

**FOOD REGULATION POLICY
OPTIONS CONSULTATION PAPER**
for the review of the 2003 Ministerial Policy Guideline
*Food Safety Management in Australia:
Food Safety Program*

Prepared for the Food Regulation Standing Committee
By the Food Safety Management Working Group
October 2010

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Introduction

This Food Regulation Policy Options paper has been developed by the Food Regulation Standing Committee's Food Safety Management Working Group (the FSM Working Group) reviewing the 2003 *Ministerial Policy Guidelines on Food Safety Management in Australia – Food Safety Programs* (2003 Policy Guideline) and endorsed by the Food Regulation Standing Committee (FRSC). Stakeholder responses to the proposed options are now being sought (see template for submission responses at Attachment 1).

Important notice to all submitters: All submissions are subject to the *Freedom of Information Act 1982* in Australia and the *Official Information Act 1982* in New Zealand. If you consider that all or part of your submission should not be released, please make this clear when making your submission and indicate the grounds for withholding the information.

A general summary of submissions will be produced and published on the Food Regulation Secretariat website at <http://www.health.gov.au/internet/main/publishing.nsf/Content/foodsecretariat-pgdev> and the New Zealand Food Safety Authority website at www.nzfsa.govt.nz.

Copyright in an original submission resides with the copyright owner of that submission, but the act of making a submission will grant the Australian Government and the New Zealand Government a licence to use the submission for the purpose of making a summary of the submission for the website and for future policy or standard development work.

Online submissions at <https://www.surveymonkey.com/s/NFLGC8R> are preferred. Otherwise submissions should be made using the response form provided (p36), or a similar format, to the email or postal addresses below.

The final date for submissions is **Friday 17 December 2010**.

<p>Australia: Submissions - Review of Ministerial Policy Guideline Food Safety Management in Australia: Food Safety Programs (2003) C/- Food Regulation Secretariat PO Box 4 WODEN ACT 2606</p> <p>Or email to: foodregulationsecretariat@health.gov.au Or fax to: (02) 6289-5100</p>	<p>New Zealand: Submissions - Review of Ministerial Policy Guideline Food Safety Management in Australia: Food Safety Programs (2003) C/- Policy Group New Zealand Food Safety Authority PO Box 2835 WELLINGTON, 6011</p> <p>Or email to: policy@nzfsa.govt.nz Or fax to: 64 4 894 2583</p>
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Scope of the options and consultation

In the past, the scope of Food Regulation Policy Options has focussed on development of policy guidance that, once agreed by the Australia New Zealand Food Regulation Ministerial Council, has been provided to Food Standards Australia New Zealand (FSANZ) to guide the development of a standard.

Following consultation with stakeholders and a review of the *Principles and Protocols for the Development of Policy Guidelines*, amendments were made in 2008 that recognised that policy guidelines need to be broader than advising on standards development alone and should take account of implementation matters.

Therefore, any policy guidelines that are agreed by the Ministerial Council, following this consultation process, may involve the future consideration of reforms to legislation (through the Model Food Provisions), national implementation plans (through the Implementation Sub Committee) as well as consideration by FSANZ in developing requirements in the Food Standards Code to manage food safety in the retail/ food service sectors.

The issues discussed and the draft policy guidelines proposed in this Consultation Paper could be applicable to other parts of the food supply chain. However, application of any policy guidance to sectors other than retail/food service arising from this process will not occur without additional consultation with those industry sectors that would potentially be affected.

Problem Definition and Purpose

Food contaminated with harmful bacteria and viruses is a serious problem. Australia-wide, it causes around:

- 5.4 million cases of gastroenteritis;
- 6,000 non-gastrointestinal illnesses (e.g. listeriosis); and
- 42,000 episodes of long-term health effects (e.g. reactive arthritis) per year¹.

The total cost of foodborne illness in Australia is estimated at \$1.25 billion per year². A significant portion of these illnesses, and therefore costs, are attributable to the general food service sectors and closely related retail sectors (retail/foodservice). Recently, OzFoodNet data (2007) indicated that approximately 66% of all reported foodborne illness outbreaks in Australia involved food prepared in retail/food service settings such as those within the scope of this review e.g. restaurants, takeaways, commercial caterers, camps, cruise/airline, national franchised fast food restaurant and delicatessen.³

National food safety laws already apply

Currently all businesses in Australia that provide food for sale (including food service and related retail sectors) must comply with fundamental hygiene requirements that relate to food safety practices and food premises/equipment. These are specified within the *Australia New Zealand Food Standards Code* (Standards 3.2.2 *Food Safety Practices and General Requirements* and 3.2.3 *Food Premises and Equipment*).

Standard 3.2.1 *Food Safety Programs* was originally intended to be part of this suite of food safety standards. It was gazetted as a model standard that could be adopted on a voluntary basis by individual States or Territories pending further work on the costs and efficacy of food safety programs (FSPs).

Research supports additional intervention in certain sectors

Since gazettal of Standards 3.2.2, 3.2.3 and 3.2.1 substantial work has been done by OzFoodNet on the incidence and causes of foodborne illness and by two national studies on, respectively food safety risk⁴ and the benefits and costs of FSPs⁵.

This work underpinned development of the *Ministerial Policy Guidelines on Food Safety Management in Australia: Food Safety Programs* (2003 Policy Guideline) (Attachments 2, p41 and 3, p42). The Guideline effectively requests Food Standards Australia New Zealand (FSANZ) to mandate Standard 3.2.1 in four industry sectors in Australia:

1. food service to vulnerable persons (e.g. hospitals, aged care facilities, delivered meals organisations and childcare centres)
2. producers harvesters, processors and vendors of raw ready-to-eat seafood,
3. catering operations serving food to the general public, and
4. producers of manufactured and fermented meats.

A fifth sector – eating establishments⁶ - was also identified as high-risk but the 2003 Policy Guideline excludes “eating establishments” (restaurants, cafes, takeaways) from the FSP requirements on benefit/cost grounds.

¹ Hall, G. and M. Kirk. (2005). *Foodborne illness in Australia: annual incidence circa 2000*, Australian Government Department of Health and Ageing.

² Abelson, P., M. Potter Forbes and G. Hall. (2006). *The annual cost of foodborne illness in Australia*, Australian Government Department of Health and Ageing.

³ OzFoodNet. (2007). *Monitoring the incidence and causes of diseases potentially transmitted by food in Australia: Annual Report*. Accessed at: [http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-cdi3204-pdf-cnt.htm/\\$FILE/cdi3204c.pdf](http://www.health.gov.au/internet/main/publishing.nsf/Content/cda-cdi3204-pdf-cnt.htm/$FILE/cdi3204c.pdf) Accessed on: January 25, 2010

⁴ Food Science Australia and Minter Ellison Consulting (2002) *National Risk Validation Project*. NSW Department of Health and the Commonwealth Department of Health and Ageing.

⁵ The Allen Consulting Group. (2002). *Food Safety Management Systems: Costs, Benefits and Alternatives*

Note: On a national level, Standard 3.2.1 has been recently implemented for businesses serving food to vulnerable persons (e.g. hospitals, aged care facilities, delivered meals and childcare centres (Standard 3.3.1 *Food Safety Programs for Vulnerable Persons*). Consequently, this industry sector has been specifically excluded from the scope of this review.

The 2003 Policy Guideline may not provide the guidance needed to develop an effective food safety management approach for retail/food service.

The guideline identifies four high-risk industry sectors where implementation of Standard 3.2.1 *Food Safety Programs* would be justified. These sectors included catering operations to the general public. A fifth sector – eating establishments⁶ – was also identified as high-risk, but the benefit-cost ratio of implementing Standard 3.2.1 was considered insufficiently high.

Requirements are now in place nationally in three of these sectors. This potentially leaves a gap in risk management in the retail/food service sector.

Additional or alternative policy guidance for general food service may be needed

National standards are now in place for sectors one, two and four but the proposed standard for catering operations (P290 *Food Safety Programs for Catering Operations to the General Public*) has been in development for a number of years without completion. The standard development process has highlighted a number of difficulties in the policy approach as it applies to the general food service sector. The key issue is that the 2003 Policy Guideline deals only with Standard 3.2.1, without considering less intensive and costly risk management interventions including, for example, less onerous FSP requirements or non-FSP measures.

As a consequence, the 2003 Policy Guideline's exclusion of eating establishments from the FSP requirements means that food safety risks in these settings are addressed only by the fundamental hygiene requirements of Standard 3.2.2 and 3.2.3. This potentially leaves a gap in risk management in the retail/food service sector. Recent OzFoodNet data (2007)³ indicates that two-thirds of all reported food-borne illness outbreaks involved food prepared in retail/food service settings (those within the scope of this review, including catering). The scope of the proposed Catering Standard⁷ (catering settings) only accounts for 16% of the total reported foodborne illness outbreaks for the same period, leaving about 50% of outbreaks attributable to eating establishments and other selected retail sectors serving potentially hazardous foods.

Secondly, the eating establishment exclusion generates a series of boundary issues – who is in and who is out. The 2003 Policy Guideline seeks to deal with some of these issues in its definition of catering and an exclusions section. However, it has proved difficult in practice to draw the boundaries satisfactorily in the draft standard, despite the use of criteria around frequency, timing and event planning. Stakeholders have raised a range of concerns, including a concern that community groups, which are exempted from the draft standard, may compete unfairly with commercial businesses, particularly in rural and regional areas.

For these reasons, in October 2009 the Australia and New Zealand Food Regulation Ministerial Council requested the Food Regulation Standing Committee to review the 2003 Policy Guideline with a particular focus on the general food service and closely related retail sectors (retail/food service)⁸. The review's Terms of Reference are provided at Attachment 6 (p67).

⁶ 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."

⁷ Catering food preparation settings implicated in foodborne illness outbreaks, in Australia, 2007: commercial caterer, institution, camp, cruise/airline

⁸ 'closely related' refers to the fact that while these retail sectors are not considered to be 'food service', they undertake similar activities such as serving food that is ready-to-eat

Objectives of the review

The primary objective of the review is to resolve concerns that the existing policy guidance could lead to anomalous regulatory outcomes in the retail/food service sectors and, in particular, leave a gap in food safety management for eating establishments.

It is also intended that the review consider the need for additional or alternative policy guidance on several matters relevant to standards development and effective, efficient and consistent implementation (see Terms of Reference, Attachment 6, p67)

Purpose of the Consultation Paper

This Consultation Paper has therefore been released to:

- explore the issues relevant for food regulation policy on food safety management in the retail/food service sectors;
- present options for revised policy underpinning food safety management in these sectors;
- seek community comment on the relevant issues and policy options, and identify a preferred policy option; and
- assist FRSC in the development of draft policy guidelines.

Purpose of the policy guidelines

The policy guidelines that are expected to result from this process are intended to provide best practice guidance on food safety management in the retail/food service sectors.

Current Status of Food Safety Management in Australia and New Zealand

Regulatory requirements relevant to food safety management in food service and related retail settings differ between Australia and New Zealand. In Australia, requirements are detailed in Chapter 3 of the *Australia New Zealand Food Standards Code*, supplemented by extra (e.g. food safety supervisor) requirements in some jurisdictions. Chapter 3 of the Food Standards Code does not apply in New Zealand. Instead food businesses in New Zealand need to comply with the regulatory regime set by the *Food Act 1981* (and associated regulations).

For more details on current food safety management in Australia and New Zealand refer to Attachment 4 (p62).

Food Safety Management in an International Context

Codex Alimentarius Commission

The Codex Alimentarius Commission implements the Joint FAO/WHO Food Standards Programme, the purpose of which is to protect the health of consumers and to ensure fair practices in the food trade.

The *Codex Recommended International Code of Practice - General Principles of food hygiene* (CAC/RCP 1-1969, Rev. 4, 2003) identifies the essential principles of food hygiene applicable throughout the food chain from primary production to the final consumer and recommends a HACCP-based approach as a means to enhance food safety. The controls described are internationally recognised as essential to ensure the safety and suitability of food for consumption.

The *Codex Code of Hygienic Practice for precooked and cooked foods in mass catering* (CAC/RCP 39-1993) has also been developed using a HACCP approach.

The specific food safety management arrangements in the international context for the European Union, the United Kingdom, the United States of America and Canada are found at Attachment 5 (p65).

Are there other international approaches to food safety management that would inform this policy process?

