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FINAL ASSESSMENT REPORT

PROPOSAL P288

FOOD SAFETY PROGRAMS FOR FOOD SERVICE TO VULNERABLE POPULATIONS

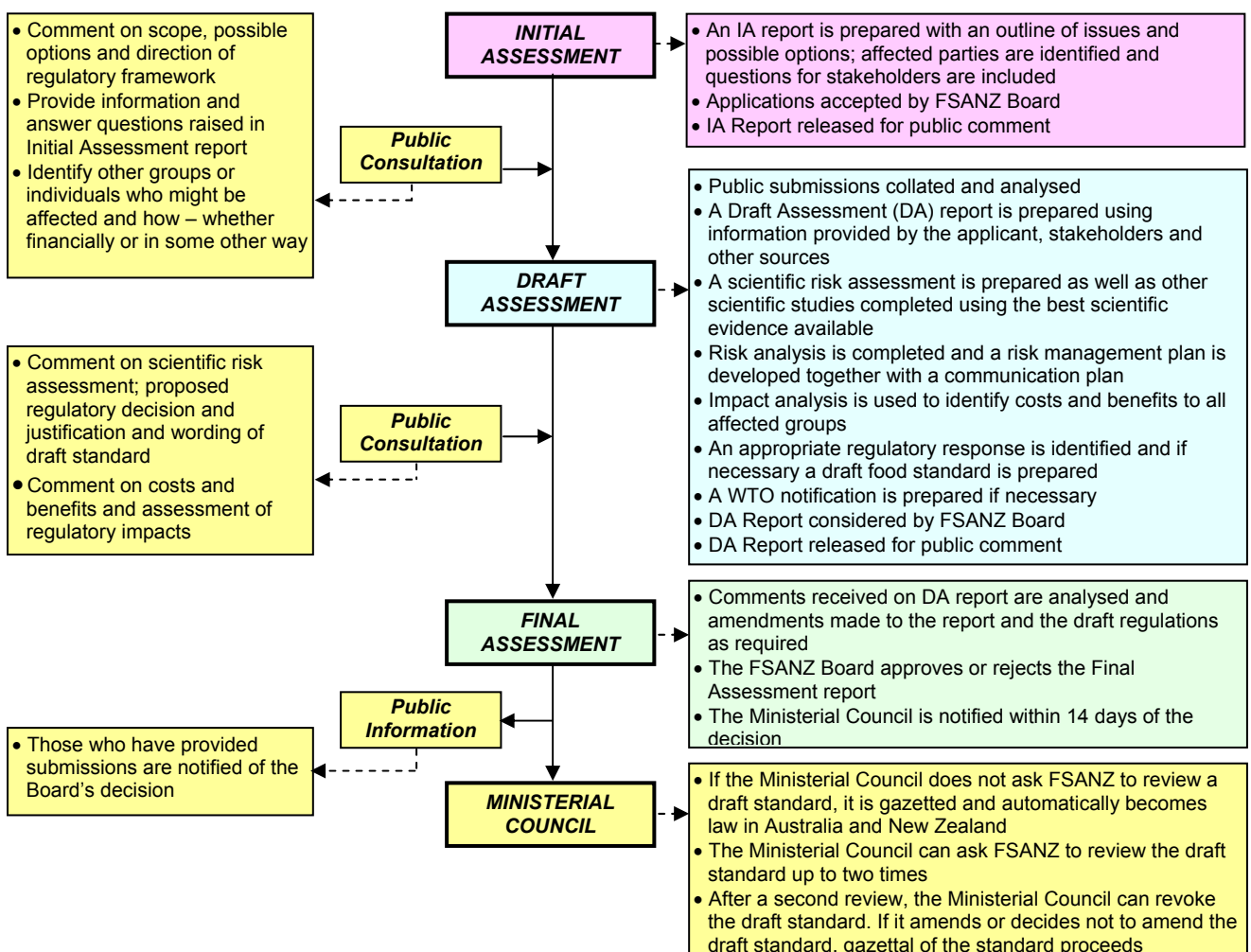
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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

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

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

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



Final Assessment Stage

FSANZ has now completed two stages of the assessment process and held two rounds of public consultation as part of its assessment of this Proposal. This Final Assessment Report and its recommendations have been approved by the FSANZ Board and notified to the Ministerial Council.

If the Ministerial Council does not request FSANZ to review the draft amendments to the Code, an amendment to the Code is published in the *Commonwealth Gazette* and the *New Zealand Gazette* and adopted by reference and without amendment under Australian State and Territory food law.

Please note, this particular proposed Standard will not apply in New Zealand.

Further Information

Further information on this Proposal and the assessment process should be addressed to the FSANZ Standards Management Officer at one of the following addresses:

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Assessment reports are available for viewing and downloading from the FSANZ website www.foodstandards.gov.au or alternatively paper copies of reports can be requested from FSANZ's Information Officer at info@foodstandards.gov.au including other general inquiries and requests for information.

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Executive Summary and Statement of Reasons

This Final Assessment Report is the last stage in the development of Proposal P288 – Food Safety Programs for Food Service to Vulnerable Populations. The proposal has been developed in accordance with the *Food Standards Australia New Zealand Act 1991* (FSANZ Act).

FSANZ raised this proposal in response to a decision of the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council), to mandate Standard 3.2.1 – Food Safety Programs to food service, whereby potentially hazardous food is served to vulnerable populations.

The amendments to the Code were developed following the guidance provided in the Ministerial Policy Guidelines on *Food Safety Management in Australia: Food Safety Programs* (Ministerial Policy Guidelines).

Over the course of this Proposal, FSANZ undertook two rounds of public consultation and held detailed discussions with an external Advisory Group consisting of consumer, industry and government representatives. As well as outlining the proposed Standard (Attachment 1), this Final Assessment Report summarises the twenty, four submissions received in the second round of public consultation and outlines the responses to those submissions (Attachment 3).

Decision

The outcome of this Proposal is Standard 3.3.1 – Food Safety Programs for Food Service to Vulnerable Persons.

The Standard requires specific businesses to comply with Standard 3.2.1.

Businesses involved in food service to vulnerable populations will be required to comply with Standard 3.3.1 if:

- They are located on site in a facility specified in Standard 3.3.1 and they process or serve potentially hazardous food for vulnerable persons
- They are located off site but their principal activity is to process food for service to vulnerable people within a facility specified in Standard 3.3.1
- They are located off site but their principal activity is to process food for service to clients of delivered meals organisations
- They are delivered meals organisations and they process food for service to their clients

The proposed Standard will not apply to food businesses that only serve milk or soy milk as, or in, a beverage or to delivered meals organisations that only deliver food because the cost of compliance outweighed the benefits.

Statement of Reasons

FSANZ recommends that the Code be varied as described above for the following reasons:

- The Ministerial Policy Guidelines require FSANZ to develop a mandatory requirement to implement Standard 3.2.1 Food Safety Programs, for the ‘high risk’ business sector, whereby potentially hazardous food is served to vulnerable populations.
- The decision of Ministers was based on:
 - the National Risk Validation Project which concluded food service, whereby potentially hazardous food is served to vulnerable populations, was a potentially high-risk sector;
 - the Allen report on the costs and efficacy of introducing food safety programs concluded that the benefits for high risk businesses outweighed the costs of implementing, utilising and auditing a food safety programs; and
 - data from Oz Food Net
- The proposed variation to the Code is consistent with the objectives of the FSANZ Act, including section 10.
- At total of thirty two (32) submissions from thirty four (34) submissions received by FSANZ during the public consultation periods at the Initial and Draft Assessment supported the proposed Standard.

1. Introduction

This Final Assessment Report represents the last stage in the development of Proposal P288-Food Safety Programs for Food Service to Vulnerable Populations. This Report summarises the submissions and the issues identified from the second round of public consultation which followed the release of the Draft Assessment Report in June 2005. The report also details the proposed approach to resolve identified issues and describes changes made to previous (proposed) drafting. In addition a summary is provided of consultation that has occurred during the development of this proposal with the Advisory Group and jurisdictional representatives.

The proposed amendment to the Code, Standard 3.3.1 –Food Safety Programs for Food Service to Vulnerable Persons (proposed Standard), is attached (Attachment 1).

2. Regulatory Problem

The Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council)¹ requested FSANZ to follow the guidance in the Ministerial Policy Guidelines on *Food Safety Management in Australia: Food Safety Programs* (Ministerial Policy Guidelines) to develop a requirement for specific ‘high risk’ businesses to implement Standard 3.2.1 –Food Safety Programs.

The Ministerial Council provided guidance in the Ministerial Policy Guidelines using the findings of three projects, the *National Risk Validation Project*², the Allen Report on *Food Safety Management Systems – Costs Benefits and Alternatives*³ and data from Oz Food Net⁴. These projects concluded that food service, whereby food is served to vulnerable populations, is a ‘high risk’ sector and the benefits from implementing a food safety program requirement for this sector outweighed the costs.

The Ministerial Policy Guidelines require FSANZ to develop a mandatory Standard for Standard 3.2.1 – Food Safety Programs, to be implemented by businesses involved in food service, whereby potentially hazardous food is served to vulnerable populations.

