be to be considered vulnerable? 3. Why should family day care be excluded? 4. Further work on existing accreditation schemes is needed. 5. Suggest that an interpretive guide should be produced for a wider target audience than enforcement officers. 6. The provision of support material is essential to reducing costs to businesses.
Western Australian Food Advisory committee	<p>Agree to the definition of vulnerable populations The sector should be provided with food safety training information and materials to increase the competency of food handling staff.</p>

Scope of Vulnerable Populations

Included	
Aged Care	<p>The proposed requirement for food safety programs will apply to food businesses that process potentially hazardous food to be supplied to all private or government funded services providing aged care services. This would include all residential, day and respite care centres.</p> <p>The aim is to cover facilities that routinely serve consumers who are:</p> <ul style="list-style-type: none"> • Aged over 70 • Immuno-compromised for example some aboriginal and Torres Strait Islander groups are more susceptible to age and lifestyle related diseases at an earlier age than the general population. Services that cater for their needs would be captured. <p>The requirement only applies to aged care with a clientele of more than five vulnerable persons per day.</p> <p>Food businesses that process potentially hazardous food that is provided to aged care facilities, such as external caterers, are covered by this requirement.</p>

<p>Hospitals</p>	<p>The proposed requirement for food safety programs will apply to the food business that processes food for service in all public and private hospitals with a clientele of more than 5 vulnerable persons.</p> <p>Some types of hospitals may be excluded from this requirement because they do not provide food to vulnerable persons; an example of this may be psychiatric hospitals.</p> <p>The requirement does not apply to hospital cafes serving to the general population even if some patients eat at the facilities. The majority of the food that is processed by this type of establishment is not specifically intended to be supplied to vulnerable persons such as patients but to hospital staff and visitors.</p> <p>Food Businesses that process potentially hazardous food that is provided in other healthcare facilities such as drug and alcohol rehabilitation centres, chemotherapy treatment centres, and other healthcare facilities where the clientele consists of six or more vulnerable persons would also be captured by the proposed Standard.</p> <p>External caterers that prepare meals for hospitals also would be required to have a food safety program.</p>
<p>Delivered Meals Organisations (DMOs)</p>	<p>The proposed requirement for a food safety program will apply to all food businesses that process food, principally for aged or disabled persons, or those persons who for a variety of reasons, are unable to prepare meals for themselves.</p> <p>The definition of process food is such that it does not cover transport of food (this is covered in Standard 3.2.2) and as such the requirement for a food safety program would exclude facilities that deliver (or transport) only.</p> <p>DMOs that provide meals to five or less vulnerable persons are excluded from the requirement.</p>
<p>Child Care centres providing meals</p>	<p>The requirement for a food safety program will apply to food businesses that process potentially hazardous food for childcare facilities that serve more than five children aged four years or less.</p> <p>The requirement would exclude childcare centres where the only potentially hazardous food served is pasteurised milk or soymilk.</p>

Excluded	
Family Day Care/ Home Based Care	<p>Family day care/home based care is excluded from the requirement to have a food safety program.</p> <p>Family day care is defined as home based care settings providing care for a maximum of four children under school age, with a total maximum of seven children (this includes the carers own children).</p> <p>These businesses are not included in the requirements to have a food safety program because they process potentially hazardous food for less than six children aged four years and under.</p>
A clientele of five people or less	<p>Food businesses that process potentially hazardous food for less than six vulnerable persons are not included in the requirement for a food safety program.</p>

Advisory Group Members

NON-GOVERNMENT

Aged Care Services
Australian Nursing Homes and Extended Care Association Ltd
Early Childhood Australia
Institute of Hospitality in Health Care
National Association of Community Based Children's Services
National Childcare Accreditation Council Inc.
National Seniors Association
NSW Meals on Wheels Association
The Aged Care Standards and Accreditation Agency Ltd
The Australian Council on Healthcare Standards
Australian Institute of Environmental Health

GOVERNMENT

Commonwealth Department of Health & Ageing
NSW Food Authority
Queensland Health
WA Department of Health
SA Department of Health
New Zealand Food Safety Authority

Ministerial Policy Guidelines on Food Safety Management in Australia: Food Safety Programs

Developed by the Food Regulation Standing Committee

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1. Purpose

These policy guidelines address food safety management in Australia and were initiated in response to a request by the Australia New Zealand Food Regulation Ministerial Council (Ministerial Council) for sound data in relation to food-borne illness, and information about the cost and impact of mandatory food safety programs.

The Board of Food Standards Australia New Zealand (FSANZ) will consider amendments to the *Food Standards Code*, having regard to these policy guidelines and following the process outlined in the *Food Standards Australia New Zealand Act 1991*¹³.

The Principles in these policy guidelines are designed to be consistent with the statutory objectives and requirements of FSANZ as outlined in the *Food Standards Australia New Zealand Act 1991*, and to safeguard consumers from food-borne illness without creating undue impost on industry or community groups.

2. Policy Principles

In addressing the particular policy issues of food safety management in Australia the following Principles apply.

6. 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.
7. That risk profiling be used to classify food businesses or food industry sectors in Australia on the basis of risk.
8. At a minimum, Food Safety 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.
9. 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.
10. That support is made available to community groups and small business to assist them meet their legislative requirements.

3. Mandatory introduction of Food Safety Standard 3.2.1 for identified highest risk areas

In keeping with the concept of basing food safety requirements to the risk posed, evidence including data from OzFoodNet, findings from the *Food Safety Management Systems - Costs, Benefits and Alternatives* report and the *National Risk Validation Project* provide a strong case for four food industry sectors to introduce food safety programs. Consequently Food Safety Standard 3.2.1 *Food Safety Programs* should be modified to include the following sectors:

1. food service, whereby potentially hazardous food is served to vulnerable populations¹⁴;
2. producing, harvesting, processing and distributing raw oysters and other bivalves;

¹³ *Food Standards Australia New Zealand Act 1991* - <http://scaleplus.law.gov.au/html/pasteact/0/31/top.htm>

¹⁴ Food Safety Standard 3.2.2 defines potentially hazardous food as - Potentially hazardous food 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.