Key Impacts

The key priority for the food regulatory system as a whole is to protect public health and safety. There are other priorities as set out in the *Overarching Strategic Statement for the Food Regulatory System*⁹ (endorsed by the Australia and New Zealand Food Regulation Ministerial Council) that are intended to make clear the context within which food regulation is undertaken in Australia. Broadly, these are to:

- enable consumers to make informed choices about food by ensuring that they have sufficient information and by preventing them from being misled;
- support public health objectives by promoting healthy food choices, maintaining and enhancing nutritional qualities of food and responding to specific public health issues; and
- enable the existence of a strong, sustainable food industry to assist in achieving a diverse, affordable food supply and also for the general economic benefit of Australia and New Zealand.

In a competitive environment of innovation and rapidly changing technological developments, it is important that the food regulatory system maintains appropriate measures to ensure ongoing public confidence in the food supply.

Within this broader context, the review of the 2003 Policy Guideline, focussing specifically on food safety management in the general food service and closely related retail sectors (“retail/food service”) and any resulting policy guidance will affect public health, consumers, industry and government. A general description of these impacts is set out below. The specific impacts on each group are considered within the discussion of the policy options described later in this paper.

Public Health Impacts

Food safety management policy must consider public health impacts, which may include impacts relevant to the whole population, specific groups or individuals.

In particular, food safety management policy must not have adverse effects upon:

- the protection of public health and safety;
- the incidence of contamination of food; and
- the incidence of foodborne illness.

The 2006 report, *Annual Cost of Foodborne Illness in Australia*², acknowledges that there is a risk that the effects of foodborne illness on the economy may increase, unless interventions can decrease the incidence of these illnesses. Further, recent data (2007)³ indicates that approximately two-thirds of the foodborne illness outbreaks reported for 2007, implicated foods prepared in retail/food service settings¹⁰. Furthermore, these settings account for about half of the total number of persons affected by the foodborne illness outbreaks for that period. Therefore, food safety management policy guidance targeted specifically at this sector may impact significantly on these key considerations by reducing the risk of both foodborne illness and contamination in a sector, which is currently over-represented in causal and costing data.

Consumer Impacts

Along with the primary objective of protecting public health and safety, there are a number of consumer interests, which may be impacted by food safety management policy tailored towards food safety management in retail/food service. This sector represents, largely, the critical interface between consumers and the food regulatory system. The increasing sophistication and breadth of consumer interests means that perceived and actual concerns must be reflected in any policy guidance.

In particular, food safety management policy should consider impacts on:

⁹ Anon. (2008). *Overarching Strategic Statement for the Food Regulatory System*. Available at: <http://www.health.gov.au/internet/main/publishing.nfs/Content/mr-yr08-dept-dept020508.htm>

¹⁰ Of the reported foodborne illness outbreaks for 2007, the retail/food service settings implicated were restaurants, takeaways, caterers, institutions, bakeries, cruise/airline, national fast food restaurant and grocery store/delicatessen.

- confidence in the food supply and food regulations;
- consumer choice;
- ability to make informed decisions;
- food prices due to costs attributable to regulatory intervention;
- consumer expectations; and
- costs from foodborne illness.

Industry Impacts

Retail/food service is largely the arena of small-to-medium enterprises (SMEs). Potential costs to industry, and the particular needs of SMEs must be considered alongside potential benefits to public health. Good regulatory practice consistent with the principle of minimum effective regulation and effective implementation will assist in achieving regulatory objectives, while having proper regard for the limited resources available to many businesses within the sector.

In particular, food safety management policy should consider impacts on:

- compliance and regulatory costs for affected business sectors;
- nationally consistent food safety measures;
- industry reputation;
- ability for industry to innovate;
- productivity costs; and
- food safety recall costs.

Government Impacts

Food safety management policy has the capacity to impact upon government at national, state/territory and local government levels. In particular, any food safety management policy guidance targeted towards retail/food service must consider the potential impacts to local government, as the key “coal-face” regulators of this sector. In many cases the enforcement agencies (including local government), food safety agencies and departments of health and trade will all be impacted, although the extent may vary.

In particular, food safety management policy should consider impacts on:

- confidence in government regulators;
- costs of foodborne illness;
- implementation costs;
- ongoing enforcement costs;
- national consistency;
- emergency care, general practitioner and specialist services; and
- surveillance, investigation and maintaining food safety systems.

Of the total \$1.25 billion annual cost of foodborne illness in Australia, it is estimated that the cost to health care services alone is \$221.9 million annually. This cost is almost exclusively borne by government at various levels.²

Are there other impacts on public health, consumers, industry and government stakeholders that should be considered?

Key Issues

The current process is a review of the existing *Ministerial Policy Guidelines on Food Safety Management in Australia – Food Safety Programs* endorsed in 2003. The review's terms of reference are provided at Attachment 6 (p67). The review is required to consider whether additional or alternative policy guidance should be provided in relation to the general food service sector and closely related retail sectors ('retail/food service'). Although the review focus is limited to these sectors, the scope of potential policy guidance is very broad as outlined in the terms of reference.

The term "food safety management", as it is used in the 2003 Policy Guideline, encompasses the range of processes and activities by which food safety risks are minimised to prevent or reduce the incidence of foodborne disease. It should include the processes that implement regulatory measures, if these are agreed, as well as those that identify and assess risks and determine the food safety management response.

The issues to consider when developing policy options for food safety management should therefore include those relevant to efficient and effective implementation of regulatory measures. In turn, the roles and responsibilities of the various players in the Australian food regulatory system may need to be considered.

The issues considered in this paper, with a focus on the food business sectors within the scope of the review, are:

1. deciding how and when to intervene,
2. implementing regulatory measures effectively and efficiently,
3. instruments available to apply, implement and verify regulatory measures,
4. food safety management roles and responsibilities, and
5. the potential scope of policy guidance.

1. Deciding how and when to intervene

Assuming that a case for action in response to a problem has been made, the intervention decision should be informed by consideration of all feasible options, including regulatory and non-regulatory approaches, and an impact analysis to determine which option will generate the greatest net benefit for the community.

Impact analysis potentially has many facets depending on the context. The policy principles in the 2003 Policy Guideline focus on the role of risk assessment and risk profiling, and the need for benefit-cost analysis, when determining the food safety management approach. However, specific guidance is provided in relation to only one risk management tool: Food Safety Standard 3.2.1 *Food Safety Programs*. No guidance is provided on alternative tools where the level of risk is less than "highest risk" and/or the benefit to cost ratio does not justify implementation of Standard 3.2.1 *Food Safety Programs*.

This raises two interrelated issues. Firstly, what alternatives to Standard 3.2.1 *Food Safety Programs* are potentially available and should policy guidance be provided? Secondly, should the concept of appropriateness – the 'right tool for the right job' – be expressly and separately considered when determining the food safety management approach? These issues are considered in Sections 1.2 and 1.4 respectively.

1.1 Risk assessment and risk profiling

The measurement of food safety risk (via risk assessment or risk profiling) as a basis for making risk management decisions is consistent with international best practice for food safety managers^{11, 12}.

¹¹ Codex Alimentarius Commission. (1999) Principles and guidelines for the conduct of microbiological risk assessment. *CAC/GL-30*. Accessed at: http://www.codexalimentarius.net/download/standards/357/CXG_030e.pdf. Accessed on: Dec 2009

Ultimately, risk assessment and risk profiling enable regulators to make evidence-based risk management decisions, including directing regulatory resources to those areas that pose the most risk to public health e.g. those classified in the highest risk categories.

The concept of risk profiling has long provided the foundation for food safety management in Australia. Risk profiling is routinely used by local councils and all State and Territory agencies to prioritise businesses according to the level of risk posed to public health. In 2009, the Productivity Commission's *Food Safety Benchmarking Report*¹³ noted that 83% of surveyed councils used risk profiling frameworks that were developed at the state/territory or national level.

Broadly, risk profiling is a process of assessing food safety risk for specific business sectors within the context of the combinations of food they sell, the types of processing undertaken, the handling and the likely consumers of their products.

At a national level, risk profiling was utilised by the 2002 *National Risk Validation Project* (NRVP)⁴ (one of the two national studies that underpin the 2003 Policy Guideline). As set out at in the Problem Definition section above, the NRVP showed the need for additional risk management controls by identifying the five highest risk Australian food industry sectors, including catering operations and "eating establishments".

Later, the 2003 Policy Guideline continues to highlight the importance of using risk profiling to inform national level food safety management decision-making processes. Specifically, the Guideline states 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
- risk profiling be used to classify food businesses or food industry sectors in Australia on the basis of risk and
- 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.

In 2007, following a lengthy development process, the Food Regulation Standing Committee (FRSC) and later the Australian Government's Productivity Commission¹³ endorsed a national risk profiling tool, the Risk Profiling Framework (the Framework). The Framework is located on the Food Regulation Secretariat web site at

<http://www.health.gov.au/internet/main/publishing.nsf/Content/foodsecretariat-publications-index.htm>

The Framework is a series of decision trees, with supporting documentation to assist its use. The approach in the decision trees is to consider:

- the nature of the potential risk from products sold by the business sector and considering both the *inherent* risk, (i.e. in the absence of existing controls) and the reliability of existing risk management actions, i.e. *managed* risk, and
- whether there are steps that are susceptible to introduction of hazards, or processes that are critical to the safety of the product at the time it is consumed.

The result from using the Framework is classification of food businesses or industry sectors into one of four classifications, from the highest risk category of Priority 1 (P1) through P2 and P3 to the lowest risk category of P4.

FRSC (2007) also agreed principles for using the Framework. Closely based on Codex principles for the conduct of microbiological risk management, the key principles focussed on ensuring that:

- that any application of the Framework is transparent

¹² Codex Alimentarius Commission. (2007b). Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM). CAC/GL 63-2007, 1-19.

¹³ Productivity Commission (2009) *Performance Benchmarking of Australian and New Zealand Business Regulation: Food Safety*, Research Report, Canberra p 130-133

- nationally consistent classification outcomes are achieved via a scientifically rigorous process
- any business sector classifications generated by the Framework would not be influenced by potential risk management decisions or other economic factors and that
- further implementation of the Framework would include a public consultation process, a process for maintaining the Framework and a process for dealing with contentious issues.

Accordingly, the Framework is a single national tool where businesses will be assigned classifications following an agreed national methodology.

An independent team of experts has used the Framework to classify a number of business types throughout the food supply chain. These business types have all been assigned draft risk classifications. There will be a separate consultation process, outside this review, to resolve any technical issues before the risk classifications are finalised.

Policy guidance that may result from this review is likely to be relevant to the business types set out in the table below.

Business Types within the General Food Service and Closely-Related Retail Sectors	
Food service – onsite and offsite catering	Bakeries – retailers and processors of potentially hazardous foods (e.g. high risk products)
Food service – ready-to-eat food prepared in advance e.g. takeaways that hot-hold ready-to-eat food, restaurants that pre-prepared ready-to-eat food,	Retailers of ready-to-eat ¹⁴ :
Food service – express order e.g. eating establishments or takeaways that do not prepare food in advance	<ul style="list-style-type: none"> • potentially hazardous bakery products (not processors) • delicatessen products; • processed seafood products; and • perishable packaged foods (e.g. packaged sandwiches).

Stakeholder input on potential uses for the Framework is sought

Application of the national Risk Profiling Framework is yet to be determined. Stakeholder comment on potential application of the Framework is sought. For example, the Framework’s classification outcomes, including the rationale derived from the decision trees, could be used to:

- assist in setting standards development priorities;
- inform development of specific standards;
- inform the choice of risk management tool(s);
- guide audit/inspection activities, including frequency, timing, and whether they are unannounced; and
- standardise enforcement action when critical violations occur.

What should Risk Profiling Framework classifications be used for?

1.2 The risk management toolkit

There are two established elements of the food safety management system in Australia that are unlikely to change. These are:

- Food Safety Standards 3.2.2 and 3.2.3; and
- State and Territory Food Acts, based on national Model Food Provisions, that:

¹⁴ As per the definition of ready-to-eat food in *Food Standards Code* Standard 3.2.1 (1)

- confer a range of compliance and enforcement powers including inspections, remedial orders, and emergency powers including food recalls;
- require notification of food businesses to the relevant State agency and enable licensing or registration; and
- enable local councils to be prescribed as “enforcement agencies” with necessary compliance and enforcement powers and a degree of guidance/coordination by the relevant State agency.

Standards 3.2.2 and 3.2.3 replaced the previous State and Territory hygiene regulations and require good hygienic practices in relation to food handling, premises, vehicles and equipment. In most jurisdictions, local government Environmental Health Officers (EHOs) conduct routine inspections in retail/food service sectors to assess compliance with the standards and respond to complaints. State-level agencies may take compliance or enforcement action in more serious cases, for example in the course of investigating foodborne illness outbreaks.