Currently, there are no mandatory requirements in the Code for Standard 3.2.1 – Food Safety Programs to be implemented by businesses involved in food service to vulnerable populations.

3. Objective

The specific objective of Proposal P288 – Food Safety Programs for Food Service to Vulnerable Populations is to reduce the incidence of food-borne illness amongst vulnerable people in Australia.

¹ Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) comprises of Health Ministers from all Australian States and Territories, the Australian Government, and New Zealand Government, as well as other Ministers from related portfolios (Primary Industries, Consumer Affairs etc) where these have been nominated by their jurisdictions

² The National Risk Validation Project – Final Report (2002)

<http://www.health.gov.au/internet/wcms/Publishing.nsf/Content/health-pubhlth-strateg-foodpolicy-pdf-validation.htm>

³ The Final Report of Food Safety Management Systems – Cost , Benefits and Alternatives (Allen Report)

www.health.gov.au/internet/wcms/publishing.nsf/Content/health-pubhlth-strateg-foodpolicy-pdf-alternatives.htm

⁴ OzFoodNet website: www.ozfoodnet.org.au

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 10 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). These are:

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

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

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

4. Background

In response to the decision by the Ministerial Council, FSANZ prepared this Proposal, P288 pursuant to section 12AA of the FSANZ Act.

The process has involved three stages, Initial Assessment, Draft Assessment and Final Assessment. During the development process there was the opportunity for public comment at the Initial and Draft Assessment stages.

In addition, FSANZ has consulted with an external Advisory Group consisting of key stakeholders members and also with representatives from each of the States and Territories (Jurisdictions) throughout the proposal development process. The organisations involved in this consultation are listed in Attachment 2.

A summary of the development of Proposal P288 in regard to consideration by the FSANZ Board, the development and subsequent public release of assessment reports, discussion of the issues raised during public consultation and details of discussions with the external Advisory Group and jurisdictions are outlined in Section 8 of this Report.

5. Relevant Issues

At the close of submissions on the Draft Assessment Report P288 'Food Safety Programs for Food Service to Vulnerable Populations, there were twenty four (24) submissions from government and non government organisations. Of the 24 submissions, 23 were in support of the proposed Standard

A summary of the 24 submissions received, grouped according to issue, is provided in Attachment 3. The main issues were:

- clarification in the Standard of the types of businesses required to comply;
- the definition of immunocompromised person;
- application of the Standard to charity groups and fundraising events;
- exemption of pasteurised milk and soymilk products;
- implementation of the Standard;
- application of the Standard to Delivered Meals Organisations;
- exemption for Family Day Care, and
- the requirement for a food safety program.

These issues and the approaches to resolve them are discussed below. FSANZ has taken into consideration advice received from the Advisory Group and the jurisdictions in identifying approaches to resolve these issues.

In some cases, the issue has been resolved by changing the drafting of the Standard provided at Draft Assessment.

Clarifying these issues has required careful comparison to the Ministerial Policy Guidelines. This has been done in close consultation with those individuals and agencies involved in the preparation of the Ministerial Policy Guidelines. FSANZ believes that the clarification described below is consistent with the intent of the Ministerial Policy Guidelines.

5.1 Clarification in the Standard of the types of businesses required to comply

5.1.1 Identification of facilities where food is served to vulnerable people

Submitters sought further clarity as to whether food businesses that operated hotels, cafés, clubs and restaurants that serve vulnerable people on occasions would be required to have food safety programs.

In determining the application of the Standard, FSANZ has referred to the Ministerial Policy Guidelines which make reference to food service to vulnerable persons who are in identified facilities. The facilities which provide food service to vulnerable people include aged care, hospitals, nursing homes and child care centres.

It was agreed by the Advisory Group including jurisdictions that the intent of the Standard is to improve the safety of the food that vulnerable people consume while they are being cared for in these facilities. To ensure that the Standard is clear that it applies to food service in these facilities, a list of the facilities and their description is included as a Schedule to the Standard.

A number of descriptions of the facilities have been adapted from the National Health Data Dictionary, version 12. This dictionary contains core definitions endorsed by the Australian Health Ministers Advisory Council as the authoritative source of national standard definitions for use in clinical care delivery.

5.1.2 The application of the Standard to food businesses that process food specifically for vulnerable people but are located in premises that are not in hospitals or other specified health care facilities

Concerns were raised by submitters and jurisdictions that the previous drafting and the use of the terms ‘specifically for service’ did not adequately clarify which food business were required to comply with the Standard.

The drafting has been amended to ensure that food businesses that prepare on-site and those that prepare off-site are included. These are food businesses that are;

- located within a facility and process food for service to vulnerable people within a facility; or
- located elsewhere but process food for service to vulnerable people located within a facility.

To further assist in determining which businesses are required to comply with the Standard it is proposed to replace the terms ‘specifically for service’ with a reference to a food businesses’ ‘principal activity’. If a food business’ principal activity is to process food for service to vulnerable people in an facility listed in the Schedule, the business will be required to comply with Standard 3.2.1.

5.1.3 Application of the Standard to cafes and restaurants located in hospitals and similar health-care facilities

Submitters queried if businesses that operated cafés or restaurants on site in any of the specified facilities e.g. hospital cafes would be required to have food safety programs.

Although patients or other clients of the facility may choose to eat at these food premises, the food business’s principal activity is to provide food to members of the public who are visiting patients in health-care facilities rather than provide food specifically prepared for vulnerable people. Therefore, these businesses would not be required to comply with the proposed Standard.

However, if a café or restaurant food premises are used by a food business whose principal activity is to prepare food for vulnerable people, then that food business is required to include the use of the premises in developing its food safety program.

FSANZ will explain the application of the Standard in relation to restaurants and cafes located in specified facilities in the Interpretative Guide to the Standard.

5.1.4 Application of the Standard to suppliers of ingredients or meal components

Submitters queried if manufacturers and suppliers of food ingredients would be required to have food safety programs.

The intent in the Ministerial Policy Guidelines is to apply the requirement for food safety programs to businesses that process food for service to vulnerable populations.

It is not the intent of the Standard to capture manufacturers of ingredients of food which are processed further by food businesses. The term ‘supplied’ has been removed from the previous drafting to avoid any confusion.

In addition, the Standard now includes a reference to processing food to a ‘ready to eat’ stage to clarify that manufacturers of ingredients such as raw meat or meal components are not included. This will also emphasise that the responsibility for ensuring that the food is safe is with the business that is processing the food because, once the food is ready to eat, there are no further processing steps that will make it safe if it is not safe by this stage.

A definition of ‘ready to eat’ is included in the Standard. It differs from that in Chapter 3 to clarify that some preparation steps, such as reheating previously cooked food, taken just prior to service do not affect the status of ‘ready to eat’ as these are steps that will not necessarily make unsafe food safe.

A reference to food being served at ‘any given time’ has been included in the proposed draft Standard. Further guidance will be provided in the Interpretative Guide.

5.1.6 Reference to food being for service to six or more vulnerable people

Submitters queried if the reference to six or more vulnerable people being served referred to six or more people at any time, on any occasion or meal opportunity or whether the number could be counted over several meal periods.

The intent of the Standard is to capture food business that prepare a quantity of food that is intended to be served to six or more vulnerable people at any given time.

The frequency that a food business prepares a quantity of food for six or more people is not a criterion. For example, a childcare centre that provides one meal a week for six or more children, but on the other days does not serve a meal, is still required to comply with the Standard.

Further guidance will be provided in the Interpretative Guide.

5.1.7 The application of the Standard in relation to drug and alcohol rehabilitation centres

Submitters sought clarification as to whether food provided to clients of drug and alcohol rehabilitation centres would be captured by the Standard.

FSANZ discussed this issue with the Advisory Group and the jurisdictions as the Ministerial Policy Guidelines were not specific on whether clients of these types of facilities were considered vulnerable to food borne illness or immunocompromised.

It was agreed that food businesses providing food in these facilities would not be included noting that they would be covered by Chapter 3. This will be included in the Interpretative Guide.

5.2 Definition of immunocompromised person

The Standard at Draft Assessment included a definition of ‘vulnerable’ person which included immunocompromised people.

A definition of ‘immunocompromised’ was also included. Submitters commented that the definition of immunocompromised was too broad and simplistic. It was also considered difficult to determine if a person was immunocompromised and therefore classed as a vulnerable person

The approach in the proposed Standard is to include a description of the facilities where food is served to vulnerable people. The food businesses providing food to the patients, residents or clients in the facilities will not necessarily be in a position to determine which of these people are vulnerable. Therefore, the vulnerable people should include all people who are receiving care in an identified facility and it would not be necessary to determine if people are immunocompromised.

However, it is not the intent to include businesses that provide food for staff or visitors to the facility. Therefore, a definition of vulnerable person has been retained but limits these persons to those who are in care in a facility listed in the Schedule or a client of a delivered meals organisation.

5.3 Application of the Standard to charity groups and fundraising events

Standard 3.2.1 contains an exemption from the requirement to have a food safety program covering occasions when the food business is providing food for a fund raising event. Submitters queried if this exemption would apply to businesses providing food for vulnerable people at a fund raising event.

