Food Safety Programs for Food Service to Vulnerable Persons

A guide to Standard 3.3.1 – Food Safety Programs for Food Service to Vulnerable Persons

Chapter 3 of the Australia New Zealand Food Standards Code (Australia Only)
February 2008



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Introduction

What is the purpose of the guide?

The guide to Standard 3.3.1 Food Safety Programs for Food Service to Vulnerable Persons is intended to help those people responsible for enforcing the Australia New Zealand Food Standards Code (the Code) to understand the intent of the clauses contained in Standard 3.3.1. It has been developed by Food Standards Australia New Zealand (FSANZ) in accordance with section 13(1)(c) of the Food Standards Australia New Zealand Act 1991. The entire Code is available on the FSANZ website at www.foodstandards.gov.au.

What is the scope of the guide?

The guide has been developed to help enforcement officers understand the general intent of individual clauses in Standard 3.3.1. It does this by providing an explanation of the legally defined terms and requirements in each clause as well as by including examples, where appropriate. The aim is to clarify to which food businesses Standard 3.3.1 applies and, therefore, which businesses are required to have food safety programs.

This guide does not provide specific guidance on how businesses should develop and implement food safety programs. A range of tools, templates and guides developed by the Australian Government and individual state and territory food authorities can be referenced by those seeking further guidance on Standard 3.2.1 *Food Safety Programs* (see Appendix 3 for information on how to obtain this guidance material).

Is the information in this guide legally binding?

The guidance provided in this document is not legally binding—only the clauses in the standard are legally binding. Persons who are uncertain about the meaning of a clause in Standard 3.3.1 can refer to the explanation in this guide for clarification. The guide includes examples where these may be helpful in explaining the meaning of a clause. However, neither the explanations in the guide nor the examples are legal requirements for food businesses.

As this standard forms only a part of Australian food legislation, state, territory and enforcement officers should also refer to other standards in the Code and to their state's or territory's legislation, as these may also contain food safety program requirements. For example, in Victoria all food businesses must already have a food safety program in place (except retail businesses selling low-risk pre-packaged food).

Can I provide feedback on this guide?

This edition of the guide will be reviewed and amended as necessary. Readers are invited to contact FSANZ if they have suggestions that would improve the guide, or if they believe additional explanation should be included. Feedback should be sent to the addresses on page ii.

How do I use this guide?

This guide provides a plain English explanation of each clause of Standard 3.3.1. A copy of the complete standard (Standard 3.3.1) is on pages 7 to 12, followed by a clause-by-clause interpretation.

The intended outcome for each clause of the standard is set out in a shaded box that precedes the explanation for that clause. For example, for clause 2 Interpretation the outcome is:

The interpretation clause defines the terms in Standard 3.3.1.

The text of each clause of the standard is included in bold type throughout the interpretive sections of the guide. The clause, subclause and paragraph numbering and lettering are the same as those in the standard.

For example:

- 1(2) This standard also applies to delivered meals organisations that
 - are food businesses; and (a)
 - process food for service to six or more vulnerable persons at any given time, (b) and the food served is ready to eat food which includes ready to eat potentially hazardous food.

An explanation of paragraph 1(2)(a) and (b) then follows this bold text. The order in which clauses appear in the standard, however, is not the order they are discussed in the guide. Clause 2 Interpretation, for example, is discussed before Clause 1 Application in order to clarify terms and definitions at the outset.

Examples are titled and provided throughout the text in shaded tables and boxes. These examples serve to illustrate the intent of the requirements. For example, the exemption from the standard under paragraph 1(3)(b) for delivered meals organisations that only deliver food is illustrated by the following example:

Example

A rural meals-on-wheels organisation uses volunteers to pick up prepared meals from the local hospital and deliver them to 15 to 20 elderly residents in the community. This organisation is not involved in any food processing, only the organisation of volunteers and meal delivery. It is not required under Standard 3.3.1 to have a food safety program.

Background

Why was Standard 3.3.1 developed?