These elements provide a strong foundation for food safety management by government and industry and are unlikely to change significantly. Any case for additional intervention will need to be made on the assumption that it will build on these arrangements.

If it is determined that there is significant risk in a particular sector(s), a range of additional regulatory or non-regulatory interventions is potentially available. These interventions are likely to be preventive rather than reactive in nature, given the suite of compliance and enforcement powers already available. In most cases intervention will involve use of a ‘risk management tool’ that may be a regulatory requirement or a non-regulatory initiative.

Potential regulatory risk management tools fall broadly into the following (not necessarily exhaustive) categories:

- business-based systems, including food safety programs;
- government-endorsed codes of practice; and
- mandatory training.

Business-based systems, including food safety programs

A spectrum of business-based systems is potentially available, broadly falling into the following types:

- food safety programs with external verification (audit);
- template-based food safety programs with external verification (audit/inspection); and
- prescribed record keeping for certain controls (inspection).

Food safety programs with external verification (audit)

These are programs developed by the business based on analysis of hazards, identification of necessary controls, and continuing documentation of the control system. These programs are subject to external verification by auditors. This is the most costly category of intervention due to the business costs associated with developing and documenting the control system and the regulatory costs associated with approval of the control system and external audits of the system. Examples include HACCP and Standard 3.2.1. *Food Safety Programs*.

Template-based food safety programs with external verification (auditing/inspection)

These are programs developed by regulators (or downstream customers such as supermarkets) external to the business and verified by auditors or inspectors. In some jurisdictions, a “template” Food Safety Program is provided and the food business is checked for compliance with the template program. This approach significantly reduces the business costs but may not be capable of managing risk in all business settings as processing activities may vary from business to business.

Prescribed record keeping for certain controls (inspection)

This approach requires businesses to keep prescribed records for certain controls that are verified by inspection. In this case the business keeps records demonstrating compliance with nominated clauses in the food safety requirements (Standards 3.2.2/3.2.3). It is therefore the least costly business-based system.

Government-endorsed codes of practice and guidelines

The former State hygiene regulations were in essence detailed and prescriptive codes of practice. Standards 3.2.2 and 3.2.3 are far less prescriptive. Outcomes rather than prescriptive requirements are specified in many areas and some prescriptive provisions, for example on temperature control, allow compliance by alternatives demonstrated to achieve an equivalent outcome.

A government-endorsed code of practice could be an appropriate regulatory measure, perhaps as one means to demonstrate compliance with outcome-based requirements, if it were evident that retail/food service businesses have difficulty understanding and/or complying with Standards 3.2.2 and 3.2.3.

A further alternative could be for businesses to be required to operate subject to educative or guidance material that may be issued by regulators to specifically apply to the food activities being undertaken. For example, this guidance material could cover safe food handling practices and other steps necessary to achieve safe and suitable food in the retail/food service sector.

Mandatory food handler training

For obvious reasons, food handling in retail/food service sectors is the primary factor in food safety risk. Food handling errors probably account for most foodborne illness attributable to retail/food service settings. For this reason, several jurisdictions have introduced mandatory food handler training. The training is linked to national competencies and provided by registered training organisations, under the vocational education and training system.

To date, these requirements have been applied to a designated “food safety supervisor” in each food business, rather than to all food handlers. Another option would be to require all food handlers to be trained, as for Responsible Service of Alcohol regulatory programs¹⁵.

Is this list of potential regulatory interventions adequately described? Are there any others that should be included in this list?

Should each intervention, including different systems-based approaches, be formally agreed and documented by Australian food regulators?

Potential non-regulatory risk management tools focus on the provision of training and information. Potential non-regulatory interventions fall broadly into the following (not necessarily exhaustive) categories:

- provision of general or targeted food safety information, including risk communication;
- voluntary training; and
- public release of regulatory information.

¹⁵ NSW Government Office of Liquor Gaming and Racing. Responsible service of alcohol. Accessed at: http://www.alcoholinfo.nsw.gov.au/responsible_supply/responsible_service_of_alcohol Accessed on: 30 March 2010

Provision of general or targeted food safety information, including risk communication

The provision of food safety information to industry and consumers is a well-established practice in most jurisdictions. The information may be general in nature or targeted to particular issues, industry sectors or population groups.

Depending on the context, the information may provide advice on regulatory requirements or best practice, or seek to raise awareness of food safety risks and ways to avoid exposure to risk. A range of delivery mechanisms may be used including websites, electronic and print media, and publications.

Voluntary training

Many local councils offer basic food handler training to retail/food service businesses, usually on a voluntary and non-accredited basis. The training is generally provided by EHOs as a non-regulatory supplement to their routine regulatory inspections.

Public release of regulatory information

Regulatory information, for example inspection/audit results or the outcomes of enforcement action, may be publicly released for various purposes. For example, governments may release aggregated and de-identified information for transparency reasons or to demonstrate regulatory performance.

There is also the potential to use public release of identified regulatory information to create incentives for improved food safety performance by food businesses.

For example, the Model Food Provisions enable publication of details of convictions for food law breaches subject to certain procedural requirements. This provision has been little used until recently, perhaps because the number of prosecutions is relatively low. In 2008, NSW enacted legislation enabling publication of details of unchallenged penalty notices as well as convictions. The information is published on an interactive and searchable web facility.

An alternative approach in place in some overseas jurisdictions is to disclose publicly the results of regulatory inspections (“Scores on Doors”). State and local governments in some Australian jurisdictions are developing or piloting voluntary schemes that assign a “food safety rating” based on routine inspection outcomes. These approaches may provide a ‘positive’ incentive by publicising good food safety performance.

Public disclosure of regulatory information to create incentives for improved food safety performance is at an early stage of development in Australia and evidence of its effectiveness remains anecdotal. However, the general trend toward greater disclosure of government information and enhanced transparency is likely to provide further impetus for these initiatives.

Is this list of potential non-regulatory interventions adequately described? Should any others be included in the list?

Should each intervention be formally agreed and documented by Australian food regulators?

1.3 Taking account of existing systems

Some food businesses participate in programs that require compliance with food safety management measures that may meet or exceed regulatory requirements. Examples include:

- *Importing country requirements* e.g. Australian meat exporters, in addition to complying with relevant Australian standards must also comply with the Export Meat Orders if they wish to supply the US, Japanese, European and other international meat markets;
- *Customer requirements* e.g. supplier approval programs operated by major supermarkets and foodservice chains.
- *Industry-based programs* e.g. voluntary quality assurance programs run by industry associations and/or industry-endorsed codes of practice.

Any proposal for new interventions should consider such requirements and programs – including their content and industry coverage. Even if additional regulatory intervention is considered warranted, it may be appropriate to recognise existing equivalent industry-based programs where these exist in particular businesses rather than require additional compliance that duplicates what is already in place.

Generally speaking, industry associations covering the retail/food service sectors do encourage members to meet or exceed the requirements of Standards 3.2.2 and 3.2.3 – most commonly by promoting food handler training. Nevertheless, currently there is no coordinated, industry-based food safety management intervention with widespread adoption among retail/food service business types.

Are there existing industry-based or other programs that would inform this policy process?

1.4 Benefit-cost analysis

Properly understanding the impacts of government action – by considering the costs and benefits of a range of options is essential to choosing the right food safety management approach. For this reason, benefit-cost analysis (BCA) is required as a matter of course, for significant regulatory proposals, by the Australian and New Zealand Governments and Australian State/Territory governments. Extensive guidance is available, including from the Council of Australian Governments (COAG) in its *Best Practice Regulation: A Guide for Ministerial Councils and Standard Setting Bodies* (2007).

The role of BCA in decision making relevant to food safety management is also embedded in the 2003 Policy Guideline – Principle 3 states “*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.*”.

A positive BCA for any future food safety risk management interventions relevant to the retail/food service sector would be a prerequisite to proceeding with implementation.

1.5 Appropriateness - the ‘right tool for the job’

The appropriateness concept can be described as ensuring the ‘right tool for the job’ is used. In accordance with the principles of best regulatory practice¹⁶, when determining the right tool for the job in relation to managing risk in the retail/food service sector, the concept of ‘appropriateness’ should be expressly considered alongside risk and benefit-cost.

Additionally, Codex food safety management guidance states that the selection of risk management tools should be based on their effectiveness and the practical feasibility and consequences of the options¹².

There is no established methodology for determining the appropriateness of a proposed risk management tool. Well-established methodologies exist for assessing the food safety risk posed by the business and analysing the benefit and cost of a range of options (e.g. risk profiling and benefit-cost analysis), but not so for appropriateness.

The overarching concern for appropriateness is whether the proposed risk management tool, including external verification (auditing/inspection), is likely to be effective and sustainable in the context of the business type and its setting and the proposed level and form of enforcement by regulatory authorities. This may require consideration of a number of factors including the:

- scale and nature of the food handling processes;
- existing systems and the food safety culture; and
- the outcomes of any past interventions.

For each of the factors listed above, a number of criteria have been developed that may assist in determining the appropriateness of risk management tools.

¹⁶ Refer *Best Practice Regulation: A Guide for Ministerial Councils and Standard Setting Bodies* (COAG, 2007) and *Best Practice Regulation Handbook* (OBPR, 2007).

The scale and nature of food handling processes are important when considering the appropriateness of risk management tools. For example, risk management tools that require the business to implement record keeping and documentation requirements are likely to be more readily maintained in settings where written communication between food handlers is an integral part of the process.

Criteria relating to the scale and nature of food handling processes are:

- whether the business sector (types) is dominated by small businesses;
- whether the product range is standardised;
- whether the process is standardised into discrete, limited steps;
- whether communication via written records between people, departments or over time is integral to the safety of the food produced;
- whether staff typically limit their activities to one defined processing step i.e. are specialists or generalists and
- whether consumer requests for product variations can be met.

Whether the business sector has the capacity and inclination to implement the risk management measure effectively and sustainably is another consideration when selecting the right tool for the job. This can depend on existing standards of operation and availability of resources, inaccessibility to training and insufficient awareness of the importance of food safety management.

Criteria relating to existing systems and food safety culture are:

- the size of the step between current requirements or practice, including industry-based initiatives, and the proposed measures; and
- whether the business type is dominated by businesses with a strong management commitment to food safety.

Where and how risk management tools have been implemented in the past is an important consideration when selecting the right tool for the job.

Criteria relating to outcomes of past interventions are:

- whether there is evidence that the intervention has either failed/succeeded in the same environment in the past; and
- for regulatory risk management interventions, whether the amount of effort required to maximise and maintain business sector compliance with the requirements (e.g. assistance materials, verification frequency (auditing/inspection)) and ongoing enforcement is sustainable.

Should 'appropriateness' be expressly considered, with risk and benefit-cost analysis, when deciding food safety risk management approaches?

Are the criteria for determining 'appropriateness' useful and should any other factors be considered when determining the right risk management tool?

1.6 Food safety tools can be used singly or together.

The right approach to managing food safety in different types of food service/retail businesses might include the implementation of single or a number of regulatory and non-regulatory tools. For example a single tool approach (such as Standard 3.2.1 for large scale catering) may satisfy risk, benefit-cost and appropriateness criteria.

An example of a multi-tool approach could be:

- food safety communication (e.g. the provision of general and targeted food safety information by regulators);

- food safety awareness and knowledge (e.g. voluntary or mandatory food safety training requirements for food handlers); and
- business-based system e.g. prescribed record keeping for certain controls (inspection) such as basic record keeping and/or documentation requirements for nominated clauses in Standard 3.2.2 and 3.2.2.

2. Implementing regulatory measures effectively and efficiently

Regulatory interventions will only improve food safety outcomes if they are properly implemented. Effective and efficient implementation helps maximise compliance while minimising the regulatory burden (for both industry and government). Implementation effectiveness and efficiency can be greatly enhanced by:

- providing implementation assistance and support to businesses; and
- ensuring consistency of approach in the interpretation and enforcement of standards.

2.1 Implementation assistance and support

The Food Safety Standards in the *Australia New Zealand Food Standards Code* are outcome-based. They replaced prescriptive regulations promulgated by each State/Territory. Outcome-based regulation has many advantages over prescription including facilitating innovation. It also places the burden of responsibility for food safety with the food industry. Businesses need to understand food safety issues relevant to their business and decide how they will be managed. This presents a significant burden for some – especially for small businesses.