The Ministerial Policy Guidelines, in discussing the application of Standard 3.2.1 to food service to vulnerable persons, do not indicate any changes to the extent of the application of Standard 3.2.1 (as is the case with proposals to apply Standard 3.2.1 to catering businesses). Therefore, the exemption for ‘fund raising events’ as described in Clause 6 of Standard 3.2.1 has been retained.

5.4 Exemption of pasteurised milk and soymilk products

The intention of the Standard at Draft Assessment was to exclude food businesses where the only potentially hazardous food served to vulnerable persons was milk. It is considered too onerous for businesses that serve only tea, coffee or milk, and non potentially hazardous food such as biscuits, to have a food safety program. Examples include a childcare centre that only serves bottled milk or an aged day care facility that only serves coffee or tea with biscuits.

Submitters queried the exemption of pasteurised milk and soy milk and other types of milk from the requirements of the Standard.

The reference to milk and soymilk being excluded from the definition of ‘potentially hazardous food’ has been removed to avoid any doubt that if milk and soy milk are used in by a food business to make other foods e.g. custard, the food business is required to have a food safety program.

The proposed Standard makes it clear that food businesses that serve only milk or soy milk as, or in, a beverage do not have to comply with the Standard. They may serve other non-potentially hazardous foods (as the Standard would not apply in any case).

Infant formula is a food for infants and is not considered to be a 'beverage'. Therefore, processing (measuring, transferring, mixing) of infant formula is processing of potentially hazardous food and the business is required to comply with the Standard.

The supply of breast milk and bottled infant formula milk by parents or guardians for consumption by their children in care is not considered to be food for sale and is not within the scope of the Standard.

To avoid doubt, it is proposed to include a definition of milk for the purpose of this Standard to clarify that milk includes flavoured and modified (such as low fat, skim, UHT) milk.

The Interpretive Guide will clarify that food businesses that qualify for the exemption are required to comply with Standard 3.2.2 Food Safety Practices and General Requirements and Standard 3.2.3 Food Premises and Equipment. This requires all foods, including beverages, to be handled safely.

5.5 Implementation of the Standard

5.5.1 Costs for food businesses associated with implementing food safety programs

Concerns were expressed by submitters about the costs to food businesses associated with implementing food safety programs and the cost of auditing these food safety programs.

The Allen Consulting Group Report *Food Safety Management Systems, Costs, Benefits and Alternatives*⁵ made an assessment of the costs and benefits of meeting Standard 3.2.1 Food Safety Programs that were additional to meeting the mandatory Chapter 3 Standards. The Allen Report found that while the implementation of Standard 3.2.1 includes costs, the benefits outweigh these costs for all but 'low risk'⁶ businesses.

The report also documented the advantages and disadvantages of alternatives to a requirement for food safety programs and ways in which compliance costs of meeting the Standards could be minimised.

*The National Risk Validation Report*⁷, included a cost benefit analysis of implementing food safety programs, specifically for high-risk food industries.

The cost benefit analysis concluded that the benefits of mandating food safety programs for businesses serving vulnerable populations outweighed the costs.

⁵ The Final Report of *Food Safety Management Systems - Costs, Benefits and Alternatives* (Allen report) is available at: www.health.gov.au/pubhlth/strateg/foodpolicy/pdf/alternatives.htm

⁶ Businesses that only handle food that is unlikely to contain pathogenic microorganisms and will not normally support their growth due to food characteristics e.g. grains and cereals, bread, sugar-based confectionery.

⁷ The National Risk Validation Project - Final Report (2002) available at: www.health.gov.au/pubhlth/strateg/foodpolicy/pdf/validation.htm

5.5.3 *Support required to assist food businesses develop food safety programs*

Submitters requested support in the form of financial and resource assistance to assist with implementing food safety programs.

In order to minimise costs associated with the initial preparation of a food safety program, particularly for smaller businesses, a number of tools have been developed, or are under development, by the Department of Health and Ageing and States and Territories, to assist businesses. A list is provided in Attachment 4 and will be included in the Interpretive Guide.

Business will have a two year interval between the gazettal of the Standard and it coming into effect in the Code to develop and implement a food safety program.

5.5.4 *Consistent national application of the Standard*

Submitters queried the consistent implementation and interpretation of the Standard across the jurisdictions.

To assist the jurisdictions with consistent interpretation and understanding of the intent of the Standard, FSANZ is developing an Interpretive Guide to the Standard in consultation with the jurisdictions. FSANZ will continue to consult with the jurisdictions and Advisory Group to finalise the Guide prior to the Standard coming into effect in the Code.

5.6 The application of the Standard to Delivered Meals Organisations

5.6.1 *Effect of the Standard on volunteer workforces*

Delivered meals organisations employ a large number of volunteers to assist with food preparation and delivery. Concerns were expressed that the need to develop and implement food safety programs would deter volunteers and would impose an additional training burden on Delivered Meals Organisations.

The existing requirements in Chapter 3 mean volunteers are already participating in food safety activities such as controlling temperature, checking deliveries and cleaning premises. The Department of Health and Ageing has developed a National Delivered Meals Organisation - Food Safety Strategy⁸ aimed at improving food safety and assisting Delivered meals organisations to comply with the national food safety standards, including assisting delivered meals organisations to develop and implement their own site-specific food safety programs.

5.6.2 *Effect of the Standard on delivered meals organisations that source meals from local businesses*

In remote areas delivered meals organisations may source meals from local food businesses and this service may be jeopardised if those food businesses are required to have a food safety programs.

⁸ National Delivered Meals Organisations (DMOs) - Food Safety Strategy available at http://www.health.gov.au/internet/wcms/publishing.nsf/Content/hacc-pub_isd_dmo.htm

The Standard applies to those food businesses that have as their principal activity the provision of food for vulnerable persons. If a food business for example, a business operating a club, provides a few meals for a delivered meals organisation as part of its normal provision of meals, this would not be considered its principal activity. If the business provides food for five or less persons it is exempt.

5.6.3 Application to delivered meals organisations that only deliver meals and do not process food

Clarification was sought as to whether delivered meals organisations that only deliver meals will be required to have food safety programs.

The proposed Standard does not require delivered meals organisations that only deliver food to have food safety programs. The Draft Assessment Report stated that the costs to a delivered meals organisation of auditing and implementing a food safety program were not justified in terms of the benefit. The obligation to comply with Standards 3.2.2 Food Safety Practices and General Requirements (which specifies food safety measures for transporting food) and Standard 3.2.3 Food Premises and Equipment (which has requirements for food transport vehicles) was sufficient to manage food safety..

5.7 Exemption for Family Day Care

Submitters queried if businesses that operated family day care facilities would be required to have food safety programs.

Family Day care refers to care for children in a person's private home. The costs for businesses operating family day care facilities to implement food safety programs was considered to outweigh the benefits due to the small number of children cared for in each family day care facility. The Ministerial Policy Guidelines considered the low benefit to cost ratio and specified an exemption for family day care to be provided in the proposed Standard.

The previous drafting excluded family day care as care is not provided for six or more children that are four years of age or less. This exclusion by association was not as clear.

The proposed Standard applies to food businesses located within identified facilities. These facilities do not include 'family day care' facilities.

The Schedule definition for 'child care centres' provides further clarification as it states that a child care facility is a 'facility which is not part of a private residential dwelling'

5.8 The requirement for a food safety program

The proposed Standard at Draft Assessment required food businesses to implement a documented food safety management system. The business could comply with Standard 3.2.1 or any other equivalent food safety management system recognised by the relevant authority. Submitters queried this requirement as the Ministerial Policy Guidelines specified that businesses should implement Standard 3.2.1.

The Standard has been amended to include a requirement for a food business to comply with Standard 3.2.1.

In addition, the reference to an equivalent food safety program has been removed to promote national consistency in implementation. It will reduce the possibility that businesses in one State or Territory may be required to comply with different criteria for a food safety program than listed in Standard 3.2.1.

This approach meets the intent of the Ministerial Policy Guidelines for food service to vulnerable persons to comply, as a minimum, with Standard 3.2.1.

5.9 Summary: Food business that will be required to comply with the Standard

The amendments to the Standard provided at Draft Assessment are intended to ensure that the food businesses that must comply with the Standard are clearly identified.

Businesses involved in food service to vulnerable populations will be required to comply with Standard 3.3.1 if:

- They are located on site in a facility specified in Standard 3.3.1 and they process or serve potentially hazardous food for vulnerable persons.
- They are located off site but their principal activity is to process food for service to vulnerable people within a facility specified in Standard 3.3.1.
- They are located off site but their principal activity is to process food for service to clients of delivered meals organisations.
- They are delivered meals organisations and they process food for service to their clients.

The proposed Standard will not apply to food businesses that only serve milk or soy milk as, or in, a beverage or to delivered meals organisations that only deliver food because the cost of compliance outweighed the benefits.

6. Regulatory Option

The regulatory option identified by this proposal is proposed Standard 3.3.1 Food Safety Programs for Food Service to Vulnerable Persons (Australia only). The proposed Standard is a mandatory requirement for certain food businesses to comply with Standard 3.2.1 Food Safety Programs.

No other option would have satisfied the Ministerial Policy Guidelines.