3. catering operations serving food to the general public; and
4. producing manufactured and fermented meat.

3.1 Food service, whereby potentially hazardous food is served to vulnerable populations¹⁵

Two issues need to be considered when assessing the vulnerability of certain population groups to food-borne disease. The susceptibility or frequency of infection in specified population groups only tells half the story. Equally as important is the sensitivity of these groups to the infection, which is represented by the severity of the outcome once infected. For example, two population groups may be equally susceptible to infection from a certain pathogen, however hospitalisation rates or mortality may be higher in one group because once infected, they experience more severe or prolonged disease. Clearly this group must be considered to be more vulnerable to food-borne disease.

Analysis of the literature identified the following as sensitive populations:

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

It also highlighted the vulnerability of residents of nursing homes, hospitals and aged care facilities and clients of organisations which provide delivered meals, such as Delivered Meals Organisations.

On the basis of the sensitivity of the populations they serve, the following sectors have been identified:

- aged care;
- hospitals;
- nursing homes;
- organisations delivering to housebound people; and
- child care centres providing meals.

Due to the large variation in size and type of organisations that are included in this sector, flexibility in auditing application and frequency is required. Where accreditation systems already exist for sectors such as child and aged care, work should 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. If systems which are deemed equivalent can be recognised, a separate infrastructure for the monitoring and auditing of food safety programs may not be required.

3.1.1 Exclusions

The public consultation highlighted some confusion over the target group intended to be covered by the term ‘sensitive population’. Several respondents thought that any restaurant or take-away establishment that served a pregnant woman would be required to implement Standard 3.2.1. This was not the intent, and accordingly, two changes were made to the title. It now reads ‘Food service, whereby potentially hazardous food is served to vulnerable populations’.

¹⁵ Food Safety Standard 3.2.2 defines potentially hazardous food as - Potentially hazardous food 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.

Due to the low benefit to cost ratio, non-government funded ‘family day care’ are not included in the proposed definition.

Businesses that serve potentially hazardous food to vulnerable populations and have a clientele of five people or less should be excluded from the requirement of Standard 3.2.1, as they would suffer an unwarranted cost and administrative burden.

3.2 Raw ready to eat seafood: raw oysters and other bivalves

The epidemiological data used in the *National Risk Validation Project* were principally derived from outbreaks associated with oysters rather than raw fish. For this reason, the focus in the raw, ready-to-eat seafood area is confined to raw oysters and other bivalves.

The Draft Assessment process for the Primary Production and Processing Standard for seafood currently under development, will address the proposed approach for oysters and bivalves. The further development of the standard on oyster and bivalves will be consistent with the Ministerial decision and directions to FSANZ by the Ministerial Council.

It should be noted that the current definition of ‘food business’ in the *Food Standards Code* and the Model Food Act specifically excludes primary production. However, the Ministerial Council previously agreed that the Primary Production and Processing Standards would become Chapter 4 of the *Food Standards Code*.

By agreeing to the inclusion of the Primary Production and Processing Standards, the Ministerial Council has signalled that jurisdictions will have to amend their relevant legislation to incorporate reference to primary production. An amendment to the *Food Standards Code* will also be required.

3.2.1 Exclusions

Due to the low benefit to cost ratio that was identified, eating establishments and other vendors who sell raw oysters and other bivalves would not be included in this category. That is, the requirement to adopt Standard 3.2.1 will cease at the ‘back door’ of a retailer’s premises.

3.3 Catering operations serving food to the general public

A definition of catering was developed in consultation with government and industry representatives with the aim that it:

- encapsulates the business types that Food Science Australia attributed to outbreaks in ‘catering’ settings;
- is enforceable;
- does not unfairly impinge on small business; and
- does not capture businesses which may be highest risk, but where there is not a strong case for food safety programs on a benefit to cost ratio.

The key areas of concern were:

- a) catering operations where there is a transport step between the preparation of the food and its sale; and
- b) large caterers and function centres where a large amount of food is prepared and served at the same time.

The proposed definition of catering is:

Businesses under this category that should have Food Safety Programs in place are:

- **those which serve potentially hazardous food at a location other than where it has been prepared; (“serve” – set out or present food for those about to eat it)**

OR

- **those whereby potentially hazardous food is provided simultaneously to all customers where the seating capacity of the food premises is 50 people or more.**

FRSC has agreed that the seating capacity figure for catering operations should be set at 50, to ensure an appropriate, risk based proportion of potential outbreaks of food-borne illness will be prevented.

Evidence from the *National Risk Validation Project* indicates that setting the seating capacity at 50 persons will potentially prevent 65% of food-borne illness outbreaks arising with catering operations.

Seating capacity refers to the maximum seating capacity of the catering operation.

As part of the standard development process, FSANZ should ensure that the final definition of catering and all other definitions are clear and easily understood by affected stakeholders. The intent of refining the final definition of catering is not to extend the requirement for food safety programs to restaurants.

Victoria has introduced food safety programs for community and non-profit organisations and important lessons can be learned from this exercise. Resources have also been created by a number of government agencies to assist such groups. Additionally, a project is currently being undertaken to assist individual Delivered Meals Organisations improve their organisations’ food safety practices over time.

3.3.1 Exclusions

While eating establishments¹⁶ were also identified as being in the highest risk group, the benefit to cost ratio was not considered significant enough to justify the implementation of this Standard.