Provision of information and support services by governments and industry for businesses is therefore key to effective and efficient implementation of regulatory measures. Information and support services such as a telephone helpline, published guidelines/templates and workshops/training for industry participants raise awareness, understanding and in turn compliance with regulatory requirements. They can also save businesses staff time and money (e.g. by reducing the need for businesses to employ food safety consultants and reducing the time taken to research and resolve food safety issues).

2.2 Consistency and a national approach

Consistent implementation of food standards is also key to minimising the compliance burden for industry.

Variations among jurisdictions in their **interpretation of food standards** is one potential source of inconsistency. On 7 December 2009 COAG decided¹⁷ that an intergovernmental agreement should be drafted which enables the provision of centralised interpretive advice in relation to food standards. The COAG timetable requires this initiative to be in place by July 2011.

Other inconsistent approaches among jurisdictions that may impact safety, competitiveness and/or the compliance burden, but are not being expressly addressed by the COAG reforms, include:

- **variable commitment to monitor and enforce compliance.** Food regulation imposes compliance costs on businesses. These costs include fees charged by food regulators but more significantly the cost of doing things right. If compliance with food standards is proactively enforced in some but not all jurisdictions – food businesses that operate in areas where regulations are being enforced may incur higher compliance costs and therefore be at a competitive disadvantage compared to businesses operating in those areas where compliance with standards is not proactively monitored and enforced.
- **variations in how compliance is monitored and enforced.** For example, different verification methods (e.g. inspection versus audit) impose different costs. Likewise different intensities of regulatory oversight (e.g. audit frequency and the extent to which it is adjusted

¹⁷ See: COAG Decision 7 December 2009, available at: http://www.coag.gov.au/coag_meeting_outcomes/2009-12-07/index.cfm?CFID=63797&CFTOKEN=74335169#coag_agenda

for business performance) and enforcement responses impose different costs. At a level of even greater detail, there may be cost-affecting variations among jurisdictions' expectations about what evidence (e.g. sampling and analysis) businesses are required to generate and keep demonstrating compliance. Inconsistency is likely to be greater where implementation depends on jurisdiction-specific legislation or other mechanisms (see sections 3.3 p22 and 3.4 p22)

Finally, differences in fees and charges among jurisdictions (at both State/Territory and local government levels) are often identified as an issue of concern. Governments have different policy positions on funding for food regulation – specifically the extent to which regulatory activities are funded by cost recovery or directly by government (i.e. through taxes or rates). The current policy process cannot address this issue.

The potential for inconsistent implementation of food standards in retail/food service sectors is high. In most cases, food standards in the retail/food service sector are administered by greater than 670 local councils in Australia.

In practice what aspects of inconsistent approaches to implementation currently have the greatest impact on regulatory compliance burden?

Do you agree that improved consistency among jurisdictions in the most significant of these will reduce regulatory compliance burden?

2.3 Minimising the “implementation burden” on government

Introducing new food safety risk management interventions imposes an implementation burden on governments. Costs may include regulation set-up costs, compliance monitoring, collection of information and record keeping and administration of regulatory instruments. Governments also incur the cost of providing information and support services for businesses (refer Section 2.1). Some or all of these costs may be recovered from the regulated food industry e.g. by licence fees and charges for audits and inspections.

Strategies that avoid duplication among Australian States and Territories will minimise the total implementation burden on governments.

For example, minimum regulation set-up costs will be incurred if amendments to the Code automatically apply in full in each jurisdiction and can be administered in each jurisdiction without making changes to jurisdiction-specific legislation (e.g. food acts and associated regulations) or administrative mechanisms. This approach would also minimise inconsistency between jurisdictions that can add to the compliance burden for industry.

Joint development of support and assistance materials is another example of where collaboration between States and Territories can minimise implementation burden.

3 Instruments available to apply, implement and verify risk management tools

Four instruments are available to Australian food regulators to apply, implement and verify risk management tools:

- The *Australia New Zealand Food Standards Code* (The Code)
- Model Food Provisions (MFPs)
- Jurisdiction-specific legislation
- Policy and administrative mechanisms

Each has advantages and disadvantages and may be appropriate in different cases.

Using the Code and/or MFPs to promulgate risk management tools will maximise national consistency and minimise implementation burden for government. Use of jurisdiction-specific legislation and/or

policy and administrative mechanisms may not be available to all jurisdictions and pose the greatest risk to national consistency.

3.1 Food Standards Code

Under the Food Regulation Agreement all Australian States and Territories have made a commitment to a single national set of food standards – the *Australia New Zealand Food Standards Code*. The Food Standards Code, including most significantly for present consideration Chapter 3 (Food Safety Standards), currently applies in all Australian jurisdictions without significant modification. Furthermore, when amendments to Chapter 3 are gazetted by FSANZ they are automatically incorporated into the laws of all Australian States and Territories. Food safety risk management measures introduced by amendment of the Food Standards Code are therefore nationally consistent.

Stringent FSANZ processes, including public consultation and regulatory impact assessment, are also in place to ensure that principles of good regulation are applied whenever changes to the Food Standards Code are considered.

The extent to which food safety management measures should be mandated in the Food Standards Code has been the subject of ongoing debate. The root cause of these debates is probably two-fold:

- Australian food regulators, and in turn the Food Standards Code, have not explicitly defined different types of food safety management systems, despite their application in practice; and
- there is no clear policy position on the extent to which verification methodologies can or should be prescribed in the Food Standards Code.

The first of these issues has been explored in Section 1.2. The latter is evidenced by the different approaches for like requirements in the Food Standards Code. For example, both Standards 3.3.1 and 4.2.4 require certain businesses to:

- identify hazards and implement controls;
- maintain a written plan for managing food safety;
- operate in accordance with the written plan; and
- keep records/evidence.

Put another way – both standards require businesses to develop and implement a documented, systems-based approach to managing food safety. The most significant difference is that the verification method for businesses subject to Standard 3.3.1 is prescribed (as external audit by a qualified food safety auditor). In contrast, Standard 4.2.4 is silent on how compliance will be verified and is therefore at the discretion of each implementing jurisdiction.

It could be argued that the verification method is an implementation issue that properly rests with the relevant implementation and enforcement agencies (Section 4.1). An alternate view is that where standards impose requirements that require significant judgement, and therefore a high level of expertise, on the part of the verifier then prescribing the verification method may be appropriate.

Prescribing verification methods in the Food Standards Code could help to address concerns about inconsistent implementation (see section 2.2 p19 above).

3.2 Model Food Provisions

The FRA also commits all Australian jurisdictions to adopting the Model Food Provisions (sometimes called the Model Food Act). For further explanation turn to Attachment 4 (p62).

The MFP do not support a broader food safety management toolkit

The MFP were drafted at a time when Australia was re-evaluating its approach to food safety management. Mandatory food safety programs for all food businesses had been proposed (Standard 3.2.1). The MFP were therefore drafted to provide the legislative framework needed to administer food safety program requirements (e.g. approval of auditors). If food safety management tools other than food safety programs, as defined in Standard 3.2.1, are now needed (Section 1.2, p13) the MFP

and in turn jurisdictions' food acts may not include the legislative machinery needed to support implementation.

For example, NSW recently introduced a requirement for certain food service and retail food business to nominate a Food Safety Supervisor who must have attended a nationally accredited food safety training course provided by an 'approved' registered training organisation (RTO). Amendments to the NSW Food Act 2003 were needed to support the requirement that RTOs be approved by the NSW Food Authority.

There may be long timeframes to amend Food Acts if the MFP are revised

All Australian jurisdictions have now enacted their Food Acts to include Annex A of the MFP. However, only three jurisdictions achieved that within the agreed 12 month timeframe. One jurisdiction proclaimed its new Food Act nine years after the initial agreement¹⁸.

3.3 Jurisdiction-specific legislation

In practice, the Code and the MFP do not always provide jurisdictions with the complete regulatory framework needed to apply implement and verify new food safety management measures. Jurisdiction-specific legislation is one way to address this gap. Examples include:

- amending State/Territory Food Acts;
- enacting subordinate legislation under State/Territory Food Acts (for which there is no national model); and
- enacting or amending other legislation (e.g. primary production acts and regulations).

The potential for duplicated effort and therefore inefficiency in this approach is high. For example, resource-intensive regulatory impact processes are required in most jurisdictions.

3.4 Policy and administrative mechanisms

Policy and administrative mechanisms may be used in some jurisdictions to implement new food safety management requirements. An example of a policy mechanism would be the issuing of guidance by a State agency to local government on routine inspection frequencies based on some criterion (e.g. risk classification). The imposition of requirements as a condition of licence in those jurisdictions where retail/foodservice businesses must be licensed to operate is an example of the use of administrative mechanisms.

Because there is no need to enact new legislation, the implementation process is streamlined. However, the potential for inconsistency may be great.

What should be prescribed in nationally consistent instruments (e.g. the Food Standards Code and/or Model Food Provisions)?

4 Food safety management roles and responsibilities

The food regulatory system comprises a complex web of agencies and entities drawn from national, state and local government in Australia and New Zealand.

Within Australia, broad roles and responsibilities are established by the Food Regulation Agreement (FRA) and do not provoke debate. However, some of the issues and challenges identified in this paper may be resolved if additional agreements, especially among implementation and enforcement agencies, about roles and responsibilities are made. The need for collaborative strategies in this regard is outlined at section 4.3 (p23) below.

4.1 Food regulatory roles and responsibilities

The food regulatory roles and responsibilities established by the FRA are explained in detail in the *Overarching Strategic Statement on the Food Regulatory System*.⁹ In summary:

¹⁸ Productivity Commission (2009) *Performance Benchmarking of Australian and New Zealand Business Regulation: Food Safety*, Research Report, Canberra p 82-85

- **food regulation policy** is developed by the Australia and New Zealand Food Regulation Ministerial Council (ANZFRMC), advised by the Food Regulation Standing Committee (FRSC);
- **food standards** are developed by Food Standards Australia New Zealand (FSANZ) with oversight by ANZFRMC;
- **implementation and enforcement** of food standards is undertaken by the eight States and Territories in partnership with 670 local councils. ANZFRMC established the Implementation Sub-Committee (ISC), comprising representatives from all jurisdictions and local government, to coordinate approaches with a view to consistency. In most jurisdictions, local councils are primarily responsible for implementation and enforcement of food standards in the retail/food service sectors.

4.2 Implications for food safety management

A best-practice approach to food safety management would ensure that any additional regulatory interventions applying to retail/food service are justified and are implemented effectively, efficiently and consistently. The issues and challenges identified in previous sections relate principally to:

- considering a broader range of risk management tools when determining potential regulatory requirements for the retail/food service sectors;
- ensuring that impact analysis considers “appropriateness” in conjunction with “risk” and “benefit-cost”;
- resolving issues about the extent to which regulatory risk management tools can be promulgated through the Food Standards Code, particularly provisions needed for implementation and verification;
- limitations of the current Model Food Provisions in enabling implementation and verification of regulatory requirements derived from an expanded risk management “toolkit”; and
- inconsistency and “implementation burden” impacts that arise when implementation and verification must be enabled by jurisdiction-specific instruments.

These issues clearly cut across the roles and responsibilities of the various food regulatory entities. Resolving them will require a collaborative approach over the short, medium and long-term.

Should these issues be addressed in any additional or alternative policy guidance?

4.3 The need for collaborative food safety management strategies

Collaborative work has been undertaken in two relevant areas, although not specifically in relation to the retail/food service sectors, and significant progress has been made.

Firstly, FRSC and ISC have done preliminary work to identify a range of regulatory and non-regulatory risk management tools. Further work is needed to define clearly the nature of the regulatory risk management tools including any implementation and verification mechanisms required to promulgate them.

Secondly, a draft Integrated Model for Standards Development and Consistent Implementation has been developed and is being piloted in development of the Primary Production and Processing Standard for Eggs and Egg Products.

- The model is based on the principle that food standards should only be presented to ANZFRMC for consideration when the associated implementation plan has been agreed. Under the model, ANZFRMC would be provided with a three-part package: the standard as prepared by FSANZ; the implementation package prepared under the auspices of ISC; and a RIS prepared by FSANZ that incorporates information from ISC concerning implementation costs and options.
- The model seeks to ensure that Ministers are provided with information concerning implementation strategies at the time draft standards are provided for consideration. If successful, the integrated process would ensure that all jurisdictions are committed to plans that provide for

effective and consistent implementation of approved food standards. The key concepts underpinning this model were strongly supported by participants at the 2009 Food Regulation Stakeholder Forum.