It is noted that 23 of the 24 submissions received by FSANZ at the Draft Assessment stage supported this regulatory option

The Standard will apply in Australia only. New Zealand has its own legislation in regard to the application of food safety programs as food safety standards are outside the scope of the Agreement between the Government of Australia and the Government of New Zealand concerning a joint food standards system (the Treaty).

7. Impact Analysis

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

- the costs and benefits of meeting previous State and Territory food safety regulations;
- the incremental costs and benefits of meeting Standards 3.1.1, 3.2.2 and 3.2.3 given current practices (at that time);
- the incremental costs and benefits of meeting Standard 3.2.1 given achievement of Standards 3.1.1, 3.2.2 and 3.2.3;
- the advantages and disadvantages of alternatives to a requirement for food safety programs; and
- ways in which compliance costs of meeting the Standards could be minimised.
- The Allen Report found that while the implementation of Standard 3.2.1 includes significant costs, the benefits outweigh these costs for all but 'low risk' businesses.

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

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

The ORR considered that these matters have been adequately addressed⁹.

7.1 Affected Parties

Only a small number of food businesses that process potentially hazardous food for service to vulnerable populations currently have food safety programs. Ninety-five per cent of aged care facilities do not have a food safety program (The Allen Consulting Group, 2002b). The situation is expected to be similar in childcare centres, delivered meals organisations and hospitals (except in Victoria where food safety programs are already mandatory in these types of food businesses). Issues associated with the costs for food businesses to implement food safety programs have been discussed in Section 5.

⁹ ORR reference number 3339

8. Consultation

8.1 Public Consultation

FSANZ established an Advisory Group in July 2004 that consists of key stakeholder representatives from industry and government sectors who have an interest in the development of this Proposal. Advisory Group members have provided information and advice to FSANZ in relation to relevant issues and have assisted in communicating with other parties who also with an interest in this Proposal. A list of agencies represented on the Advisory Group is in Attachment 2.

FSANZ has also consulted with representatives from the State and Territory authorities, (jurisdictions) during the development of this proposal. The jurisdictions have provided valuable advice in relation to relevant issues affecting this proposal and have assisted in communicating with consumers, enforcement officers and industry sectors. A list of jurisdictional representatives involved in consultation is outlined in Attachment 3.

FSANZ made a Draft Assessment of this Proposal on 25 May 2005. The Draft Assessment Report was released for public comment on 20 June 2005 and discussed:

- the issues raised in the Initial Assessment report.
- discussed rationale for food safety programs for high risk sector
- the facilities covered by the proposal
- outlined regulatory options proposed
- implementation issues for food businesses and enforcement authorities
- an impact analysis
- the consultation conducted to date and;
- provided a draft of the proposed Standard.

The Draft Assessment Report sought comment on:

- the rationale for mandating food safety programs for food service to vulnerable populations;
- definition of immuno-compromised person;
- exclusion of pasteurised milk and soymilk from the definition of potentially hazardous food;
- exclusion of hospital cafés and kiosks;
- exclusion of delivered meals organisations that deliver only;
- exclusion of fund raising events;
- implementation issues for food businesses and enforcement agencies;
- the regulatory options identified; and
- the proposed draft Standard.

A total of twenty four (24) submissions were received in response to the DAR from industry, government regulators and consumers. Twenty three (23) of the submissions supported the proposed Standard. The following agencies made submissions:

- Queensland Health Home & Community Care Program (QLD HACCC)
- Town of Vincent
- Correct Food Systems (CFS)
- Dept of Human Services Victoria (VIC)
- The Environmental Health Association (Australia) (EHAA)
- Food Technology Association of Victoria Inc.
- City of Canning WA
- Aged & Community Services WA – (ACS WA)
- South East Sydney Area Health Service (SESAHS)
- Australian Food & Grocery Council (AFGC)
- City of Tea Tree Gully
- South Australia Department of Health – (SA)
- Australian Government Department of Health and Ageing Home and Community Care (HACC)
- Aged & Community Services Australia – (ACSA)
- Aged Care Services – (ACS)
- Institute of Hospitality in Healthcare Ltd – (IHHC)
- Queensland Health – (QLD)
- SAI Global - (SAI)
- Gold Coast City Council (GCCC)
- New Zealand Food Safety - (NZFSA)
- Health Department of Western Australia - (WA)
- Australian Institute of Environmental Health - (AIEH)
- NSW Food Authority - (NSWFA)
- National Heart Foundation of Australia (NHF)

A summary of the submissions made according to the issues raised is provided in Attachment 4.

The responses to the issues raised in this round of public consultation have been discussed earlier in Section 5 – ‘Relevant Issues’ of this Report.

8.2 World Trade Organization (WTO)

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

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

9. Implementation and review

9.1 Auditing of food safety programs

The proposed Standard will require food businesses to comply with Standard 3.2.1 – Food Safety Programs.

A requirement of this Standard is for food businesses to ensure that the ‘food safety program is audited by a food safety auditor at the auditing frequency applicable to the food business’. The accreditation of auditors for the purposes of this proposed Standard, as well as the implementation of the audit system, is a matter for the State and Territory jurisdictions.

9.2 Combining existing accreditation audits with food safety audits

The Ministerial Policy Guidelines recognised that there are existing accreditation arrangements for businesses that operate facilities within the sectors identified and stated that flexibility in auditing and frequency is required. It was suggested that work was undertaken as part of the Standard development process to explore merging the audit requirements for Standard 3.2.1 with the existing accreditation and audit framework for the health care sector. A summary of the existing accreditation arrangements is provided as Attachment 8

An investigation into the existing accreditation arrangements for aged care, hospitals and childcare in the Draft Assessment Report established that the requirements of Standard 3.2.1 do not duplicate any of the requirements of the accreditation arrangements for these facilities. This is consistent with the findings of a report by Food Safety Victoria (Liu and Strickland, 2002).

The possibility of limiting the number of audits by combining an accreditation audit with the audit of the food safety program was investigated by FSANZ at Draft Assessment. Given the scope of the accreditation audit and the qualifications of the auditor, this was not considered to be feasible. This situation was reviewed at the time of completing this Final Assessment Report and there were no significant changes to these findings.

The members of Food Regulation Standing Committee’s, Implementation Sub Committee, have agreed to develop and endorse a ‘National model for food safety auditing processes and management’. This work is aiming to provide a national framework for auditors that will facilitate a reduction in the numbers of audits of businesses in Australia.

9.3 Implementation of food safety programs by food businesses

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

9.4 Implementation of the proposed Standard by State enforcement agencies

FSANZ, in consultation with jurisdictions and other stakeholders, has been working on two Interpretative Guide documents:

- Interpretative Guide to proposed Standard 3.3.1 – Food Safety Programs for Food Service to Vulnerable Persons
- Interpretative Guide to Standard 3.2.1 – Food Safety Programs.

The primary purpose of these guides is to promote nationally consistent interpretation of the Standards by State and Territory enforcement officers. The Guide to Standard 3.3.1 was originally proposed to be an attachment to the Guide to 3.2.1, however there will now be a separate Guide to accompany this Standard.

The Guides will both be similar in format to *Safe Food Australia*¹⁰ (the guide to Standards 3.1.1, 3.2.2 and 3.2.3), which was first released in 2000. A draft of the Interpretative Guide to 3.3.1 will be trialled with enforcement agencies in late 2006.

10. Conclusion and Recommendation

10.1 Statement of Reasons

The outcome of this proposal is Standard 3.3.1 Food Safety Programs for Food Service to Vulnerable Persons.

The Standard requires specific businesses to comply with Standard 3.2.1.

Businesses involved in food service to vulnerable populations will be required to comply with Standard 3.3.1 if:

- They are located on site in a facility specified in Standard 3.3.1 and they process or serve potentially hazardous food for vulnerable persons.
- They are located off site but their principal activity is to process food for service to vulnerable people within a facility specified in Standard 3.3.1.
- They are located off site but their principal activity is to process food for service to clients of delivered meals organisations.
- They are delivered meals organisations and they process food for service to their clients.

The proposed Standard will not apply to food businesses that only serve milk or soy milk as, or in, a beverage or to delivered meals organisations that only deliver food because the cost of compliance outweighed the benefits.

FSANZ recommends that the Code be varied above for the following reasons:

- The Ministerial Policy Guidelines require FSANZ to develop a mandatory requirement for the 'high risk' business sector whereby, potentially hazardous food is served to vulnerable populations, to implement Standard 3.2.1 Food Safety Programs. The decision of Ministers was based on:
 - the National Risk Validation Project which concluded food service, whereby potentially hazardous food is served to vulnerable populations was a potentially high-risk sector;

¹⁰ *Safe Food Australia* is available for viewing at <http://www.foodstandards.gov.au/mediareleasespublications/publications/safefoodaustralia2nd519.cfm>

- the Allen report on the costs and efficacy of introducing food safety programs concluded that the benefits for high risk businesses outweighed the costs of implementing, utilising and auditing a food safety management system;
- data from Oz Food Net

- The proposed amendment to the Code is consistent with the objectives of the FSANZ Act, including section 10.