Restaurants, even if they occasionally conduct functions where food is served simultaneously to 50 people or more, are not included in the definition, as it could not be justified by the benefit to cost ratio. It is recommended that such businesses introduce a voluntary food safety program.

Although the *National Risk Validation Project* also identified buffets as very high risk, restaurants with a buffet service are not included in the definition, as they cannot be justified by the benefit to cost ratio. Under the definition of catering, food businesses offering buffets are only included if:

- potentially hazardous food is served at a location other than where it has been prepared;
or

¹⁶ The *National Risk Validation Project* characterised Eating Establishments thus – “The intention is that these are direct cook-serve operations, home delivery/takeaway of hot foods anticipated for immediate consumption. On the basis of similar modes of operation this would include restaurants, cafes, hotel/motel restaurant, clubs, takeaway – home delivery and fast food businesses”.

- food is provided simultaneously to all customers, and the seating capacity of the food premises is 50 people or more.

Although community or charitable fund raising events that undertake catering are included in the identified highest risk group, they are specifically excluded from the provisions of Standard 3.2.1. As part of the standard development process, consideration will be given to alternative food safety management options that maybe more appropriate for these groups.

3.4 *Producing manufactured and fermented meat*

During the process of developing the Policy Guidelines, a proposal to amend Standard 1.6.2 of the *Food Standards Code* in relation to the processing of uncooked comminuted fermented meat (UCFM) products has been approved by Ministers and subsequently gazetted. As such, a food safety program approach to the management of the public health and safety risks posed by these products has already been established.

An amendment has been made to Standard 1.6.2, making reference to Standard 3.2.1.

However, the amendments to Standard 1.6.2 apply only to UCFMs and not to manufactured meat products. Consequently, a separate Application or Proposal will need to be made for FSANZ to develop a standard that will require the manufactured meat sector to introduce Standard 3.2.1.

It should be noted that since the mid 1990's, regulatory authorities and larger retail companies have required implementation of HACCP-based food safety programs for meat processing through to the meat retail sector.

3.5 *Timeframe for the introduction of Food Safety Standard 3.2.1*

The specified end date for the national implementation of mandatory food safety programs for highest risk sectors where the benefit to cost ratio justifies implementation as identified in these guidelines, will be two years after the amendment to the *Food Standards Code* is gazetted.

4. Monitoring and Review

National monitoring and surveillance of food-borne illness (such as surveillance currently provided by OzFoodNet – Australia's enhanced food-borne illness surveillance network) will provide an indication of any change in food-borne illness following the introduction of Standard 3.2.1. OzFoodNet investigations will not only assess trends in relation to the incidence of food-borne illness in the future, but case-control studies and outbreak investigations can highlight causes of problems and whether a food safety management intervention could have prevented a food safety failure. In time, a database which identifies breakdowns in food safety in particular industry sectors (or products) will provide the evidence to guide future policy formation and enforcement priorities. Other sources, such as the Australian Food Surveillance Network will also be utilised.

It is envisaged that the risk profiling process and the risk categories and associated policy will be reviewed by FRSC two years after implementation of Standard 3.2.1 by States and Territories.

5. The Way Forward

These Policy Guidelines will be used to form the parameters within which the Board of FSANZ will consider amendments to the *Food Standards Code*, following the process outlined in the *Food Standards Australia New Zealand Act 1991*.

This will represent the start of a process whereby FSANZ will undertake work involving two rounds of public consultation to clearly articulate what changes to Standard 3.2.1 will be required.

The standard development process will further investigate and clarify a number of issues. This work will include, for example, detailed information to clearly identify 'who is in and who is out', refining the definition of catering, and potential exclusions from food safety programs.

The document entitled "Principles and Protocols for Setting Ministerial Council Policy Guidelines" (<http://www.foodsecretariat.health.gov.au/pdf/principles.pdf>) aims to clarify the scope of policy guidelines and the process for their development. The document clarifies the respective roles of the policy departments and the regulatory agencies in the various jurisdictions. The then Australia New Zealand Food Standards Council (the Ministerial Council) endorsed this document on 24 May 2002. However, the Ministerial Council noted that further work may be necessary as more experience is gained through the development of policy guidelines.

The Food Regulation Agreement gives FSANZ the responsibility to determine appropriate standards, within the policy framework set by the Ministerial Council. Section 10(2)(e) of the *Food Standards Australia New Zealand Act 1991* states that in developing or reviewing food regulatory measures and variations of food regulatory measures, FSANZ must have regard to any written policy guidelines formulated by the Ministerial Council. FSANZ is required to publish any such guidelines on the Internet.

Attachment 1: Supporting information

Background

In October 1999, FSANZ recommended four national Food Safety Standards to Commonwealth, State, Territory and New Zealand Health Ministers (then meeting as the Australia New Zealand Food Standards Council). The following three standards¹⁷ were adopted on 24 August 2000 and are being progressively implemented by State and Territory governments:

- Food Safety Standard 3.1.1 *Interpretation and Application*
- Food Safety Standard 3.2.2 *Food Safety Practices and General Requirements*
- Food Safety Standard 3.2.3 *Food Premises and Equipment*

Health Ministers recommended that the Council of Australian Governments (COAG) defer endorsement of Food Safety Standard 3.2.1 *Food Safety Programs*, and that further studies needed to be undertaken on the costs and efficacy of food safety programs.

In the interim, Standard 3.2.1 was gazetted in November 2000 as a model standard that could be adopted by State and Territory Governments.

A food safety program requires businesses to:

- identify potential food safety hazards;
- implement and document measures that will control those hazards; and
- keep written records to demonstrate ongoing compliance with the food safety program to an approved food safety auditor.