The work in these two areas could provide a useful starting-point for development of a national approach to food safety management in the retail/food service sectors that addresses the five issues summarised in section 4.2 (p23) above.

5 Potential scope of policy guidance

Under the Food Regulation Agreement, the core function of Ministerial policy guidelines is to provide guidance to FSANZ when developing food standards. However, there is no reason why policy guidelines may not also address broader food safety management issues such as those summarised in section 4.2 (p23) above. These issues are not addressed by the 2003 Policy Guideline under review.

Additional or alternative policy guidance on food safety management in Australia could address the issues outlined above by:

- considering a broader range of risk management tools, both regulatory and non-regulatory, including food safety programs meeting the requirements of Standard 3.2.1 of the Code;
- extending decision-making criteria from food safety risk and benefit-cost analysis to also include consideration of “appropriateness”;
- encouraging the integrated development of regulatory requirements, including the legislative, administrative and/or policy mechanisms needed for effective implementation; and
- encouraging the use (and, if necessary, further development) of nationally consistent instruments, such as the Food Standards Code and the Model Food Provisions, to apply, implement and verify regulatory requirements.

Potential for a staged approach to implementation of additional regulatory interventions

The previous discussion suggests that determining whether additional regulatory intervention is warranted in a particular sector(s) requires, in an iterative fashion:

- risk assessment/risk profiling of the business types;
- identification of potential risk management tools;
- assessment of appropriateness (right tool for the job); and
- benefit-cost analysis.

However, it may be that even the best evidence available does not enable optimum calibration of the intervention to the profiled risks in some of the settings under consideration. There may be significant room for debate on whether a particular risk management tool, especially if relatively high-cost, is warranted for the relevant settings.

These are situations where a staged approach may be appropriate. Under this approach, the risk management tool that is clearly justified and appropriate on the available evidence is implemented first. The impact of this intervention is then evaluated to determine its effectiveness and in particular, to assess the extent of residual unmanaged risk in the settings flagged for potential additional intervention. The evaluation process would generate the evidence required to consider whether additional intervention is warranted in these sectors.

Several criteria can be identified that may assist in making the judgment whether a staged approach is appropriate in particular circumstances. For example:

1. Has risk assessment/profiling identified a need for intervention in sector(s) that include a diverse range of settings with setting-specific risks?
2. Is there at least one risk management tool that would be justified and appropriate in all the settings?

3. If so, is it possible that intervention will sufficiently minimise risk in all or most settings such that additional intervention may not be justified and appropriate?
4. In those settings where it is considered that there may be significant residual unmanaged risk, are there unresolved issues and/or a lack of evidence that prevent a clear case being made at this stage for additional intervention?

It may be useful for the additional or alternative policy guidance to identify the option of implementing regulatory risk management tools in stages following evaluation and review of the previous stage.

Should any additional or alternative policy guidance encourage collaboration on implementation strategies?

Should an additional or alternative policy guidance provide for a staged approach to implementing food safety management measures?

Policy Options and Analysis

This Policy Options Consultation Paper presents two policy options for consideration:

Option 1 - Status Quo: The existing 2003 Policy Guideline (*Ministerial Policy Guidelines on Food Safety Management in Australia – Food Safety Programs*) continues to apply to food safety management in the general food service sector and closely related retail sectors including catering (“retail/food service”); and

Option 2 - Develop Additional or Alternative Policy Guidance: For the retail/food service (including catering) sector, additional or alternative food safety management policy guidance is developed.

Introduction

The 2003 *Ministerial Policy Guidelines on Food Safety Management in Australia – Food Safety Programs* may not provide the guidance needed to develop an effective food safety management approach for retail/food service. It focuses on application of a single risk management tool (food safety programs as prescribed by Standard 3.2.1) and elaborates two criteria (risk and benefit-cost analysis) to determine whether this tool should be implemented in a particular industry sector.

The Guideline identifies four high-risk industry sectors where implementation of Standard 3.2.1 *Food Safety Programs* would be justified, including catering operations to the general public. Requirements are now in place nationally in three of these sectors.

The proposed standard for catering operations (Proposal P290 – Food Safety Programs for Catering Operations) has been in development for a number of years without completion. A fifth sector – ‘eating establishments’ – was also identified as high-risk, but the benefit-cost ratio of implementing Standard 3.2.1 was considered insufficiently high. This potentially leaves a gap in risk management in the food service sector.

The review scope is ‘general food service and closely related retail sectors’, referred to as ‘retail/food service’. This encompasses the business types in the table at section 1.1 (p11), principally comprising food businesses described in the 2003 Guideline as catering operations and eating establishments.

In relation to food safety management in retail/food service, the review has identified five critical issues that are not addressed by the 2003 Policy Guideline. These were described earlier at section 4.3 (p22). The first two issues impact on FSANZ’s capacity to formulate a cost-effective risk management approach to these sectors. The remaining issues relate to effective, efficient and consistent implementation.

Description of policy options

Option 1 - Status Quo: The existing 2003 Policy Guideline (*Ministerial Policy Guidelines on Food Safety Management in Australia – Food Safety Programs*) continues to apply to food safety management in the general food service sector and closely related retail sectors including catering (‘retail/food service’).

Specific guidance in relation to food safety management for retail/food service (including catering) would continue to relate only to the application of Standard 3.2.1 *Food Safety Programs*.

FSANZ would re-activate and complete *Proposal 290 – Food Safety Programs for Catering Operations to the General Public* (Proposal 290).

No policy guidance would be provided in relation to consideration of other potential risk management tools, nor in relation to “appropriateness” as a distinct criterion that can be applied in conjunction with the risk and benefit-cost criteria as part of the impact analysis. Therefore, there would be no policy basis to identify alternative, and potentially more cost-effective, risk management approaches for

catering, or to address the serious incidence of foodborne illness attributable to the remaining retail/food service sectors.

If, despite the absence of policy guidance, FSANZ were to formulate risk management alternatives to Standard 3.2.1, there would be no policy guidance in relation to the implementation issues identified by the review.

Option 2 - Develop Additional or Alternative Policy Guidance: The 2003 Policy Guideline, as it applies to industry sectors that are beyond the scope of the review and have already implemented Standard 3.2.1. *Food Safety Programs*, would be retained. Additional or alternative policy guidelines would be developed that would address the issues detailed in section 4.2 (p23).

Under this option, FSANZ would need to consider the overall risk management approach for retail/food service. The policy guidance would enable FSANZ to take a holistic view of retail/food service by considering a broad range of risk management tools, including Standard 3.2.1, and determining their appropriateness for the different business types within the sector. This would necessarily include reconsideration of Proposal P290.

The policy guidance would also require FSANZ and jurisdictions (through FRSC and ISC) to develop strategies to address the implementation issues identified by the review.

Rationale for the two-option approach

When developing a policy or regulatory approach to a problem, three or more options (including the status quo) are generally identified.

However, it is considered appropriate for the purposes of this review simply to put forward the two options identified above. The reasons relate to the circumstances of the review and its terms of reference. The review was established due to concerns that the 2003 Policy Guideline may not provide adequate or appropriate guidance for food safety management in the retail/food service sectors. The review's terms of reference require it to consider whether additional or alternative policy guidance is needed.

As noted above, the review identified five critical issues, not addressed by the 2003 Policy Guideline, that impact on FSANZ's capacity to formulate a cost-effective risk management approach to these sectors and on jurisdictions' capacity to implement regulatory requirements effectively, efficiently and consistently. The review concluded that additional or alternative policy guidance could address these issues in four ways outlined at p24.

From this perspective, there are really only two options: leave the 2003 Policy Guideline in place **or** develop additional or alternative policy guidance to address the issues identified by the review. The analysis of the two options at pp28-29 explores the impacts of these options and a draft example of the policy guidance under Option 2 is provided.

This provides stakeholders with all the information needed to comment on or critique the review's analysis and express a view on whether change to the status quo is warranted. The presentation of Option 2 and the draft example also give stakeholders the opportunity to comment on any aspect of the proposed policy approach to the review's findings.

It is considered that the review's findings, and the proposed response, are an integrated 'package' and so for this reason the Consultation Paper does not identify further options that would in effect be subsets of the proposed response. However, stakeholders are nonetheless able to provide critical comment or suggest changes in relation to any aspect of the proposed response.

Analysis of policy options

The tables below present the analysis of the impacts of both Option 1 and 2 in relation to four key areas. In summary, the main impacts will be in relation to: incidence of foodborne illness; national consistency; industry compliance costs; and consumer confidence, consumer choice and food prices.

Table 1. Option 1 - Status Quo

	Advantages	Disadvantages
Public Health	The introduction of the Catering Standard is likely to result in fewer foodborne illness outbreaks attributable to the catering sector.	Requirements for many retail/food service businesses (outside the scope of the FSANZ Proposal 290) will remain unchanged. Therefore, the number of foodborne illness outbreaks attributable to this sector is not likely to change (about half of foodborne illness outbreaks in 2007 ³) and that the retail/food service sector will continue to be over-represented amongst the sectors causing foodborne illness.
Industry	<p>Businesses subject to the Catering Standard would be required to implement nationally consistent requirements thus addressing any issues arising from jurisdiction specific requirements.</p> <p>A decline in the number of food-borne illnesses attributable to the catering sector is likely to have a beneficial effect on the catering sector's reputation.</p> <p>No extra costs are likely to be imposed or resources needed for the retail/food service sector as requirements for this sector are outside the scope of Proposal 290 and are likely to remain unchanged.</p>	<p>Compliance with Standard 3.2.1 <i>Food Safety Programs</i> may be particularly onerous for certain businesses subject to the proposed Catering Standard. For smaller businesses, those with limited resources or for those hosting infrequent catering events, implementing and maintaining Standard 3.2.1 <i>Food Safety Programs</i> may prove to be unsustainable resulting in poor compliance and/or ineffective programs and fewer businesses able or willing to undertake catering activities.</p> <p>Individual jurisdictions may implement own legislation/requirements in the absence of national risk management tools resulting in possible increased compliance costs.</p>
Government	<p>The introduction of the Catering Standard mitigates food safety risk posed by the catering sector.</p> <p>The record keeping requirements set out in Standard 3.2.1 enable regulators to verify that businesses are adequately managing food safety hazards over time.</p>	<p>Implementing Proposal 290 is likely to require high levels of Government resources. Certain businesses are likely to require assistance in the form of assistance materials; an extended period to implement compliant programs; and may initially require several follow up visits by the regulatory agency.</p> <p>Responding to foodborne illness outbreaks attributable to the retail/food service sector (outside the scope of Proposal 290) continues to require Government resources e.g. enforcement and other public health related resources.</p> <p>Government reputation may be negatively affected if a major foodborne illness outbreak/s occurs in the retail/food service sector.</p>
Consumer	Greater consumer confidence in the catering sector may result.	<p>Consumer choice may be diminished as the availability of businesses capable of or willing to undertake catering activities declines in response to implementing the Catering Standard.</p> <p>Businesses are likely to pass on to consumers the compliance costs associated with implementing the Catering Standard.</p>

Table 2. Option 2 - Develop Additional or Alternative Policy Guidance:

	Advantages	Disadvantages
Public Health	New or alternative guidance is likely to result in integrated requirements that will more effectively manage food safety risks for the retail/food service sectors (including catering) resulting in fewer foodborne illness outbreaks attributable to these sectors.	Policy development processes and any subsequent Standards development processes take time. Foodborne illness and food contamination rates attributable to the retail/food service sectors are unlikely to change during this period.
Industry	Higher levels of industry compliance and lower implementation costs are expected with fit-for-purpose risk management tools. National consistency is expected to be achieved, as regulatory tools are likely to be implemented by nationally consistent instruments such as the Food Standards Code or the Model Food Provisions.	The policy development and consultation process takes time. In the interim, the reputation of the retail/food service industry may be affected, as the number of likely foodborne illness outbreaks attributable to retail/food service is likely to remain unchanged. Implementing risk management tools for the retail/food service sector is likely to require industry resources.
Government	New or alternative guidance is likely to minimise implementation burden on regulatory agencies, as nationally consistent instruments will be available to implement risk management tools. Implementation effort is likely to be minimised as ‘fit-for-purpose-tools’ can be selected from a broad range tools. It is likely that the resultant higher levels of compliance will require fewer regulatory resources to manage and respond to food safety risk posed by the retail/food service sector.	Communicating complex requirements internally and to industry stakeholders may require more resources. The development of a multi-tool, multi-sector risk management approach is complex compared with the approach taken in Standard 3.2.1 <i>Food Safety Programs</i> .
Consumer	In the long term, consumer confidence in the retail/food service sector is likely to improve if food contamination rates decline in response to the introduction of risk management tools in the retail/food service sectors. Implementing risk management tools requires resources and it is likely that industry would pass these costs on to the consumer in the form of food price increases. However, as industry and government are implementing fit-for-purpose, nationally consistent risk management tools, it is likely that increases to food prices will be minimised.	Policy development processes and any subsequent Standards development processes take time. Foodborne illness and food contamination rates attributable to the retail/food service sectors are therefore unlikely to change during this period. Consumer confidence in the food produced by the retail/foodservice sector and the food regulatory system may be adversely affected during this period. In response to the additional or alternative guidance for the retail/food service sector, possible increases in implementation costs borne by industry are likely to be passed on to the consumer in the form of increased food prices.