- At total of thirty two (32) submissions from thirty four (34) submissions received by FSANZ during the public consultation periods over the Initial and Draft Assessment stages, stated support for the proposed Standard

ATTACHMENTS

1. Draft variation or standard to the *Australia New Zealand Food Standards Code*
2. Details of Advisory Group Members and Jurisdiction representatives involved in consultations
3. Summary of the submissions received for the Draft Assessment Report according to the issues identified.
4. Details of tools and templates for use by food businesses to develop food safety programs
5. Summary of existing accreditation arrangements for the sectors identified in the Ministerial Policy Guidelines
6. References

DRAFT VARIATION OR STANDARD TO THE *AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE*

To commence: 24 months from gazettal

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

STANDARD 3.3.1

FOOD SAFETY PROGRAMS FOR FOOD SERVICE TO VULNERABLE PERSONS

(Australia only)

Purpose and commentary

This Standard requires food businesses that process food for service to vulnerable persons to implement a documented and audited food safety program.

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

Table of Provisions

- | | |
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| 1 | Application |
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Clauses

1 Application

- (1) This Standard applies to food businesses that engage in one of the activities listed and described in the Table to this subclause.

Table to subclause 1(1)

Activity 1	Process or serve potentially hazardous food within a facility listed and defined in the Schedule to six or more vulnerable persons at any given time
Activity 2	The principal activity is processing food into ready to eat food for service in a facility listed and defined in the Schedule and the processed food – (a) is for service to six or more vulnerable persons at any given time; and (b) includes ready to eat potentially hazardous food.
Activity 3	The principal activity is processing food into ready to eat food for delivery by a delivered meal organisation and the processed food – (a) is for service to six or more vulnerable persons at any given time; and (b) includes ready to eat potentially hazardous food.

Editorial note:

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

A number of the definitions of the facilities listed in the Schedule are adapted from the National Health Data Dictionary, version 12. This Dictionary contains core definitions endorsed by the Australian Health Ministers Advisory Council as the authoritative source of national standard definitions for use in clinical care delivery.

- (2) This Standard also applies to delivered meals organisations that –
- (a) are food businesses; and
 - (b) process food for service to six or more vulnerable persons at any given time, and the food served is ready to eat food which includes ready to eat potentially hazardous food.

Editorial note:

‘Potentially hazardous food’ is defined in Standard 3.2.2 as food that has to be kept at certain temperatures to minimise the growth of any pathogenic micro-organisms that may be present in the food or to prevent the formation of toxins in the food.

- (3) This Standard does not apply to –
- (a) food businesses that only serve milk or soy milk as, or in, a beverage; or
 - (b) delivered meals organisations that only deliver food.
- (4) Subclause 1(2) of Standard 1.1.1 does not apply to this Standard.

2 Interpretation

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

milk includes flavoured and modified milk.

ready to eat in relation to food means food that is ready for consumption, but includes food that may be re-heated, portioned or garnished or food that undergoes similar finishing prior to service.

vulnerable person means a person who is in care in a facility listed in the Schedule or a client of a delivered meals organisation.

3 Food safety programs

- (1) A food business to which this Standard applies must comply with Standard 3.2.1
- (2) Clause 6 of Standard 3.2.1 applies to a food business to which this Standard applies.

SCHEDULE

Column 1	Column 2
Facility	Definition
Acute care hospitals	<p>Establishments which provide at least minimal medical, surgical or obstetric services for inpatient treatment or care, and which provide round-the-clock comprehensive qualified nursing services as well as other necessary professional services. Most patients have acute conditions or temporary ailments and the average stay per admission is relatively short. Acute care hospitals include:</p> <ul style="list-style-type: none"> (a) Hospitals specialising in dental, ophthalmic aids and other specialised medical or surgical care; (b) Public acute care hospitals; (c) Private acute care hospitals; (d) Veterans' Affairs hospitals.
Psychiatric hospitals	<p>Establishments devoted primarily to the treatment and care of inpatients with psychiatric, mental or behavioural disorders including any:</p> <ul style="list-style-type: none"> (a) Public psychiatric hospital; (b) Private psychiatric hospital.
Nursing homes for the aged	<p>Establishments which provide long-term care involving regular basic nursing care to aged persons and including any:</p> <ul style="list-style-type: none"> (a) Private charitable nursing home for the aged; (b) Private profit nursing home for the aged; (c) Government nursing home for the aged.
Hospices	<p>Freestanding establishments providing palliative care to terminally ill patients, including any:</p> <ul style="list-style-type: none"> (a) Public hospice; (b) Private hospice.
Same day establishments for chemotherapy and renal dialysis services	<p>Including both the traditional day centre/hospital that provides chemotherapy and/or renal dialysis services and also freestanding day surgery centres that provide chemotherapy and/or renal dialysis services including any:</p> <ul style="list-style-type: none"> (a) Public day centre/hospital (b) Public freestanding day surgery centre (c) Private day centre/hospital (d) Private freestanding day surgery centre that provides those services. <p>Day centres/ hospitals are establishments providing a course of acute treatment on a full-day or part-day non- residential attendance basis at specified intervals over a period of time.</p> <p>Freestanding day surgery centres are hospital facilities providing investigation and treatment for acute conditions on a day-only basis.</p>

Respite care establishments for the Aged	Establishments which provide short-term care including personal care and regular basic nursing care to aged persons.
Same – day aged care establishments	Establishments where aged persons attend for day or part-day rehabilitative or therapeutic treatment.
Low care aged care establishments	Establishments where aged persons live independently but on-call assistance, including the provision of meals, is provided if needed.
Child care centres	<p>A facility which is not a private residential dwelling and is designated for the purpose of childcare and provides long day care, employer sponsored childcare, or occasional care, for children four years of age or less, but does not include the following:</p> <ul style="list-style-type: none"> (a) a service for providing preschool education conducted by a school; (b) a service principally conducted to provide: <ul style="list-style-type: none"> (i) therapeutic services; (ii) residential facilities; (iii) instruction in a particular activity e.g. dance, music or a sport; (iv) tutoring, coaching or religious instruction; (v) a recreational activity, for example, a camp or party. (c) a service for which, ordinarily, the children in care are entirely or mostly different on each occasion child care is provided, for example, resort care for children of guests of the resort.

ADVISORY GROUP MEMBERS AND JURISDICTIONS INVOLVED IN CONSULTATION

Advisory Group Members

NON-GOVERNMENT

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

GOVERNMENT

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

Jurisdictional Representatives

New South Wales Food Authority
Queensland Health
Western Australian Department of Health
South Australian Department of Health
Australian Capital Territory Health Protection Service
Department Human Services Victoria
Northern Territory Health Service
Department of Health and Human Services Tasmania

SUMMARY OF SUBMISSIONS ACCORDING TO ISSUES IDENTIFIED

List of submitters

There were 24 organisations that made submissions to FSANZ regarding the Draft Assessment Report. These organisations included:

- Queensland Health Home & Community Care Program (QLD HACC)
- Town of Vincent
- Correct Food Systems (CFS)
- Dept of Human Services Victoria (VIC)
- The Environmental Health Association (Australia) (EHAA)
- Food Technology Association of Victoria Inc.
- City of Canning WA
- Aged & Community Services WA – (ACS WA)
- South East Sydney Area Health Service (SESAHS)
- Australian Food & Grocery Council (AFGC)
- City of Tea Tree Gully
- South Australia Department of Health – (SA)
- Australian Government Department of Health and Ageing Home and Community Care (HACC)
- Aged & Community Services Australia – (ACSA)
- Aged Care Services – (ACS)
- Institute of Hospitality in Healthcare Ltd – (IHHC)
- Queensland Health – (QLD)
- SAI Global - (SAI)
- Gold Coast City Council (GCCC)
- New Zealand Food Safety - (NZFSA)
- Health Department of Western Australia - (WA)
- Australian Institute of Environmental Health - (AIEH)
- NSW Food Authority - (NSWFA)
- National Heart Foundation of Australia (NHF)