Prior to the October 1999 meeting of Health Ministers, some sectors of the food industry, primarily the food-service sector and community groups, raised concerns that the proposed Standard 3.2.1 would represent a significant cost impost and would not reduce food contamination or food-borne illness.

In light of these concerns, Health Ministers agreed to a proposal that the Commonwealth work with States and Territories to undertake research and investigations to provide sound data about food-borne illness, and the cost and impact of mandatory food safety programs. Such data would enable better-informed decisions about whether food safety programs should be mandated and if so, what form they should take.

Health Ministers also asked the Commonwealth to use some of the funding for studies and evaluation to assist businesses with implementation of the food safety program requirement in those jurisdictions which proceeded with the early adoption of this Standard.

This has been the case in Victoria where, in addition to complying with the new national standards, most Victorian businesses have to submit a food safety program under a two-class system.

- All Class 1 food premises (Hospitals, Nursing Homes, Child Care Centres and Meals-on-Wheels Organisations) are required to have audited food safety programs under the Victorian Food Act.

¹⁷ A comprehensive description of the standards is available in the publication *Safe Food Australia* available on the FSANZ web site <http://www.foodstandards.gov.au/mediareleasespublications/publications/safefoodaustralia2nd519.cfm>

- Class 2 food premises (which are defined as all other food premises other than Class 1 or retailers of low risk prepackaged food) can choose to either develop their own independent food safety program and be third party audited or develop a food safety program from a State registered template and undergo a compliance check by local government rather than an audit.

The Commonwealth, through the Population Health Division within the Department of Health and Ageing, initiated 15 projects in six key areas designed to complement each other and meet the expectations of Health Ministers. The key areas are:

- determining the incidence and causes of food-borne illness (OzFoodNet);
- assessing the costs, benefits and justification for food safety programs;
- developing resources to assist local, state and territory governments implement, interpret and enforce the national food safety standards consistently;
- developing resources to assist charities, not-for-profit groups and volunteer organisations make safe food;
- developing resources to assist industry implement food safety programs and meet the national food safety standards; and
- providing information to consumers on good food safety practice.

Projects undertaken as part of the program of work were not developed in isolation. In February 2000, the Department of Health and Ageing convened a Food Safety Forum to shape a work program that would meet the needs of industry, government and consumers. Participants included representatives of peak food industry and public health bodies, Commonwealth agencies, consumer groups, state and territory health authorities and food safety research organisations. A second Food Safety Forum was convened in February 2001 to seek further input into the work program.

To ensure the work program met the needs of Commonwealth, State and Territory jurisdictions, the Department of Health and Ageing convened the National Food Safety Projects Steering Committee. This Committee meets regularly and has overseen the Department's food safety projects. It consists of representatives from all State and Territory Health Departments, FSANZ, the Australian Government Department of Agriculture, Fisheries and Forestry and Safe Food Production NSW.

In addition, Steering Committees and/or Project Management Groups have overseen each of the 15 projects, which comprise the work program. These committees had representatives from Commonwealth, State and Territory Governments and the food industry including Restaurant and Catering Australia, The Australian Hotels Association, and the National Child Care Association.

The program of work on food safety provides an evidence base for developing policy in relation to food safety regulation in Australia.

Three critical projects provide the evidence used to develop the current proposal:

- 1) evidence including data from OzFoodNet on the incidence of food-borne illness and its causes;
- 2) findings from the *Food Safety Management Systems - Costs, Benefits and Alternatives* report*; and

3) findings from the *National Risk Validation Project* report*.

Statement of the problem

Introduction

Food safety is an important aspect of population health. As ‘sight and smell’ are insufficient to evaluate the safety of food, consumers are not in a position to avoid unsafe products and there is broad community expectation of some degree of government intervention to secure a safe food supply. The impact to the consumer from a food safety failure can vary from unpleasant symptoms to serious long-term health consequences and even death. Impacts can also affect individual retailers and have wider economic costs that arise from loss of confidence in the safety of food.

The last decade has seen major reforms in the way that governments regulate. The food legislation, agreed to by all jurisdictions, exhibits many of these reforms in comparison to the legislative frameworks it replaces. It shifts both the legal paradigm and public and private expenditure towards prevention, rather than ensuring premises meet prescriptive standards, testing food already on sale, and reacting to outbreaks of food-borne illness.

Public Health Issues

A system of enhanced surveillance for food-borne illness is seen by the World Health Organization and many countries as an essential tool to help reduce food-borne illness. In Australia, enhanced surveillance for food-borne illness is undertaken by OzFoodNet, a collaborative project with State and Territory health authorities as part of the work program on food safety.

OzFoodNet, through the National Centre for Epidemiology and Population Health, conducted a national survey of gastroenteritis during 2001-2002¹⁸. Of the 17.2 million cases of gastroenteritis each year in Australia, there are 5.4 million cases that are **conservatively** estimated to be due to contaminated food, resulting in the loss of 6.5 million days of paid work. When the calculations used in the *Food Safety Management Systems – Costs, Benefits and Alternatives* report are adjusted for the most recent and more accurate estimation of food-borne gastroenteritis, the estimated cost to Australia is \$3.75 billion annually.

No robust work has been undertaken to estimate the amount of food-borne illness that is due to poor consumer food handling in Australia. The UK has estimated that 12% of food-borne illness is due to poor consumer handling.

Industry Issues

While food safety programs introduce a preventive approach to food safety, they do impose certain costs on both the food industry and the regulator, such as preparing the program and subsequent record keeping and auditing. In order to make soundly based decisions on whether to mandate food safety programs, it is necessary to understand the nature and magnitude of the costs, as well as the anticipated benefits resulting from improved food safety.

