

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 foodborne illness, and information about the cost and impact of mandatory food safety programs.

The Board of Food Standards Australia New Zealand (FZANZ) 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*¹.

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 foodborne 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.

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, 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.
4. That the risk classification of a business or an industry sector may change when new data on the causes and incidence of foodborne 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.
5. 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 populations²;
2. producing, harvesting, processing and distributing raw oysters and other bivalves;
3. catering operations serving food to the general public; and
4. producing manufactured and fermented meat.

¹ *Food Standards Australia New Zealand Act 1991* - <http://scaleplus.law.gov.au/html/pasteact/0/31/top.htm>

² 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.

3.1 Food service, whereby potentially hazardous food is served to vulnerable populations³

Two issues need to be considered when assessing the vulnerability of certain population groups to foodborne 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 foodborne disease.

Analysis of the literature identified the following as sensitive populations:

- pregnant women;
- the immunocompromised;
- 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’.

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 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.

3.2 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 foodborne 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 foodborne 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 establishments⁴ 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
- 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.

⁴ 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”.

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 foodborne illness (such as surveillance currently provided by OzFoodNet – Australia's enhanced foodborne illness surveillance network) will provide an indication of any change in foodborne illness following the introduction of Standard 3.2.1. OzFoodNet investigations will not only assess trends in relation to the incidence of foodborne 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 standards⁵ 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 foodborne 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 foodborne 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.
- 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.

⁵ 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>

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 foodborne 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 foodborne 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*.

* 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>

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 foodborne illness.

Public Health Issues

A system of enhanced surveillance for foodborne illness is seen by the World Health Organization and many countries as an essential tool to help reduce foodborne illness. In Australia, enhanced surveillance for foodborne 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 2001-2002⁶. 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 foodborne gastroenteritis, the estimated cost to Australia is \$3.75 billion annually.

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

⁶ The current burden of foodborne gastroenteritis in Australia, Summary paper, February 2003

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 foodborne 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

Category	Implementation Training and development per business (\$)	Ongoing Record keeping and review per business (\$p.a.)	Ongoing Audit cost per business (\$ p.a.)
<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 foodborne 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 foodborne illness is hard to quantify and relates to the estimates and assumptions used to quantify:

1. the current level of foodborne illness and associated costs; and
2. the size of any decreases in foodborne 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 foodborne 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 foodborne 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

Foodborne 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 foodborne 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 foodborne 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 foodborne illness outbreaks. Using a mixture of Australian and overseas data, the three most frequently encountered causes of foodborne 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 foodborne 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 seafood⁷;
3. catering operations serving food to the general population;
4. eating establishments; and
5. producers of manufactured and fermented meats⁸.

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 listericidally⁹ by heat;
- 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.

⁷ 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.

⁸ Consumption data for these products could not be calculated.

⁹ 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.

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 foodborne 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 foodborne illness outbreaks in Australia were in excess of \$1.6 billion¹⁰ annually. The cost of foodborne illness per meal was derived by dividing the total annual cost of foodborne 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 foodborne illness could be achieved.

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

	<i>Cost of foodborne illness per meal (\$)</i>	<i>Benefit to Cost Ratios¹¹ 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 ¹²	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

¹⁰ 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 foodborne illness in Australia is \$3.75 billion.

¹¹ 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.

¹² The cost of foodborne 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.

Of particular note is the difference in the cost of foodborne illness between eating establishments (6 cents a meal) and catering operations serving food to the general population (49 cents a meal). The cost of foodborne 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 foodborne 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.

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.