SUMMARY OF SUBMISSIONS ACCORDING TO ISSUES

DRAFT ASSESSMENT REPORT JULY 2005

P288 – Food Safety Programs for Food Service to Vulnerable Populations

ISSUE	Comments Received
<p>1. Clarification of scope of the Standard particularly Clause 1(1) and further definition of businesses required to comply</p>	<p>Clarification of scope</p> <ul style="list-style-type: none"> • Clarification required of the scope of the standard for 5 vulnerable persons or less if a business cares for more than 5 vulnerable persons during a short period e.g. home care during school vacation periods. (CFS) • Suggests the exclusion of hospital cafe / kiosks should not apply if: <ul style="list-style-type: none"> - the business prepares high risk meals or items for patients - the businesses food preparation area is used as an alternative to the normal hospital food preparation area - If the businesses facilities are used for washing patient crockery (CFS) • Suggests the food businesses for which the proposed Standard would apply could be defined based on the predominant activity of the business e.g. ‘All food premises operated by a food business where the food is handled or sold that is high risk and ready to eat and handled prior to sale and is to be consumed predominantly by at risk vulnerable populations’. An exclusion clause could then be added for businesses serving 5 or less vulnerable people. (VIC) • The rationale for 4 and 70 years needs to be explained. (SESAHS) • The Standard should not apply to food businesses that serve food to the general population even though the business may provide food to some customers who are vulnerable persons.(SA) • Suggests the wording of Clause 1 (1) could be improved to clearly define what businesses the standard will apply to. Current wording suggests café’s, restaurants, clubs, manufactures of food like baby food etc will be included if they serve 6 or more vulnerable persons.(SA) • Suggests the wording of Clause 1 (1) of the proposed Standard is not specific enough to define the food businesses that will be required to comply with the Standard. The current wording may result in food businesses such as hotels and clubs being required to comply with the Standard if a group of 6 or more vulnerable persons eats there at one time. (VIC) • Suggests guidelines should be developed to clearly identify the nature of organisations to be captured by the Standard (ACSA) • Suggests further investigation of the application of the Standard in relation to ‘Supportive Residential Facilities’ (SRF) is required as SRF may cater for 6 or more vulnerable persons at different periods of time. Suggest including a provision in the Standard for businesses that have the ‘potential’ to provide potentially hazardous food to vulnerable persons.(AIEH) <p>Application of Standard in situations described in remote locations</p> <ul style="list-style-type: none"> • Concerned that consideration has not been given to the diverse nature of organisations that provide and prepare meals for vulnerable persons and the impact that the requirements of the Standard will have on these organisations, particularly organisations operating in remote areas.(ACSA) • Suggests that food businesses on remote sites that serve vulnerable persons should not be required to comply with any additional requirements compared to a food business (SESAHS)

SUMMARY OF SUBMISSIONS ACCORDING TO ISSUES

DRAFT ASSESSMENT REPORT JULY 2005

P288 – Food Safety Programs for Food Service to Vulnerable Populations

ISSUE	Comments Received
	<p>Application of the Standard for food businesses supplying 6 or more vulnerable persons</p> <ul style="list-style-type: none"> • Does not agree that food businesses who serve less than 5 vulnerable people should be excluded from the requirements of the Standard (Tee Tree Gully) • Considers all high-risk food businesses that serve food to vulnerable persons should operate under a food safety program regardless of the number of people they serve.(AFGC) • Suggests that the rationale provided by FSANZ for the exclusion of food businesses that serve 5 vulnerable persons or less is practical, however Quality Food Services does not comment on the suitability of 5 as a cut off point. (SESAHS) • Considers all food businesses that serve potentially hazardous food irrespective of the size of the vulnerable population they serve should be required to operate under a food safety program. (EHAA) • Suggests the inclusion of a time frame in the drafting of Clause 1(1) to further define if food businesses that process potentially hazardous foods specifically intended to be supplied to six or more vulnerable persons per day, week, month etc are included.(QLD) • Agrees with the inclusion of the type of businesses as outlined in DAR, 5.1.1(GCCC) • Agrees with the proposal to exclude premises serving 5 vulnerable persons or less from the proposal (GCCC) • Suggests clarification is required in relation to ‘specifically’ intended to assist in determining which food businesses will be required to comply with the Standard e.g. if a majority of vulnerable persons are catered for. (AIEH) <p>Application of the Standard for businesses that manufacture food for vulnerable persons</p> <ul style="list-style-type: none"> • Queries the application of the proposed Standard to businesses that manufacture foods consumed by vulnerable persons such as baby foods, infant formula, milk, ice cream, fruit juice etc.(EHAA) • Clarification is required in relation to the application of the Standard for food businesses that supply and deliver diabetic food and if diabetic people are considered in the proposal to be vulnerable people.(AIEH)
<p>2. Definition of immuno-compromised person</p>	<ul style="list-style-type: none"> • Suggests the definition of immunocompromised person is considered too broad. Rather that the definition being further defined in the Standard, a guidance document based on medical advice could be prepared for use in conjunction with the Standard.(VIC) • Suggests the definition of immunocompromised could be improved by specifying the immune function is abnormally suppressed.(EHAA) • Suggest definition of immunocompromised person could be further explained with reference to the range of conditions that can cause an immuno-compromised state. (SESAHS) • Proposes that the definition of vulnerable person is expanded to include persons with medical conditions, which are not immunocompromised but can contribute to an increase in the risk of those persons contracting a food borne disease. This may include people with chronic diseases. (SESAHS) • Suggests the definition of immuno-compromised could be improved by specifying the immune function is abnormally suppressed.(AFGC)

SUMMARY OF SUBMISSIONS ACCORDING TO ISSUES

DRAFT ASSESSMENT REPORT JULY 2005

P288 – Food Safety Programs for Food Service to Vulnerable Populations

ISSUE	Comments Received
	<ul style="list-style-type: none"> • Suggests the definition of immuno-compromised requires more clarification. Should definition include reference to specific medical conditions (Tee Tree Gully) • Concerned the definition of immuno-compromised is too broad and subjective. Suggest a definition which refers to a person whose immune system is reduced or defective rather than ‘abnormal’(SA) • Suggests that the definition of immuno-compromised be expanded to provide further clarification for regulatory agencies. Definition might include ‘a person whose immune system is functioning in an abnormal or incomplete manner and is unable to protect the body from disease or is unable to protect the body from pathogens and other foreign substances, and unable to destroy infected malignant or broken down cells.(QLD) • Suggests the current definition of immuno-compromised is aligned with standard dictionary terms e.g. ‘Incapable of developing a normal immune response, usually as result of disease, malnutrition or immunosuppressive therapy’(GCCC) • Satisfied with the definition of immuno-compromised and the type of businesses identified in the proposal.(WA) • States that the current definition of immuno-compromised it too simplistic. Suggests guidelines for further explanation of the Standard to provide regulators and food businesses with assistance in determining which businesses the Standard applies too.(NSW FA)
<p>3. Application of the Standard in relation to charity groups, fundraising events, donations</p>	<ul style="list-style-type: none"> • Queries if the proposed standard will apply to charitable groups who provide services including food provision to immuno-compromised persons. (CFS) • Queries if food donations, hampers and food parcels donated by members of the public to people with HIV AIDS will be required to comply with the Standard. (CFS) • Suggests that the standard should apply to organisations preparing food for vulnerable persons for fund raising purposes if the occasion is more than a ‘one off event’ (CFS) • The inclusion of Clause 3 (3) is not supported as it is not consistent with Standard 3.2.1 Clause 6. Further clarification in relation to these two Clauses is required.(VIC) • Concerned that food safety management systems will have a impact on small delivered meals organizations particularly if staffed by volunteers (ACC WA) • Supports the exclusion of fundraising events from the requirements of the standard particularly in relation to volunteers being required to attend training if food safety management systems are required.(ACC WA) • Suggests that volunteers could be excluded from the training requirements of food safety management systems particularly considering the rationale presented for the exclusion of fundraising events (Clause 6 Standard 3.2.1).(ACC WA) • Does not agree with the exclusion of community or charitable food businesses that serve potentially hazardous food to 6 or more vulnerable persons on an ongoing basis.(SA) • Highlights the point that volunteers operating services that provide meals to vulnerable populations are not considered in the same context as volunteers who prepare meals for fund raising organisations, which are provided with an exemption from the standard.(ACS) • Requests clarification of the exemption of food businesses that fall within

SUMMARY OF SUBMISSIONS ACCORDING TO ISSUES

DRAFT ASSESSMENT REPORT JULY 2005

P288 – Food Safety Programs for Food Service to Vulnerable Populations

ISSUE	Comments Received
	<p>the scope of Clause 6 of Standard 3.2.1 and welcomes discussion in relation to charity based organisations that provide potentially hazardous food to vulnerable people on a regular basis.(NSW FA). Suggests FSANZ progressing discussions with jurisdictions around the following options:</p> <ol style="list-style-type: none"> 1. proceed with amended interpretation to Clause 6 2. do not include Clause 6 exemption within drafting for vulnerable populations 3. include revised exemption within vulnerable populations drafting that is more risk based.
<p>4. Exemption of pasteurised milk and pasteurised milks products</p>	<ul style="list-style-type: none"> • Suggests clarification of the definition of pasteurized milk, should it cover other types of milk including rice and oat milk which people may have allergies too. (CFS) • Supports the exclusion of pasteurised milk and soymilk but suggests the definition should be expanded to ensure milk is produced and pasteurised in accordance with a food safety plan and is protected from contamination. Suggested wording ‘For the purpose of this standard, milk is not considered potentially hazardous if it has been treated by a process at least equivalent in bactericidal effect to pasteurisation, hermetically sealed and packaged and supplied by a registered commercial milk processor’ (EHAA) • States that the exclusion of pasteurised milk and soymilk for the purpose of the standard is appropriate and suggests that these items should be kept refrigerated without temperature monitoring. (SESAHS) • Queries if FSANZ should consider a similar exclusion for breast milk and possibly infant formula if milk is stored in the parents or patients room (SESAHS) • Supports the exclusion of pasteurised milk and soymilk but suggests the definition should be expanded to ensure milk is produced and pasteurised in accordance with a food safety plan and is protected from contamination. Suggested wording ‘For the purpose of this standard, milk is not considered potentially hazardous if it has been treated by a process at least equivalent in bactericidal effect to pasteurisation, hermetically sealed and packaged and supplied by a registered and audited commercial milk processor’ (AFGC) • Agrees that pasteurised milk and pasteurised soymilk are excluded. Queries if other pasteurised drinks such as pasteurised orange juice should also be included.(Tee Tree Gully) • Supports the exclusion of pasteurised milk after considering the rationale provided in the Draft Assessment Report (QLD) • Agrees with the proposal to exclude pasteurised milk delivered to the business in a sealed package from the Standard (GCCC) • Supports the exclusion of pasteurised milk and pasteurised soy milk from the standard with a recommendation that editorial notes included in the Standard mention good food handling practises and procedures to prevent the contamination and mishandling of pasteurised milk and pasteurised soy milk production(WA) • Agrees with the exclusion of pasteurised cow and pasteurised soymilk providing other pasteurised milk products such as yoghurt etc are not captured by the exclusion. (NSW FA) • Requests clarification of the status of expressed breast milk under the Food Standards Code (SESAHS)