Comparing the Options

Option 2 is likely to have a greater impact on the incidence of foodborne illness attributable to retail/food service because it enables a holistic approach to food safety management across all the business types in the sector. In contrast, Option 1 provides food safety management guidance only in relation to catering operations.

Option 2 also provides the basis to develop the most cost-effective approach to food safety management by considering a range of risk management tools and assessing their appropriateness in relation to each business type. In contrast, Option 1 enables only the application of Standard 3.2.1 across all catering operations, even though more cost-effective approaches might be possible for some catering business types.

In summary, Option 2 provides the basis to develop an effective national food safety management approach for retail/food service that complies with the principles of best practice regulation. In the absence of a national approach, it is likely that individual jurisdictions will consider it necessary to introduce State/Territory-specific regulatory requirements as has occurred already in Victoria, Queensland and NSW.

Option 2 is also more likely to enable effective, efficient and consistent implementation of regulatory requirements. It would encourage the integration of standards development and implementation planning and facilitate the collaborative development of implementation strategies.

To proceed with Option 2, a **separate** Policy Guideline for retail/food service that combines retained material from the 2003 Policy Guideline with the additional or alternative policy guidance could be developed. Another approach would be to amend the 2003 Policy Guideline to include all the additional or alternative policy guidance for retail/food service.

The first approach has been taken for the purposes of this paper. An example of a draft Policy Guideline has been provided in the next section.

What is your preferred policy option?

Are there other advantages or disadvantages for public health, industry, government and consumers that should be considered here?

Indicative next steps if Option 2 is endorsed

To help stakeholders understand the implications of the proposed Policy Guideline, this section briefly outlines the processes that are likely to follow.

The overall intention is to facilitate an integrated and best-practice approach to food safety management in the retail/food service sectors. Guidance is provided in relation to both standards development and implementation. It therefore relates to the roles of FRSC, ISC and individual jurisdictions, as well as FSANZ, and encourages a collaborative approach, building on current arrangements.

It would be inappropriate and preemptive to outline precisely what the next steps might be or the order in which they would occur. However, the policy guideline would encourage and guide the following:

- review by FSANZ of the scope of proposal P290 *Food Safety Programs for Catering Operations*;
- consultation on the draft risk classifications of key business types and their finalisation in accordance with the Risk Profiling Framework;
- agreement on a set of potential risk management tools, building on work already undertaken by FRSC and ISC; and
- agreement on a process to integrate food safety management standards development and implementation planning related to the retail/food service sectors.

It is likely, based on existing data on food safety risk, that a revised P290 (or alternative proposal) would include eating establishments as well as catering operations in its scope, and perhaps closely-related retail sectors such as delicatessens. However, the standards development process would consider a full range of potential risk management tools and the impact analysis would address appropriateness as well as risk and benefit/cost issues. This process would be undertaken in consultation with industry and jurisdictions.

A complementary process involving FSANZ and all jurisdictions would undertake implementation planning in parallel with the standards development process.

If additional regulatory requirements are proposed, a key consideration for both processes would be to find ways to apply and implement these through nationally consistent instruments, in particular the Food Standards Code and the Model Food Provisions. Recognition of existing equivalent industry-based systems may facilitate this.

Example of a Draft Policy Guideline on Food Safety Management for General Food Service and Closely Related Retail Sectors

The following example shows how the second policy option may translate into a draft policy guideline.

BACKGROUND

The fundamentals of good hygienic practice are incorporated into the Australian food regulatory system by Standards 3.2.2 and 3.2.3 of the *Australia New Zealand Food Standards Code*. State and Territory Food Acts contain nationally consistent provisions that enable compliance and enforcement action by State and Territory agencies and local government. In combination, they are a strong foundation for food safety management by government and industry.

Additional intervention may be warranted in some circumstances. This intervention should be (or is intended to be) preventive rather than reactive in nature, given the compliance and enforcement powers already available. Intervention will involve the use of ‘risk management tools’ that may be a regulatory requirement (e.g. a food safety management system or mandatory training) or a non-regulatory initiative (e.g. an information campaign or voluntary training).

The 2003 *Ministerial Policy Guidelines on Food Safety Management in Australia – Food Safety Programs* identifies four high-risk industry sectors where implementation of the food safety program requirements of Standard 3.2.1 of the *Australia New Zealand Food Standards Code* would be justified. These sectors include catering operations to the general public. Requirements consistent with these requirements are now in place nationally in three of these sectors¹⁹ but the proposed standard for catering operations (*P290 Food Safety Programs for Catering Operations to the General Public*) has been in development for a number of years without completion.

A fifth sector – eating establishments⁶ – was also identified as high-risk, but at the time of the policy guideline’s implementation the benefit-cost ratio of implementing Standard 3.2.1 *Food Safety Programs* in this sector was considered insufficiently high.

SCOPE/AIM

This policy guideline provides guidance on food safety management in Australia in the general food service and closely related retail sectors (“retail/food service”). Businesses subject to the recently implemented Standard 3.3.1 *Food Safety Programs for Food Service to Vulnerable Persons* are specifically excluded.

The policy guideline **supersedes** the 2003 *Ministerial Policy Guidelines on Food Safety Management in Australia – Food Safety Programs* (in particular Part 3.3 at p414) **in relation to retail/food service**, including catering operations and eating establishments. It also includes guidance from the 2003 Policy Guideline that continues to be relevant for food safety management in retail/food service.

The business types that fall within the scope of this guideline include the following:

General food service sector

- on and off-site catering; and
- eating establishments.

Closely related retail sectors²⁰

¹⁹ These sectors are: food service to vulnerable persons; producer, harvesters, processors and vendors of raw ready-to-eat seafood; producers of manufactured and fermented meats.

²⁰ ‘closely related’ refers to the fact that while these retail sectors are not considered to be ‘food service’, they undertake similar activities such as serving food that is ready-to-eat

Retailers of ready-to-eat²¹:

- potentially hazardous bakery products (including processors);
- delicatessen products;
- processed seafood products; and
- perishable packaged foods (e.g. sandwiches).

The aim of the policy guideline is to ensure that food safety management:

- reduces foodborne illness by ensuring food is safe;
- targets food safety risk in a cost-effective manner; and
- is consistent with international best practice.

The policy guideline recognises the strong foundation provided by Standards 3.2.2 and 3.2.3 of the Australia New Zealand Food Standards Code and by State and Territory Food Acts. It seeks to ensure that any additional food safety standards that may apply to retail/food service are justified and are implemented effectively, efficiently and consistently.

The policy principles are directed to the implementation process as well as the standards development process. They encourage a collaborative approach involving FSANZ, the Food Regulation Standing Committee (FRSC) and its Implementation Sub-Committee (ISC), and individual jurisdictions and agencies.

While this guideline applies only to retail/food service, it is anticipated that the generic principles may have wider application subject to consultation with the affected industry sectors.

“HIGH ORDER” POLICY PRINCIPLES

The *Food Standards Australia New Zealand Act 1991* establishes a number of objectives for FSANZ (‘the Authority’) in developing or reviewing of food standards.

1. The objectives (in descending priority order) of the Authority in developing or reviewing food regulatory measures and variations of food regulatory measures are:
 - (a) the protection of public health and safety; and
 - (b) the provision of adequate information relating to food to enable consumers to make informed choices; and
 - (c) the prevention of misleading or deceptive conduct.
2. In developing or reviewing food regulatory measures and variations of food regulatory measure the Authority must also have regard to the following:
 - (a) the need for standards to be based on risk analysis using the best available scientific evidence;
 - (b) the promotion of consistency between domestic and international food standards;
 - (c) the desirability of an efficient and internationally competitive food industry;
 - (d) the promotion of fair trading in food;
 - (e) any written policy guidelines formulated by the Council for the purposes of this paragraph and notified to the Authority.

These objectives apply to the development of standards regulating food safety management within the scope of this guideline.

A number of other policies are also relevant to the development of food standards including COAG Principles (Australia only), the New Zealand Code of Good Regulatory Practice, the Agreement between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System, and WTO agreements.

²¹ As per the definition of ready-to-eat food in *Food Standards Code* Standard 3.2.1(1)

SPECIFIC POLICY PRINCIPLES – Overarching Principles

These policy principles are intended to guide the processes for determining and implementing the appropriate risk management tools for specified retail/food service sectors or business types. Regulatory risk management tools, including standards or other regulatory requirements, should be determined in accordance with principles of best regulatory practice²².

1. Impact analysis should be used to assess feasible options and determine which option generates the greatest net benefit. The key issues, to be considered iteratively, relate to risk, benefit-cost, and appropriateness. Assessment of risk will play a primary role in addressing the threshold issue of whether or not to regulate.
2. The following components should be available, or be developed as necessary, to support the processes that determine and implement risk management tools:
 - an agreed set of potential regulatory and non-regulatory risk management tools;
 - legislative, administrative and/or policy instruments to implement regulatory risk management tools;
 - when regulatory risk management tools are determined, strategies to apply them consistently across Australia and implement them effectively and consistently;
 - strategies to minimise the implementation burden on States and Territories and on industry including, where appropriate, implementation assistance for small business and community groups; and
 - evaluation and review processes.
3. The intervention determined for a particular retail/food service sector or business type(s):
 - may include more than one risk management tool;
 - may combine regulatory and non-regulatory risk management tools;
 - should be consistently applied and implemented by States and Territories;
 - should be evaluated and reviewed after implementation; and
 - may be implemented in stages following evaluation and review of the previous stage.

Specific policy principles related to risk

The 2003 Policy Guideline includes several principles related to risk that continue to be relevant to food safety management in retail/food service. These have been updated to current circumstances and are included below.

4. The level of regulatory requirements and their verification should be proportionate to the level of risk.
5. Risk profiling by an agreed national methodology should be used to classify retail/food service business types in Australia on the basis of risk. The risk classification of a business type, and the rationale for that classification, should inform consideration of any additional intervention.
6. Risk classification of a business type may change when new data on the causes and incidence of foodborne illness that affect the risk profile become available, or when the specific circumstances of an individual business type justify such change.

²² Refer Best Practice Regulation: A Guide for Ministerial Councils and Standard Setting Bodies (COAG, 2007) and Best Practice Regulation Handbook (OBPR, 2007).

Specific policy principles related to benefit-cost

COAG has agreed that, where appropriate, benefit-cost analysis will be used to improve the quality of regulation impact analysis.

7. Benefit-cost analysis should be used to assess a range of feasible interventions. The intervention determined should generate greatest net benefit for the community.

Specific policy principles related to appropriateness

The appropriateness concept can be described as ensuring that the 'right tool for the job' is used. Although the concept could be seen as inherent to risk and benefit-cost analysis, a stronger focus on the appropriateness of a potential risk management tool will be beneficial.

8. The overarching concern for appropriateness is whether the proposed risk management tool, including external verification (auditing/inspection), is likely to be effective and sustainable in the context of the business type and its setting. This may require consideration of a number of factors including the scale and nature of the food handling process, existing systems and the food safety culture, and outcomes of any past interventions.
9. Consideration of appropriateness may be linked to and help inform the application of other policy principles, for example:
 - whether the available set of potential risk management tools is adequate; and
 - whether a staged approach to intervention in a particular sector or business type(s) is desirable.

Specific policy principles related to implementation strategies

Legislative, administrative or policy instruments are used to apply and implement regulatory requirements, including any necessary verification (e.g. by audit). Depending on the nature of the risk management tool, this may be done entirely through the Food Standards Code and State and Territory Food Acts based on the current Model Food Provisions. Otherwise, jurisdiction-specific instruments must be used (for example, in implementing some requirements of the Primary Production and Processing Standards).