The cost of preparing and implementing a food safety program for business, especially small business has been a concern for some sectors of the food industry since they were first mooted by FSANZ in 1996.

* Both of these studies are available on the Department of Health and Ageing web site <http://www.health.gov.au/pubhlth/strateg/foodpolicy/pdf/alternatives.htm> and

<http://www.health.gov.au/pubhlth/strateg/foodpolicy/pdf/validation.htm>

¹⁸ The current burden of foodborne gastroenteritis in Australia, Summary paper, February 2003

The requirement for keeping written records and the time impost this places on owners and managers has been of particular concern. The food service sector has also questioned the efficacy of food safety programs in reducing food contamination and food poisoning.

To provide more information on the impact of mandatory food safety programs the Department of Health and Ageing commissioned a national study entitled *Food Safety Management Systems, Costs, Benefits and Alternatives*. In addition, the Department co-funded an initiative of the New South Wales Health Department, the *National Risk Validation Project*. These two studies examine food safety programs from different perspectives and should be read in conjunction with each other.

Impact analysis

Analysis of the mandatory introduction of Food Safety Standard 3.2.1

In preparing the *Food Safety Management Systems, Costs, Benefits and Alternatives* study, the Allen Consulting Group projected the costs and benefits of introducing a food safety management system that meets the outcomes of proposed Standard 3.2.1 across all food businesses.

Food businesses have historically incurred costs associated with food safety regulations. This must be taken into consideration in determining the baseline for the calculation of the incremental costs and benefits of suggested regulatory changes. The costs incurred have been in the order of \$200–600 million per annum Australia-wide, depending on the assumptions made about how much activity is directly attributable to the food regulations as opposed to being part of standard business practice.

Standards 3.1.1, 3.2.2 and 3.2.3 are designed to replace the regulation covering food safety in previous State and Territory regulations in a nationally consistent manner. There are additional requirements and costs in relation to:

- the up-front skills and knowledge costs in the order of \$16.4 million across all industries;
- (one-off) purchase of thermometers at a total industry cost of \$11.6 million; and
- ongoing costs of \$6.3 million per annum relating to changes in sanitising practices.

The compliance cost is relatively constant across industries except manufacturing and aged-care categories have a relatively low burden and the not-for-profit sector having a markedly higher burden.

These three standards were adopted on 24 August 2000 and are being progressively implemented by each State and Territory Government. If the standards are enforced, they are likely to have benefits in terms of reduced food-borne illness, as there will be improved practices in some of the key risk areas. This is likely to be the major source of benefits.

The consultant found that the introduction of Standard 3.2.1 and its requirement for food safety programs is a significant step up from the requirements of Standards 3.1.1, 3.2.2 and 3.2.3, and would require changes to business practices in a significant majority of small businesses.

The report by the Allen Consulting Group estimated that the costs of implementing Standard 3.2.1 would comprise:

- one-off aggregate development costs such as training and the development of the food safety program in the order of \$192.2 million, or an average of \$1,440 per business (with exemptions for primary industry and not-for-profit categories as per the current working of Standard 3.2.1);

- aggregate ongoing costs (including record keeping, program review and audit costs) in the order of \$235.5 million per annum or an average of around \$1,700 per business per annum; and
- additional costs to government in the order of \$10 million per annum for 10 years.

The report revealed that there are significant fixed costs associated with implementing a food safety program (Table 1). Many of the costs involve time rather than cash, nevertheless businesses would feel the burden of extra hours of work and related stress. Since the variable costs increased only slightly with the size of a business, the smaller the business, the larger the relative burden of the regulation. In addition, the report highlighted one area, family day care, which would be faced with a disproportionate burden due to lower annual revenues compared with other small businesses.

Table 1: Median cost drivers by industry category

<i>Category</i>	<i>Implementation Training and development per business (\$)</i>	<i>Ongoing Record keeping and review per business (\$p.a.)</i>	<i>Ongoing Audit cost per business (\$ p.a.)</i>
<i>Food Service</i>	1500	1600	133
<i>Transport</i>	1700	1200	133
<i>Retail</i>	1510	1230	133
<i>School Canteen</i>	740	1230	133
<i>Not-for-profit</i>	700	960	N/A
<i>Manufacturing</i>	1280	2693	133
<i>Primary Industry</i>	2100	1900	N/A
<i>Child Care</i>	1010	1485	133
<i>Aged Care</i>	2180	1540	133
<i>Family Day Care</i>	940	1400	133

No significant difference was found in costs between businesses in different States and Territories, though regional and remote businesses may face higher audit costs if travel time is reflected in audit charges, in addition to audit time.

The main benefits of food safety programs arise from reductions in food-borne illness. The consultant found that the benefits of introducing Standard 3.2.1 outweighed the cost for all but ‘low risk’ businesses. However, food safety programs are a ‘high cost and high benefit’ option. The consultant estimated that if Standard 3.2.1 were introduced across all businesses, it would take 10 years before the annual benefits outweigh the cost.

The size of any reduction in food-borne illness is hard to quantify and relates to the estimates and assumptions used to quantify:

1. the current level of food-borne illness and associated costs; and
2. the size of any decreases in food-borne illness attributable to food safety programs.

Food Science Australia estimate that adherence to Standard 3.2.2 could have prevented 41 of the 193 Australian outbreaks assessed in the *National Risk Validation Project*. A further 115 outbreaks could have been avoided if a robust food safety program was in place.

The most recent and conservative estimate of the incidence of food-borne illness (ie. single incidents and multi case outbreaks) in Australia is 5.4 million cases annually. Using this figure (minus 20% for cases caused by poor practices by consumers) indicates median level benefits of \$450 million per annum, which is based on a reduction in food-borne illness of only 15%.