ISSUE	Comments Received
<p>5 Implementation of the Standard</p>	<p>Auditing</p> <ul style="list-style-type: none"> • States that currently there are no legislative mechanisms in Western Australia that apply to any aspect of auditing of food safety programs. (EHAA) • Suggests FSANZ develops guidance on the management of auditing processes (for hospitals and suppliers) to ensure a consistent approach nationally. (EHA) • Suggests further discussion in relation to auditing and State and Territory requirements at the Implementation Sub Committee level. (EHA) • Suggests auditing costs of food safety programs are inhibitive for small services (ACC WA) • Suggests local government EHOs should become qualified auditors and carry out audits of food safety programs at reduced cost to food businesses however many meals on wheels organizations are services delivered by local government so there could be a clash of interests. (WA) • Outlines concerns with the costs of auditing for food businesses required to comply with Standard, as subsidies do not cover those costs. (HACC) • Requests clarification of the auditing requirements (HACC) • Concerned with auditing costs associated with food safety plans (ACSA) • Suggests a system of food safety plan registration should be developed to monitor the potential for unqualified persons developing and implementing unsatisfactory food safety plans (AIEH) • Suggests that although States and Territories will be responsible for implementing the standard and for the auditing function, Environmental Health Officers should continue to conduct inspections as performed in the Victorian situation. (AIEH) <p>National Consistency</p> <ul style="list-style-type: none"> • Implementation is an issue for States and Territories and suggests FSANZ should provide guidance to States and Territories to ensure national consistency to reduce duplication and improve efficiency. (AFGC) • Believes that the implementation and application of the Standard across the States and Territories should be universal and consistent (ACSA) • The Standard must be easily interpreted by food businesses and Environmental Health Officers (SA) • Strongly supports the development of an interpretive guide to provide clarification and assist consistent enforcement. (NZFSA) • Suggests the interpretive guide should: <ul style="list-style-type: none"> - Define the meaning of ‘sale’ as referred to in the definition of ‘process’ - provide clarification of ‘potentially hazardous food’ including food prepared for immediate service and food prepared and stored prior to serving - Clarification of ‘specifically intended’ to ensure the standard does not apply to food businesses who process food for the general population. Provide a list of food businesses specifically excluded from compliance with the standard. (NZFSA) <p>Cost of implementation</p> <ul style="list-style-type: none"> • In accordance with Principle Three of the ‘Ministerial Policy Guidelines’ Standard 3.3.1 should be implemented in those businesses / sectors involved in operations identified as high risk and where the benefit to cost ration justifies the implementation of food safety programs (HACC) • Suggests careful evaluation of the benefit cost ratio for implementation of food safety programs in Meal on Wheels (MOW) agencies operating with a large volunteer workforce. (HACC)

ISSUE	Comments Received
	<ul style="list-style-type: none"> • Suggests that although tools are being developed to assist businesses develop food safety plans, small organisations will require additional resources and assistance to cover costs involved in developing food safety plans.(HACC WA) • Suggests the implementation cost for businesses has been underestimated. Provides an example where a large multi site businesses in Victoria, required to implement food safety program had costs as high as \$9000 compared to \$2180 quoted in the report.(ACSA) • Requests concerns raised are taken into serious consideration particularly the cost burden that may be experience by businesses (IHHC) • In accordance with Principle Five of the ‘Ministerial Policy Guidelines’, support is to be made available to community groups and small businesses to assist them in meeting their legislative requirements. (HACC) • Believes small organisations and the aged care sector should be provided with financial assistance to enable the implementation of the Standard (ACSA) • States businesses may require assistance either financial, with resources or with appropriate time frames to meet the requirements of the Standard.(IHHC) <p>Tool template development</p> <ul style="list-style-type: none"> • Suggests significant support in the form of templates, training, audits and realistic time frames for implementation will be required for implementation if MOW services in Queensland are required to implement Standard 3.3.1 (HACC) • Supports the development of templates and tools to assist service providers to implement the standard and offers to provide advice in this regard.(L Dredge, ACSA) • The concern expressed by industry in relation to the costs associated with implementation of food safety plans is noted and states that industry and regulators are seeking additional support from FSANZ and the Department of Health and Ageing to develop food safety plan templates and training and education packages for food businesses captured by the Standard.(WAFAC)
<p>6. Drafting</p>	<ul style="list-style-type: none"> • Considers the definition of process should be amended to include the terms ‘ refrigeration’ or ‘cooling’ on the basis that ‘heating’ is included(GCCC) • Suggests the title should include a reference to ‘which’ the Standard applies.(NZFSA) • Agrees that existing accreditation arrangements do not duplicate the requirements of Standard 3.2.1(NSW FA) • Recommends any definitions in the Code are aligned with the Model Food Act e.g. ‘Appropriate Enforcement Agency(NSW FA) • Suggests Sub clause 3 (2) (a) is imprecise and should be amended to include ‘Standard 3.2.1 (Division 2)’(NSW FA) • Raises concern that Sub clause 3 (2) (b) has the potential to create double standards and potential for inconsistency across States and Territories. Suggests deleting Sub clause 3 (2) (b).(NSW FA) • Suggests further definition / explanation of ‘Food Safety Management System’ as it is not defined in either Standard 3.3.1 or 3.2.1 but is stated in the standard.(QLD) • The nomenclature within Standard 3.3.1 and 3.2.1 should be examined to clarify the definition of food safety plans and food safety management systems (AIEH) • In relation to the drafting for Standard 3.3.1, suggests the following points are considered:

ISSUE	Comments Received
	<ul style="list-style-type: none"> - The purpose and commentary section of the Standard requires clarification as not all hospitals serve 6 or more vulnerable persons and other businesses such as drug and alcoholic rehabilitation centres are not listed. Suggests changing drafting to ‘This standard requires food businesses that process potentially hazardous food specifically for supply to 6 or more vulnerable persons (children of four years of age or less, persons of seventy years of age or more, pregnant persons and those who are immuno-compromised) at one time (per meal opportunity) to implement a documented and audited food safety management system’ - Suggests in Clause 1 (1) the intent is to capture food businesses that process potentially hazardous food specifically intended to be supplied to six (6) or more vulnerable persons at one time. Therefore recommend that amendment to wording is made to include ‘per meal opportunity’. Also recommends that the definition of ‘potentially hazardous food’ is further explained in the interpretative guide to assist businesses and industry. (NSW FA)
<p>7. Delivered Meals Organisations (DMOs) and the application of the Standard</p>	<ul style="list-style-type: none"> • Agrees with the exclusion of delivered meals organisations, as the risk will be managed by implementation of the Standard by the processing food business.(SA) • Supports the exemption of organisations who deliver meals only (HACC) • Concerned regarding the impact of the standard in relation to delivered meals organisations (DMOs) which operate in rural and remote areas. Currently some DMOs obtain meals from businesses who do not specifically prepare food intended to be supplied to vulnerable persons e.g. mining company kitchen, local cafes. What is the scope of the standard in relation to these situations? (ACC WA) • Outlines the following concerns in relation to food safety programs (FSPs) being required for Meals on Wheels Services (MOW): <ul style="list-style-type: none"> - Staff numbers in MOW organisations are limited - A large number of volunteers work at MOW services. The requirements of food safety programs may discourage volunteers - Smaller organisations have limited funds, personnel and capacity to develop and implement FSPs - If meals for MOW services are obtained from hotels, cafés and mine kitchens in remote areas, will these food businesses be required to comply with the Standard? - FSPs will need to be simple, adaptable and cater for diverse nature of MOW services (HACC) • Queries the application of the Standard in certain situations, for example, services currently being provided include: <ul style="list-style-type: none"> - meals being prepared in local hotel and being provided for 15 vulnerable persons one day a week - ethnic community member preparing culturally appropriate meals at home for delivery to a cultural group who may be vulnerable people. • delivered meals service in remote location sourcing meals from local café’s, hotel and mining company (ACSA) • Suggests that Delivered Meals Organisations (DMOs) should not be excluded from the standard, as a food safety program would not be too onerous to implement considering appropriate temperature control is required to not render the food unsafe or unsuitable (QLD) • Suggests food safety programs are warranted for DMOs, as vulnerable populations are more vulnerable to temperature fluctuations and food safety programs for DMOs would provide continuity of control over food control from production to delivery.(QLD)