Use of jurisdiction-specific instruments generates an 'implementation burden' for jurisdictions and leads to inconsistency that may increase the compliance burden on industry.

Expansion of the set of potential risk management tools carries with it the challenge to find ways to apply and implement these tools through nationally consistent instruments. The aim should be to ensure that food standards are fully and effectively implemented in a consistent manner.

10. To the extent possible, regulatory requirements and the legislative, administrative and/or policy mechanisms necessary for effective implementation should be developed by a single or integrated process.
11. To the extent possible, regulatory requirements and implementation mechanisms should be promulgated through nationally consistent instruments such as the *Australia New Zealand Food Standards Code* and the Model Food Provisions.
12. To the extent possible, implementation mechanisms should enable recognition of existing equivalent industry-based systems.

If you favour Option 2, please provide your views on the desirability and relevance of each Specific Policy Principle?

Are there other Specific Policy Principles that should be included?

Attachment 1 – The Consultation Process

How do I respond to the Policy Options Consultation Paper?

Individuals, business, government and industry/consumer/professional associations are invited to respond to this paper. The easiest way to respond is:

online: visit <https://www.surveymonkey.com/s/NFLGC8R> and follow the prompts.

Or send your response in writing by:

post:

Australia: Submissions - Review of Ministerial Policy Guideline Food Safety Management in Australia: Food Safety Programs (2003) C/- Food Regulation Secretariat PO Box 4 WODEN ACT 2606	New Zealand: Submissions- Review of Ministerial Policy Guideline Food Safety Management in Australia: Food Safety Programs (2003) C/- Policy Group New Zealand Food Safety Agency PO Box 2835 WELLINGTON, 6011
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email: foodregulationsecretariat@health.gov.au (Australia)

policy@nzfsa.govt.nz (New Zealand)

fax: (02) 6289 5100 (Australia)

64 4 894 2583 (New Zealand)

The final date for submissions is 17 December 2010

How do I structure my response?

It is not necessary to respond to all the issues raised in this paper. You may comment on as many or as few as you wish.

It will assist if you support your comments or opinions with reasons and any available evidence. Please feel free to attach supporting documents.

You may find the submission coversheet provided overleaf useful for summarising your position (note submissions will be accepted with or without the coversheet).

If you have any questions in relation to this document, please call the NSW Food Authority Helpline 1300 552 406 (61 2 9741 4850) in Australia.

**FOOD REGULATION POLICY OPTIONS CONSULTATION FOR REVIEW OF THE
MINISTERIAL POLICY GUIDELINE *FOOD SAFETY MANAGEMENT IN AUSTRALIA:
FOOD SAFETY PROGRAMS (2003)***

Submission Coversheet

Contact Details:

Name: _____ Tel: _____
Organisation: _____ Fax: _____
Address: _____ Mobile: _____
_____ E-mail: _____

International context:

1. Are there other international approaches to food safety management that would inform this policy process? (p8 and 65)

Yes / No

If yes, please attach details

Key impacts:

2. Are there other impacts on public health, consumers, industry and government stakeholders that should be considered? (p9)

Yes / No

If yes, please attach details

Key issues:

Deciding how and when to intervene

- 3a. What should Risk Profiling Framework classifications be used for? (tick all that apply): (p11)

- Assist in setting standards development priorities
 Inform the development of specific standards
 Inform the choice of risk management tool(s)
 Guide audit/inspection activities, including frequency, timing and whether they are unannounced
 Standardise enforcement action when critical violations occur
 Other _____

Details of your reasons would be useful to the review

- 4a. Is this list of potential regulatory interventions adequately described? Are there any others that should be included on this list? (p135)

Yes / No

If no please attach reasons and alternatives/additions

- 4b. Should each intervention, including different systems-based approaches, be formally agreed and documented by Australian food regulators? (p15)

Yes / No

Details of your reasons would be useful to the review

5a. Is this list of potential non-regulatory interventions adequately described? Are there any others that should be included on this list? (p16)

Yes / No

If no please attach reasons and alternatives/additions

5b. Should each intervention be formally agreed and documented by Australian food regulators? (p16)

Yes / No

Details of your reasons would be useful to the review

6. Are there existing industry-based or other programs that would inform this policy process? (p17)

Yes / No

If yes please attach details

7. Should 'appropriateness' be expressly considered, with risk and benefit-cost analysis, when deciding food safety risk management approaches? (p18)

Yes / No

Details of your reasons would be useful to the review

8. Are the criteria for determining 'appropriateness' useful? (p18)

Yes / No

If no please attach reasons and alternatives/additions

If you can think of others please provide details

Implementing regulatory measures effectively and efficiently

9a. In practice what aspects of inconsistent approaches to implementation currently have the greatest impact on regulatory compliance burden (*rank in order of significance, 1=most significant, 7=least significant*)? (p20)

Interpretation of the Food Standards Code

Content of regulatory requirements

Government commitment to enforcing standards (e.g. complaint-triggered versus proactive inspections)

Method of external verification (e.g. audit versus inspection)

Intensity of regulatory oversight (e.g. inspection frequency)

Enforcement responses (e.g. warnings versus fines)

Other _____

Examples of impacts and estimates of the associated costs would be useful to the review

9b. Do you agree that improved consistency among jurisdictions in the most significant of these will reduce regulatory compliance burden? (p20)

Yes / No

Details of your reasons would be useful to the review

Instruments available to apply, implement and verify regulatory measures

10. What should be prescribed in nationally consistent instruments (e.g. the Food Standards Code and/or Model Food Provisions)? (*tick all that apply*): (p22)

- Food safety outcomes
- Risk management tools
- Verification methods (external to the business) (e.g. audit)
- Verification methods (internal to the business) (e.g. sampling and analysis)
- Other _____

Details of your reasons would be useful to the review

Food safety management roles and responsibilities

11. Should these issues be addressed in any additional or alternative policy guidance? (p23)

Yes / No

Are there any other issues?

Details of your reasons would be useful to the review

Potential scope of policy guidance

12. Should any additional or alternative policy guidance encourage collaboration on implementation strategies? (p25)

Yes / No

Details of your reasons would be useful to the review

13. Should any additional or alternative policy guidance provide for a staged approach to implementing food safety management measures? (p25)

Yes / No

Details of your reasons and examples would be useful to the review

Policy Options and Analysis:

14. What is your preferred policy option (*tick one*): (p30)

- Option 1 (Status quo)
- Option 2 (Develop additional or alternative policy guidance)

Details of your reasons would be useful to the review

15. Are there other advantages or disadvantages for public health, industry, government and consumers that should be considered? (p30)

Yes / No

Details and data would be useful to the review

Example of Draft Policy Guideline:

16a. If you favour Option 2 please provide your views on the desirability and relevance of each Specific Policy Principle: (p35)

	Agree	Agree with amendment	Disagree
Principle 1	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Principle 2	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Principle 3	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Principle 4	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Principle 5	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Principle 6	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Principle 7	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Principle 8	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Principle 9	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Principle 10	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Principle 11	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Principle 12	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If 'agree with amendment' or 'disagree' please provide reasons and alternatives/amendments.

16b. Are there other Specific Policy Principles that should be included? (p35)

Yes / No

If yes please provide details

Attachment 2 – A summary of the 2003 Ministerial Policy Guidelines on Food Safety Management in Australia – Food Safety Programs

Summarising the Policy Objectives

The *Ministerial Policy Guidelines on Food Safety Management in Australia: Food Safety Programs* (2003 Policy Guideline) contains an overarching policy objective, namely to safeguard consumers from foodborne illness without creating undue impost on industry or community groups. This was to be achieved by adopting the following principles:

1. Regulations dealing with food safety management in Australia to be based on risk.
2. Risk profiling to be used to classify businesses or food industry sectors.
3. Standard 3.2.1 *Food Safety Programs* to be implemented as the minimum requirement in businesses/sectors identified as high risk **and** where the benefit-cost ratio justifies implementation.
4. Risk classifications to be reviewed and amended (as appropriate) where new data became available.
5. Support to be provided to community groups and small business to assist in meeting regulatory requirements.

Four industry sectors were identified as being appropriate for the introduction of food safety programs (based on risk and benefit-cost data). These are:

1. food service (of potentially hazardous food) to vulnerable populations
2. production, harvest, processing and distribution of raw oysters and other bivalves
3. catering operations serving food to the general public
4. processors of manufactured and fermented meat.

Exclusions :

Low benefit-cost ratios led to the following food businesses being excluded from the application of the 2003 Policy Guideline:

- Non-government funded family day care and businesses that serve a clientele of less than five people
- Eating establishments (including retail food service and restaurants) although some food businesses offering buffets are included in specific circumstances, and
- Other vendors who sell raw oysters and other bivalves

Several objectives relating to planned future work (in conjunction with the standards development process) were also contained within the 2003 Policy Guideline. These included:

- Refining the definition of catering
- Exploring potential exclusions from food safety programs

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*²³.

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 populations²⁴;
2. producing, harvesting, processing and distributing raw oysters and other bivalves;

²³ *Food Standards Australia New Zealand Act 1991* - <http://scaleplus.law.gov.au/html/pasteact/0/31/top.htm>

²⁴ 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 populations²⁵

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'.

²⁵ 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 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 establishments²⁶ 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

²⁶ 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 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 standards²⁷ 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

²⁷ 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>

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 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* report¹; and
- 3) findings from the *National Risk Validation Project* report¹.

¹ 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 2001-2002²⁸. 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

²⁸ The current burden of foodborne gastroenteritis in Australia, Summary paper, February 2003

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 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

<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 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 seafood²⁹;
3. catering operations serving food to the general population;
4. eating establishments; and
5. producers of manufactured and fermented meats³⁰.

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 listericidally³¹ 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.

²⁹ 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.

³⁰ Consumption data for these products could not be calculated.

³¹ 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

	Initial costs		Ongoing costs (per year)	
	Cost per business (\$)	Total cost (\$M)	Cost per business (\$)	Total cost (\$M)
<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 billion³² 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

	Cost of foodborne illness per meal (\$)	Benefit to Cost Ratios ³³ Class 1 outbreaks (No.)
Food service for sensitive populations	0.21	6.5
Producers, harvesters, processors and vendors of raw ready to eat seafood ³⁴	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

³² 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.

³³ 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.

³⁴ 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.

Attachment 4 – Current Status of Food Safety Management in Australia and New Zealand

Regulatory requirements relevant to food safety management in food service and related retail settings differ between Australia and New Zealand. In Australia, requirements are detailed in Chapter 3 of the *Australia New Zealand Food Standards Code*, supplemented by extra (e.g. food safety supervisor) requirements in some jurisdictions. Chapter 3 of the Food Standards Code does not apply in New Zealand. Instead food businesses in New Zealand need to comply with the regulatory regime set by the *Food Act 1981* (and associated regulations).

1. Food safety management in Australian food businesses

Food safety management in Australia includes both national and State/Territory specific requirements that manage food safety risk in food businesses.

1.1 A strong foundation for food safety management is in place nationally

Two elements constitute the foundation for food safety management in Australia:

1. Food Safety Standards 3.2.2 and 3.2.3 of the Food Standards Code; and
2. State and Territory Food Acts based on national Model Food Provisions.

At a national level, Standards 3.2.2 and 3.2.3 specify fundamental food safety requirements for all food businesses. These standards include food safety requirements relating to food handling, premises, vehicles and equipment. Introduced between 2001 and 2003, these Standards apply only to food businesses, not to primary food production.

Standards 3.2.2 and 3.2.3 replaced previous State and Territory government food hygiene regulations that were often nationally inconsistent, out of date and overly prescriptive. In contrast, Standards 3.2.2 and 3.2.3 largely specify outcome based requirements. Where they are prescriptive e.g. temperature control in relation to cooking, cooling and storing food, they allow businesses to demonstrate compliance by alternative means or by equivalent processes.

The Model Food Provisions are a nationally generated template for use by States and Territories outlining baseline enforcement and administration requirements. The Model Food Provisions, now enacted in State and Territory Food Acts, provide for the effective and consistent administration and enforcement of the Food Standards Code (including the Food Safety Standards).

Annex A of the Model Food Provisions forms the core provisions which each state and territory agreed to adopt. In the most part, States and Territories have adopted all the provisions in Annex A either with the same wording or with different wording but with the same intent.³⁵ Annex A provisions mainly relate to definitions, offences and defences and provides the method of adoption of the Food Standards Code. They confer a range of compliance and enforcement powers including inspections, remedial orders, and emergency powers including food recalls.