There is evidence of other benefits, such as improved quality, reduced wastage, better staff awareness and morale and improved routine. While it is difficult to quantify these benefits, they are significant.

Risk Profiling

Food-borne illness remains a substantial economic and social cost to the Australian community. There is a range of measures, including legislation, that can make a significant reduction to the 5.4 million cases of food-borne illness annually without causing undue impost on the food industry.

The key is to match the degree of risk for specific food businesses that combinations of food type, processing, handling and clientele pose. This is where the concept of risk profiling provides the foundation for food safety management in Australia.

Risk Profiling is a process of initially evaluating a food safety problem, and its context, to identify its potential public health impact. By focusing on highest risk areas there is less impact to the overall food industry compared with a 'whole of industry' approach that would affect many more businesses.

The process for risk profiling food businesses has begun through the *National Risk Validation Project*, which used available data to identify areas of highest risk. If the concept of risk profiling is supported, further work will be undertaken to identify a valid process that is nationally applicable to classify all food businesses on the basis of risk.

As part of a framework based on classifying food businesses on the base of risk there is value in defining a lowest risk category of food business, which because of the nature of the food sold, would face little or no food safety inspections: for example, the sale of pre packaged confectionary by newsagents. This has the potential to lower the requirements for those businesses classified in the very low risk sector. It is proposed that work will also be undertaken in parallel to investigate legislative or other measures that may be put in place for identified levels of risk other than highest and lowest. Options other than audited food safety programs will be explored by FRSC in more depth in the future through a process that will involve further public consultation.

It should be noted that State and Territory jurisdictions currently have different food regulatory regimes and therefore there is a need to work closely with all jurisdictions to harmonise a national system for food safety management based on risk profiling.

Editorial note

The overall concept of risk profiling was strongly supported in the submissions and initial work is being undertaken by Food Science Australia to fully scope this project. Once this process is complete, additional draft policy guidelines, for legislative or other measures, will be prepared through an open and transparent process for Ministerial endorsement covering food safety management for businesses other than those identified as highest risk. These draft policy guidelines will also cover process and operational issues that relate to risk profiling and the potential for changes to risk categories. Any further regulatory policy guidelines need to demonstrate that they are necessary and that the cost/benefit is justified, which would be established through the usual Regulation Impact Statement process.

Risk Profiling: identifying highest risk processes

The *National Risk Validation Project* consisted of two pieces of work: one undertaken by Food Science Australia and the other by Minter-Ellison Consulting and the Atech Group.

Food Science Australia identified those food operations, which presented the highest risk, and conducted an assessment of the risks associated with these selected industries to determine the potential food safety risks to the consumer. The complementary report by Minter Ellison Consulting used data stemming from the Food Science Australia report to determine the cost of food-borne disease outbreaks associated with specific highest risk industries, and the cost and benefits of implementing food safety programs.

Food Science Australia reviewed epidemiological data from local and overseas sources to identify those businesses that were consistently linked to food-borne illness outbreaks. Using a mixture of Australian and overseas data, the three most frequently encountered causes of food-borne illness were found to be temperature misuse, inadequate handling and contaminated raw materials.

In undertaking the risk profiling analysis, Food Science Australia used three key factors to assign levels of risk: food operation, probability/frequency of illness in terms of amount of food consumed, and the severity of illness. The initial risk profiling was augmented by a detailed study of the epidemiology of reported food-borne illness in the last 10 years, to refine the risk profiling of business categories.

The *National Risk Validation Project* identified the following food businesses/sectors as being of highest risk in order of priority:

1. food service for sensitive populations;
2. producers, harvesters, processors and vendors of raw ready to eat seafood¹⁹;
3. catering operations serving food to the general population;
4. eating establishments; and
5. producers of manufactured and fermented meats²⁰.

Six other sectors/businesses also presented as being of very high risk but there was insufficient Australian data available to warrant their ranking at the same level as the above five business sectors, or include them in the cost benefit analysis of food safety programs.

These are:

- processed raw foods not treated listericidally²¹ by heat;

¹⁹ This category was later amended by FRSC to 'Raw ready to eat seafood: raw oyster and other bivalves to the back door of retailers' premises.

²⁰Consumption data for these products could not be calculated.

- fresh cut fruits and vegetables;
- unpasteurised fruit and vegetable juices;
- sprouts;
- processed foods treated listericidally by heat, but subject to potential recontamination during subsequent handling; and
- vegetables in oil.

As more data becomes available through OzFoodNet and other sources, such as the Australian Food Surveillance Network, there may be opportunities to reassess the risks these sectors pose in the future.

Analysis to assess the viability of the highest risk areas implementing Food Safety Standard 3.2.1

Table 2 shows the cost of implementing Standard 3.2.1 in highest risk industry sectors.

Table 2: Costs of implementing Standard 3.2.1 in highest risk industry

	<i>Initial costs</i>		<i>Ongoing costs (per year)</i>	
	<i>Cost per business (\$)</i>	<i>Total cost (\$M)</i>	<i>Cost per business (\$)</i>	<i>Total cost (\$M)</i>
<i>Hospital and Aged Care</i>	2,180	8.6	1,673	6.6
<i>Raw ready to eat seafood</i>	2,100	1.0	2,033	0.9
<i>Catering operations</i>	1,500	25.2	1,733	29.1
<i>Eating establishments</i>	1,500	67.6	1,733	78.1
<i>Processed meats</i>	1,280	0.1	2,826	0.3
<i>Childcare</i>	700	15.7	710	16.0

The cost of food-borne illness (on a per meal basis) varies widely across the industries that were identified as highest risk (Table 3). Using outbreak data (only) from the epidemiological risk assessment, the report found that the aggregate costs associated with food-borne illness outbreaks in Australia were in excess of \$1.6 billion²² annually. The cost of food-borne illness per meal was derived by dividing the total annual cost of food-borne illness for a particular sector by the estimated number of meals consumed from that sector.