ISSUE	Comments Received
8. Family Day Care Exemption	<ul style="list-style-type: none"> • Suggests if family day care businesses are to be excluded, they should be excluded as a Class of business particularly if they care for 7 persons at different times or alternatively the definition of food businesses serving food to vulnerable people should include a reference to the number of people served at one time.(Tee Tree Gully) • If family day care businesses are to be excluded then all businesses serving people from home based facilities to vulnerable persons should be exempt.(Tee Tree Gully) • Agrees that family day care type organisations are excluded from the Standard.(NSW FA) • States that in NSW no family day care services will be required to comply with the Standard, as none would cater for 6 or more vulnerable persons due to the requirements of the NSW Department of Community Services.(NSW FA) • Supports the exclusion of family day care type organisations from the standard and recommends that the editorial notes included in the Standard recommends good food handling practice guidelines are developed by family day care(WA) • Suggests family day care providers should not be exempt from the standard especially local government, religious and other organisations where food safety templates, forms and reporting are already in place.(SAI)
14. Other Issues	<p>Improved collection of data for incidences of food borne disease</p> <ul style="list-style-type: none"> • Supports the development of risk assessment tools and further collection of data on the incidence of food borne illness attributable to food handling to determine if HACCP based food safety programs should be implemented in other food business areas.(EHAA) • Suggests that the claim that mandatory food safety programs will reduce the incidence of food borne disease should be supported by improved enteric disease surveillance and follow up action particularly to differentiate between illness caused by infectious microbiological agents compared to non infectious agents. (EHAA) (AFGC) <p>Regulatory Problem miss quote of situation in WA</p> <ul style="list-style-type: none"> • States the wording in the Draft Assessment Report under Section 2 - Regulatory Problem ‘All food businesses in Australia (Except Western Australia) are currently required to comply with the Food Safety Standards in Chapter 3 of the Code’ is incorrect. Western Australia has adopted the whole of the Food Standards Code including Chapter 3 under the Health (ANZ Food Standards Code Adoption) Regulations 2001 However the current Western Australian ‘<i>Health (Food Hygiene) Regulations 1993</i>’ are to be read in conjunction with Chapter 3 of the Food Standards Code (Code) and if there is any inconsistency between Chapter 3 of the Code and the <i>Health (Food Hygiene) Regulations 1993</i>, the regulations prevail to the extent of the inconsistency. This scenario will apply until the proposed Western Australian Food Act and Model Food Provisions, Annex A and Annex B replace the Health (Food Hygiene) Regulations. (WA Health, EHAA) <p>General</p> <ul style="list-style-type: none"> • States that there have been no reported cases of food poisoning to the Queensland Meals on Wheels Service. (HACC) • Supports the principles of Hazard Analysis Critical Control Point (HACCP) analysis as a tool to manage food safety. Believes food safety plans represent the most effective way to ensure safe food for vulnerable populations. (EHAA)

ISSUE	Comments Received
	<ul style="list-style-type: none"> • Suggests the wording ‘pregnant person’ is taking political correctness too far (EHAA) (AFGC) • Supports the Ministerial Guidelines and the implementation of Standard 3.2.1 in the five high risk food businesses areas identified in the National Risk Validation Study (EHAA) (AFGC) • Supports further development of primary production and processing standards to reduce the levels of contamination in raw ingredients (EHAA) • The effectiveness of food safety plans is dependant on the introduction of food safety plans in the primary production and processing areas for raw high-risk foods such as meat, chicken and dairy products.(AFGC) • States that detail required for Food Safety Programs is to be condensed and succinct (City of Canning WA) • Suggests FSANZ should consult with people from vulnerable populations rather than just immuno-compromised people. • Suggest patients and family members with information (knowledge) should have control over what foods they consume as they do at home.((SESAHS) • Suggests that there are additional food safety concerns beyond Listeriosis (food-borne illness) which are relevant to the health care sector including texture modification, protein load and sodium levels. (SESAHS) • Suggests information in addition to the FSANZ Brochure on Listeria should be provided for patients and families about preparing food at home. (SESAHS)Supports further drafting of the Standard. (SA) • Concerned that clients and residents of aged care facilities may be discouraged from participating in food preparation activities and from using food preparation facilities if the aged care provider is required to comply with the Standard (ACSA)
<p>General Support for Standard</p>	<ul style="list-style-type: none"> • Supports in principle the adoption of Standard 3.3.1. (QLD HACC) • Supports Standard 3.3.2 in principle (Town of Vincent) • Support is given for the intent of Option 2 but the wording of the proposed Standard is not supported. (VIC) • Support given for the Ministerial Policy Guidelines and the requirement for Food Safety Programs to be implemented in high risk food businesses involved in the service of food to vulnerable populations. (EHAA) • Supports the proposal and Option 2 – to adopt Standard 3.3.1(Food Tech VIC) • Supports the proposal (City Canning WA) • Supports the mandating of food safety management systems for food businesses that process potentially hazardous food intended to be supplied to vulnerable persons (ACC WA) • Fully supports the proposed requirement for food businesses that prepare food for vulnerable populations to operate under a documented food safety program.(AFGC) • Proposal P288 is supported subject to additional comments (Tee Tree Gully) • Supports amending the Code to include Standard 3.3.1 with the intent of mandating of food safety programs for food businesses that provide food specifically intended for vulnerable people (SA) • Support the intent of proposal, requiring written food safety programs (HACC) • Supports the general intent of the Standard.(ACSA) • States agreement with the Draft Assessment Report Proposal P288 (ACS) • Supports the implementation of food safety programs for food service to vulnerable populations (IHHC) • Supports the overarching principles outlined in the Ministerial Guidelines. Supports the implementation of Option 2 to adopt Food Safety Standard 3.3.1 with consideration of comments provided. (QLD) • Supports the proposal (SAI)

ISSUE	Comments Received
	<ul style="list-style-type: none"> • Supports regulatory option 2, to adopt Standard 3.3.1(NZFSA) • Supports in principle Option 2 to adopt Standard 3.3.1(WA) • Supports in principle the adopting of Standard 3.3.21 as proposed on Option 2(AIEH) • Supports regulatory Option 2 however suggests that food safety management systems should be mandatory for all food businesses (NHF)

ATTACHMENT 4

SUMMARY OF FOOD SAFETY PROGRAM TOOLS AVAILABLE FOR FOOD BUSINESSES

Tool Development Project	Current Status	Responsible Agency
Commercial Food Service Establishments	Complete, an electronic copy of the tool has been distributed to State/Territory Governments	Department of Health and Ageing Food Safety and Surveillance Section ph: (02) 6289 5131 foodsafety@health.gov.au
Children's Services Operations	Complete, an electronic copy of the tool has been distributed to State/Territory Governments	Department of Health and Ageing Food Safety and Surveillance Section ph: (02) 6289 5131 foodsafety@health.gov.au
Small/Medium Hospitals and Nursing Homes	Draft Complete for consideration by ISC	Department of Health and Ageing Food Safety and Surveillance Section ph: (02) 6289 5131 foodsafety@health.gov.au
Delivered Meals Organisations (DMOs)	Still in production, copies will be distributed to individual DMOs - expect this to happen by end 2006	Department of Health and Ageing Food Safety and Surveillance Section ph: (02) 6289 5131 foodsafety@health.gov.au
Industry Guide to Developing a Food Safety Program (Hospitals and Aged Care)	Available electronically on NSW Food Authority website for use by food businesses.	NSW Food Authority PO Box 6682 Silverwater NSW 1811. Tel 1300 552 406 www.foodauthority.nsw.gov.au

SUMMARY OF EXISTING ACCREDITATION REQUIREMENTS

Existing accreditation arrangements

Child care

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

The QIAS currently has two principles childcare providers must meet which concern the safety of food. These are Principle 6.2: *Staff implement current food safety and hygiene practices* and Principle 6.6: *The centre acts to control the spread of infectious diseases and maintains records of immunisations* (National Childcare Accreditation Council, 2001). To comply with these principles the centre must demonstrate compliance with the requirements of the relevant authority. Compliance may be checked during the audit through viewing inspection or audit reports from the relevant authority but the audit does not check to see that the centre is complying with the requirements at the time of the audit. These two principles are only a small part of a large accreditation system consisting of 33 principles.

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

Aged care

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

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

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

Hospitals

The major accreditation body in Australia for Hospitals and other healthcare establishments is the Australian Council on Healthcare Standards (ACHS).

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

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

REFERENCES

Food Science Australia and Minter Ellison Consulting (2002) *The National Risk Validation Project - Final Report 2002*. www.health.gov.au/pubhlth/strateg/foodpolicy/pdf/validation.htm.

Liu, M. and Strickland, P. (2002) *Recognition of Accreditation Systems for Class 1 Food Premises*. Food Safety Victoria, Department of Human Services, Melbourne.

The Allen Consulting Group (2002a) *Food Safety Management Systems - Costs, Benefits and Alternatives*. Australian Government Department of Health and Ageing, Canberra. www.health.gov.au/pubhlth/strateg/foodpolicy/pdf/alternatives.htm.