Annex B forms the non-core provisions and its adoption by State and Territory governments is voluntary. There is considerably more variation among jurisdictions in their adoption of these provisions either with the same wording or with different wording but same intent.¹³ Annex B includes provisions that address notification of the existence of a food business, licensing, registration, food safety programs and auditing..

³⁵ Productivity Commission (2009) *Performance Benchmarking of Australian and New Zealand Business Regulation: Food Safety*, Research Report, Canberra p 79-80

State and Territories with additional food safety requirements

Several States have implemented or adopted food safety requirements for food businesses that are in addition to those in Standards 3.2.2 and 3.2.3.

Victoria has two additional requirements: food safety programs and food safety supervisors. Victorian food businesses within the scope of this review (general food service and closely related retail sectors) must implement audited food safety programs based on Standard 3.2.1 *Food Safety Programs*. Food businesses have the option either to:

- develop their own food safety program and have it audited every year by an approved auditor; or
- implement a customised Food Safety Program Template provided by the Victorian Department of Health. Template-derived programs are assessed annually by a local government Environmental Health Officer (EHO).

Additional requirements for food handlers have been introduced in several States. Victoria and, more recently, Queensland and NSW have introduced mandatory Food Safety Supervisor (FSS) legislation. The legislation requires a food business to nominate an FSS to take a lead role in supervising food safety in the business. The FSS must have been certified by a registered training organisation as having met specified national food safety competencies.

The scope of these requirements (e.g. the business sectors affected) varies from State to State. In Victoria, all food businesses are required to nominate an FSS. However, it is intended to amend the requirements to exempt businesses that sell only packaged food, thus aligning more closely with Queensland's FSS requirements. In NSW, FSS requirements are currently limited to hospitality and certain retail sectors.

2. Food safety management in New Zealand food businesses

2.1 Food safety requirements for food businesses are set out in the Food Act 1981 and the Food Hygiene Regulations 1974.

New Zealand food businesses are required either to comply with the Food Hygiene Regulations, or to operate using a food safety programme (see 2.2 below). An exemption from this requirement is, however, available to food businesses that operate registered risk management programmes, or are covered by certain regulated control schemes under the *Animal Products Act 1999*, or that operate under wine standards management plans under the *Wine Act 2003*.

The Food Hygiene Regulations spell out specific requirements, which focus on the ways that food risk, can be managed or avoided. These requirements relate to the conduct and maintenance of food premises, the conduct of workers and to specific food sectors. Territorial authorities enforce the Regulations, including by inspecting premises.

New Zealand food businesses are also subject to the joint Food Standards Code; the New Zealand standards that apply; and the general requirements of the Food Act and related regulations and tertiary measures. In addition, there is a requirement that food premises are registered under the *Health Registration of Premises Regulations 1966* unless an exemption applies.

2.2 Food businesses have the option to implement food safety programmes.

If a New Zealand food business chooses to operate using a food safety programme (a HACCP-based food safety program) then it is exempt from having to comply with the Food Hygiene Regulations. Food safety programmes are verified by independent auditors approved by the New Zealand Food Safety Authority (NZFSA), and generally enforced by NZFSA (and by Public Health Units of District Health Boards under contract).

2.3 A new option for food service and catering sectors; 'off-the-peg' Food Control Plans (FCPs).

While a new Food Bill is under development in New Zealand, NZFSA has introduced an additional voluntary option for the food service and catering sectors. Businesses in these sectors can now choose to operate under an 'off-the-peg' food control plan (FCP). The FCP, prepared by the NZFSA, is

designed to be a ready-to-use package for managing food safety. If a business chooses to operate using an 'off-the-peg' FCP, then it is exempt from the requirement to comply with the Food Hygiene Regulations.

Attachment 5 - Food Safety Management in an International Context

European Union

The EU has introduced a legislative framework covering all aspects of food products from farm to table. HACCP principles are embedded in the legislation as a pro-active hazard management system, apply to all food businesses carrying out any activities related to any stage of production, processing and distribution of food, and include retail, catering operations, restaurants and other similar food service operations. The EU approach aims to keep contamination of food with microorganisms, chemical substances or physical contaminants under control to produce safe food.

The EU approach allows HACCP based procedures to be implemented with flexibility to ensure that they can be applied in all situations. For example, the need for establishing documentation and records is commensurate with the nature and the size of the food business.

United Kingdom

The UK has adopted the new EU legislation and applies this legislation to all food businesses, including caterers (and restaurants), primary producers (such as farmers), manufacturers, distributors and retailers. The legislation is structured to ensure that the appropriate level of public health protection is in place without placing unnecessary burdens on businesses. Food businesses can apply the legislation flexibly and proportionately according to the nature of the business. The UK Food Standards Agency has developed various food safety management packs to assist businesses comply with the new requirements.

United States of America

State and local agencies have primary responsibility to regulate the retail food and foodservice industries in the USA. They are responsible for the inspection and oversight of food establishments including restaurants and grocery stores.

The FDA *Model Food Code* is referred to by many states and localities for guidance when adopting new food safety and sanitation regulations for restaurants and retail stores. The *Model Food Code* incorporates HACCP-based principles into the guidelines for restaurant and foodservice safety and sanitation. The *Model Food Code* is not law, but rather guidance that can be adopted as regulation by state or local agencies. Most states have adopted the Food Code to regulate retail and food service establishments.

The FDA has also developed a manual, *Managing Food Safety: A Manual for the Voluntary use of HACCP Principles for Operators of Food Service and Retail Establishments*, based on the FDA *Model Food Code* that focuses on a preventive approach and provides a roadmap for evaluating retail and food service establishments based on the application of HACCP principles.

Proposed USA food safety reforms focus on improving risk-based preventive controls to reduce foodborne illness. A new food safety bill recently passed by the House of Representatives (H.R. 2729, the “Food Safety Enhancement Act of 2009”) is now under consideration in the Senate. This new public-health focused approach to food safety is based on three core principles: prioritizing prevention, strengthening surveillance and enforcement, and improving response and recovery.

Key provisions relevant to food hygiene will require facilities engaged in manufacturing, processing, packing, or holding food for consumption to be registered; conduct hazard analyses; and write and implement preventative control plans. Facilities do not include farms; restaurants; other retail food establishments; non-profit food establishments in which food is prepared for or served directly to the consumer; or most fishing vessels. However, restaurants and retail establishments will be subject to new provisions relating to record keeping and product tracing.

Canada

In Canada, provisional/territorial governments are responsible for inspection of food service, retail, and mass catering establishments.

The Canadian government and industry have developed model regulation, *the Food Retail and Foodservice Regulation* as well as an accompanying code of practice for the food service and food retail industries (*Food Retail and Food Services Code*). The two documents provide a common set of harmonized food safety standards and operational guidelines that are recognised by government, the food industry and consumers. The model regulation embodies sound scientific, risk-based approaches to food safety including food safety training and HACCP based management systems.

In jurisdictions, the model regulations are either legislated or the legislation is under development.

Are there other international approaches to food safety management that would inform this policy process?

Attachment 6 – Working Group Terms of Reference

Food Regulation Standing Committee

Review of Ministerial Policy Guideline Food Safety Management in Australia: Food Safety Programs Terms of Reference³⁶

1. Context and purpose of the Review

The 2003 Ministerial Policy Guideline *Food Safety Management in Australia: Food Safety Programs* (2003 Policy Guideline) was developed principally to guide risk management decisions to mandate the otherwise voluntary Standard 3.2.1 *Food Safety Programs*. It effectively asked FSANZ to mandate 3.2.1 for four food industry sectors based on analysis of two national studies on risk and benefit-cost.

While the FSM Policy Guideline also sets out some useful general principles for food safety management, including the potential role of risk profiling, it does not provide practical guidance on the development and implementation of food safety management measures other than 3.2.1. Similarly, the 2002 *Overarching Policy Guideline on Primary Production and Processing Standards* (the PPP Policy Guideline) focuses primarily on roles and responsibilities during the standards development process.

Since the endorsement of the FSM and PPP Policy Guidelines, food safety management standards covering a range of food industry sectors have been developed or are underway. Each standards development process entails risk assessment of the relevant food industry sectors and consideration of appropriate risk management measures.

The review was originally proposed due to concerns that completion of the draft standard *Food Safety Programs for Catering Operations* could result in anomalous food safety management outcomes in the general food service sector. In particular, it was noted that food safety risks attributable to “eating establishments” (not covered by the draft Standard) would continue to be managed only by the baseline requirements of Standards 3.2.2 and 3.2.3. Therefore, the review’s first priority should be to consider the policy guidance in relation to the general food service sector and closely related retail sectors such as delicatessens and bakeries.

Any additional or alternative policy guidance developed for the general food service sector is likely to have generic relevance to food safety management in other sectors. However, the need to consider sector-specific issues and consult with affected sectors would be likely to prevent timely resolution of food safety management policy issues for the general food service sector.

2. Scope of the Review

The Working Group will review the FSM Policy Guideline with a particular focus on the adequacy and appropriateness of its food safety management guidance in relation to the general food service sector and closely related retail sectors. See key examples in the table below. The Working Group is specifically required to exclude from the focus of its review businesses subject to the recently implemented Standard 3.3.1 *Food Safety Programs for Food Service to Vulnerable Persons*.

³⁶ Terms of Reference endorsed by the Ministerial Council at its meeting, 23 October 2009.

Business Types within the General Food Service and Closely-Related Retail Sectors	
<p>Food service – onsite and offsite catering</p> <p>Food service – ready-to-eat food prepared in advance e.g. takeaways that hot-hold ready-to-eat food, restaurants that pre-prepared ready-to-eat food,</p> <p>Food service – express order e.g. eating establishments or takeaways that do not prepare food in advance</p>	<p>Bakeries – retailers and processors of potentially hazardous foods (e.g. high risk products)</p> <p>Retailers of ready-to-eat³⁷:</p> <ul style="list-style-type: none"> • potentially hazardous bakery products (not processors) • delicatessen products; • processed seafood products; and • perishable packaged foods (e.g. packaged sandwiches).

* draft classification

In carrying out its review, the Working Group will:

- a) consider whether additional or alternative policy guidance is needed in relation to these sectors and, if applicable, develop draft amendments to the FSM Policy Guideline or a separate draft Policy Guideline;
- b) if it considers that this draft policy guidance may be relevant to food safety management in other industry sectors, make recommendations for further work.

In making any recommendations for further work, the Working Group should have regard to the relative priority of relevant sectors taking into account:

- food safety risk;
- whether or not standards development processes are underway or complete; and
- nature and extent of consultation required to develop additional or alternative policy guidance.

3. Scope of policy guidance

The Working Group will consider the need for additional or alternative policy guidance in relation to:

- food safety management options generally, without being limited to Standard 3.2.1 *Food Safety Programs*;
- the respective roles of Food Standards Australia New Zealand (FSANZ), the Implementation Sub-Committee (ISC) and jurisdictions, including consideration of the *Draft Food Safety Management Framework*;
- legislative mechanisms (including the Food Standards Code, the Model Food Provisions, and jurisdiction-specific legislation) required to implement food safety management measures;
- use of the Risk Profiling Framework including the list of risk-profiled food industry sectors accepted by FRSC; and
- the potential role of evaluation, including its use in staged implementation of food safety management measures, which may include evaluation of jurisdiction-specific measures.

4. Deliverables

The Working Group will provide a report including the review findings and, if applicable:

- recommended draft amendments to the FSM Policy Guideline (or a separate draft Policy Guideline) in relation to the general food service sector and closely related retail sectors; and

³⁷ As per the definition of ready-to-eat food in *Food Standards Code* Standard 3.2.1 (1)

- recommendations for further work on policy guidance for food safety management in other industry sectors.

5. Process and timeline

The review will be conducted in accordance with the requirements of the *Principles and Protocols for the Development of Food Regulation Policy Guidelines*.

The Working Group will use its best endeavours to submit its report, as approved by the Food Regulation Standing Committee, for consideration by the Australia and New Zealand Food Regulation Ministerial Council at its October 2010 meeting. An indicative timeline is provided below. If this target cannot be met, the approved report is to be submitted to the Ministerial Council's May 2011 meeting.

Date	Output /Activity
October 2009	FRMC agrees to Review and Working Group is established
March 2010	FRSC approves Policy Options paper
	Consultation period
	Working Group prepares report
September 2010	FRSC considers/approves report
	Working Group finalises report with OOS FRSC approval if required
October 2010	ANZFRMC – considers report