The benefit, which is derived from Food Science Australia’s work, assumes a 70% reduction of outbreaks should food safety programs be introduced. This was based on outbreak data where it was reasonable to assume that the cause of illness would have been detected and remedied by measures put in place under a food safety program. This is in keeping with the work undertaken by the Allen Consulting Group, that found that the benefits from Standard 3.2.1 outweigh the costs under a range of scenarios and would stay positive if a minimum of 14% reduction of food-borne illness could be achieved.

²¹ Treated listericidally means any process (e.g. fermentation, heat) which prevents growth and results in a reduction of pathogenic *Listeria* to levels which pose no risk to public health and safety.

²² Subsequent to the completion of the report, OzFoodNet data has shown that the incidence of foodborne illness is significantly higher than that used in the consultancy. As such, a more realistic estimate of the cost of food-borne illness in Australia is \$3.75 billion.

Table 3: Benefit to cost ratios of food safety programs for highest risk food sectors/operations

	<i>Cost of food-borne illness per meal (\$)</i>	<i>Benefit to Cost Ratios²³ Class 1 outbreaks (No.)</i>
Food service for sensitive populations	0.21	6.5
Producers, harvesters, processors and vendors of raw ready to eat seafood ²⁴	4.87	25.8
Catering operations serving food for the general population	0.49	9.9
Eating establishments	0.06	0.8
Producers of manufactured and fermented meats	0.39	115.9

Of particular note is the difference in the cost of food-borne illness between eating establishments (6 cents a meal) and catering operations serving food to the general population (49 cents a meal). The cost of food-borne illness associated with raw ready to eat seafood on a "per meal consumed" basis overshadows all other industry sectors.

The economic evaluation in the report showed that the benefit to cost ratio justifies businesses in the following areas being required to implement food safety programs:

1. food service to sensitive populations;
2. producing, harvesting, processing and selling raw ready to eat seafood;
3. catering operations serving food to the general public; and
4. producing manufactured and fermented meat.

While eating establishments were also identified as being in the highest risk group, the benefit to cost ratio was not significant enough to justify the introduction of mandatory food safety programs.

The *Food Safety Management Systems - Costs, Benefits and Alternatives* report and the *National Risk Validation Project* report stress the need for a carefully staged and managed implementation framework as this will affect both costs and benefits.

Implementation issues

Legislative means alone will not achieve a reduction in food-borne illness unless there is an understanding by those that sell food, including community groups, of good food handling practices and a will to follow them.

Particular problems in compliance are faced by micro businesses and groups staffed by volunteers. Difficulties in coming to terms with legislative obligations and ensuring safe food is sold are compounded where English is a second language and for those businesses and community groups which are located in rural and remote areas. Successful implementation of Food Safety Standard 3.2.1 by these groups will require assistance and targeted intervention by government. The arrangements for implementing Food Safety Standard 3.2.1 will also have to take into account the potential impact on small business.

²³ Note: 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.

²⁴ The cost of food-borne illness on a per meal basis for producers, harvesters, processors and vendors of raw ready to eat seafood was principally derived from outbreaks associated with oysters rather than raw fish.

The *Food Safety Management Systems - Costs, Benefits and Alternatives* report suggested that the successful implementation of Food Safety Standard 3.2.1 would require a number of prerequisites including compliance and application of Standards 3.1.1, 3.2.2 and 3.2.3. Other issues such as resourcing and changes in enforcement and support activity as well as cost-effective implementation were also highlighted in the report.

Editorial note

FRSC agreed that it is imperative for jurisdictions to make independent decisions on the staging and order of the implementation of Food Safety Standard 3.2.1 into the four highest risk sectors identified in these draft policy guidelines. This would give jurisdictions the ability to ensure that prerequisites for each industry sector are fulfilled before additional requirements are introduced.

The Australian Government Department of Health and Ageing in cooperation with State and Territory Health Authorities has conducted an assessment of the strategies used for the implementation of Food Safety Standards. Campbell Research & Consulting was commissioned to undertake this study that aims to develop a ‘best practice model’ for the implementation of food safety standards in Australia. The final report has been completed and has provided Australian, State and Territory Governments with valuable information on best-practice implementation of legislation. It will also assist jurisdictions by providing information on lessons learned and a best-practice model to ensure that new legislation is introduced effectively and efficiently.

Review of the findings in the report highlight that the timing of the Standards’ adoption and the availability of an implementation budget has a critical impact on the nature and the scope of subsequent implementation strategies, and stakeholder attitudes toward the process.

The development of a number of resources to assist industry is currently underway. As an example, the Department of Health and Ageing in cooperation with State and Territory Government Departments, is developing tools to enable hospitals, nursing homes, children’s services, commercial food service establishments and the seafood sector implement their own site-specific food safety management systems with minimal cost and time.

A National Delivered Meals Organisations (DMOs) - Food Safety Strategy has been developed (<http://www.hacc.health.gov.au>) and has undergone public consultation. It is envisaged that this strategy (to be implemented by March 2005) will assist individual DMOs improve their organisations’ food safety practices over time.

Other resources that have been developed by the Department of Health and Ageing in partnership with State and Territory Health and food agencies to promote food safety include:

- *Looking after our kids*: a national school canteen food safety video and workbook;
- *Food Safety – Levelling the playing field*: a national training package for Environmental Health Officers;
- *Food Safety Matters*: video, posters, student workbooks and a teachers manual for high school students;
- *Safe food is good food*: information for Aboriginal Community Stores; and
- *Food Safety Guidelines for Community Food Events*: a video in eighteen languages.

Attachment 2: Consultation

Public Consultation on the draft document *Food Safety Management in Australia - Risk Profiling and Food Safety Programs* commenced on 20 March 2003 and closed on 17 April 2003. A consultation summary was prepared and is also available at www.foodsecretariat.health.gov.au/pdf/consult_summary.pdf.

Public Consultation Summary

Disclaimer

Opinions expressed in this Public Consultation summary are those of submitters and not necessarily those of the Department of Health and Ageing. While every effort has been made to capture the key issues that arose from the public consultation, this summary does not attempt to capture the views of all individual respondents.

The Public Consultation on *Food Safety Management in Australia - Risk Profiling and Food Safety Programs* commenced on 20 March 2003 and closed on 17 April 2003.

The Commonwealth with State and Territory collaboration collated an e-mail list of 1,060 key stakeholders. An e-mail announcing the consultation and directing individuals to the Food Regulation Secretariat web-site to obtain the consultation documentation was sent to industry organisations and community groups, government agencies and all local governments in Australia on 20 March 2003.

Newspaper advertisements appeared in Government Gazette on 20 March 2003 and *The Australian* and local newspapers as chosen by each State and Territory on Saturday 22 March 2003 and again in *The Australian* on Wednesday 19 March 2003.

A total of 69 submissions were received from the following groups: Local Government (30), Food Consultants (4), Industry Groups (13), Industry Associations (13), Research Organisations (2), Government Agencies (4), Community Group (1), Stakeholder Group (1) and unknown (1).

In order to assist respondents in considering the issues, a consultation response sheet was developed and distributed with the consultation paper. The consultation response sheet asked ten questions, which reflected issues in the consultation paper. A summary of responses to each of the questions is outlined below.

Q1. Do you agree with the overarching principles?

The majority of respondents agreed with the overarching principles with some suggesting amendments. For example, a handful of organisations suggested that Specific Principle 1 be amended so that food safety regulation (rather than management) is based on risk profiling. In addition to comments on the actual principles many respondents stated that all high risk (and some stated all) food businesses should implement a food safety program and exemptions should not be based on a cost/benefit ratio. Further research on the quantifiable benefits and impacts of food safety programs was also requested.

Q2. Do you agree with the role of risk profiling in food regulation?

While most respondents agreed with the role of risk profiling, it was stated that the system should be based on adequate data and clear definitions. Issues such as type of food, processes used and clientele around individual premises should be addressed. It was also highlighted that the risk, not the cost/benefit ratio should be the issue.

A number of respondents suggested further categorising to sub-levels, with some recommending using less emotive terminology (eg. 'highest risk' may imply a higher than actual risk).

Q3. Do you agree with the implementation of Food Safety Standard 3.2.1 in?

- (a) Food service to sensitive (vulnerable) populations;
- (b) Producing, harvesting, processing and selling raw oyster and other bivalves;
- (c) Catering operations serving food to the general public; and
- (d) Producing manufactured and fermented meat.

The majority of respondents agreed with the implementation of Food Safety Standard 3.2.1 in the proposed groups.

However, it was pointed out that non-profit groups and small business may suffer undue impost. Resources/support may be required to assist them implement Food Safety Standard 3.2.1.

More specifically, it was pointed out that it would be difficult to identify businesses servicing sensitive populations, and that businesses should not be required to move in and out of the requirement based on their clientele at a particular time.

While the implementation of Food Safety Standard 3.2.1 for the raw oysters and other bivalves sector was strongly supported, it was stated that eating establishments and vendors should be included. Implementation in the manufactured and fermented meat sector was also strongly supported. However, it was highlighted that clarification of roles and responsibilities around administration, monitoring and auditing was required for both groups.

Many respondents stated that eating establishments should be included with the catering operations group. While there was some support for voluntary food safety programs for eating establishments, it was also stated that they would not provide adequate protection. Further deliberation and research on the huge variation and unique risks that exist across the catering industry were requested.

Q4. Do you agree with the definition of sensitive population?

While the majority of respondents agreed with the definition, many additional groups were suggested for inclusion. These included individuals that are physically disabled, rehabilitated, sick and affected by allergies, children's services, church/charity entities and Aboriginal and Torres Strait Islanders. It was reiterated that it might be difficult to identify businesses servicing this group, in particular pregnant women and immunocompromised individuals. It was also suggested that the age limit for 'the elderly aged 70 and over' be lowered.

Q5. Do you agree with the definition of catering?

Respondents were evenly split in their agreement/disagreement on the definition of catering, with many stating a need for revision. Many respondents agreed with Part 1 of the definition. Two main issues were raised with Part 2 of the definition. Some stated that this part of the definition should be deleted, while others stated that the proposed 'cut off' figure of 100 for the capacity of the premises should be lowered. It was argued that the risk lies with the activities of the food premises, not the capacity. It was also suggested that buffets and restaurants be included in this group.

Q6. Can you see any additional implementation issues that need to be considered?

While there were many suggestions around the implementation of Food Safety Standard 3.2.1, it should be noted that it was proposed that Food Safety Standards 3.1.1, 3.2.2 and 3.2.3 be fully implemented first. In considering additional implementation issues, there were requests for support through the provision of resources such as templates and raising awareness amongst environmental health officers, auditors and industry. Training was also suggested to address the need for suitable, qualified auditors.

It was suggested that prior to implementation, a wide-ranging consultation and communication with stakeholders be undertaken to ensure national consistency and that a review should be undertaken following implementation. A need for clear definitions for premises as well as proposed roles and responsibilities of enforcement bodies was also outlined.

Q7. Additional comments?

Some concern was expressed with the research data used, the proposed exemptions and the financial burden. A need for support for business and community groups and consistency by government in the way forward were raised.

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