In December 2003 the Australia New Zealand Food Regulation Ministerial Council endorsed the *Ministerial Policy Guidelines on Food Safety Management in Australia* (Ministerial Policy Guidelines). The Ministerial Policy Guidelines identify those food businesses that should be required to have a food safety program, as defined in Standard 3.2.1, based on the food safety risk that they pose. Food businesses involved in food service where potentially hazardous food is served to vulnerable populations were identified as being high risk. Three other food industry sectors were also identified:

- production, harvesting, processing and distribution of raw oysters and other bivalves
- catering operations serving food to the general public
- production of manufactured and fermented meat.

In determining the businesses that should be required to have a food safety program, the following were referred to:

- information from OzFoodNet¹, a collaborative network of epidemiologists and microbiologists who conduct enhanced surveillance and applied research into foodborne disease across Australia
- a report called *Food safety management systems: costs, benefits and alternatives*² that examines closely the costs and benefits for food businesses in having a food safety program, the benefits for consumers of this approach and other systems that might deliver a similar level of food safety
- the findings of the National Risk Validation Project³ that identified the food handling sectors in Australia that posed the greatest food safety risk.

In accordance with the Ministerial Policy Guidelines, FSANZ has developed Standard 3.3.1 to require food businesses providing food to vulnerable persons to have a food safety program.

What is Standard 3.3.1?

Standard 3.3.1 is one of the national food safety standards in Chapter 3 of the *Australia New Zealand Food Standards Code* that outline the responsibilities of food businesses to ensure that the food the businesses produce is safe and suitable. Standard 3.3.1 requires businesses providing potentially hazardous food to vulnerable persons to comply with Standard 3.2.1 and implement a documented and audited food safety program.

¹ OzFoodNet website, <www.ozfoodnet.org.au>.

The Allen Consulting Group, 2002, Food safety management systems: costs, benefits and alternatives: final report to the Commonwealth Department of Health and Ageing (Allen Report). Department of Health and Ageing, Canberra, ACT. Accessed November 2007, <www.health.gov.au/internet/wcms/publishing.nsf/Content/health-publith-strateg-foodpolicy-pdf-alternatives.htm>.

Food Science Australia & Minter Ellison Consulting, 2002, *National Risk Validation Project: final report*. Department of Health and Ageing, Canberra, ACT. Accessed November 2007, <www.health.gov.au/internet/wcms/publishing.nsf/Content/health-publith-strateg-foodpolicy-pdf-validation.htm>.

What are Chapter 3 food safety standards?

There are currently five food safety standards in Chapter 3 of the Code:

Standard 3.1.1 Interpretation and Application

Standard 3.1.1 sets out the interpretation and application provisions that apply to all of the Chapter 3 food safety standards.

Standard 3.2.1 Food Safety Programs

Standard 3.2.1 specifies the requirements for food safety programs. A food safety program is a written document indicating how a food business will control the food safety hazards associated with the food handling activities of the business.

Standard 3.2.2 Food Safety Practices and General Requirements

Standard 3.2.2 sets out specific food handling controls related to the receipt, storage, processing, display, packaging, transportation, disposal and recall of food. Other requirements relate to the skills and knowledge of food handlers and their supervisors, the health and hygiene of food handlers, and the cleaning, sanitising and maintenance of the food premises and equipment within the premises.

All food businesses are required to comply with Standard 3.2.2. There are some exemptions from some requirements in the standard for charities, community groups and businesses operating from temporary food premises and private homes.

Standard 3.2.3 Food Premises and Equipment

Standard 3.2.3 sets out the requirements for food premises, fixtures, fittings, equipment and food transport vehicles. All food business are required to comply with Standard 3.2.3, with some exemptions for businesses operating from temporary food premises and from private homes as per Standard 3.2.2.

Standard 3.3.1 Food Safety Programs for Food Service to Vulnerable Persons

Standard 3.3.1 requires food businesses involved in food service to vulnerable persons to comply with Standard 3.2.1 Food Safety Programs. Standard 3.3.1 was adopted into Chapter 3 of the Code in October 2006.

Which food businesses are required by Standard 3.3.1 to comply with Standard 3.2.1 Food Safety Programs and by when?

The food businesses identified in Standard 3.3.1 that are required to have a food safety program include those businesses involved in food processing and service to six or more vulnerable people at any given time. Vulnerable people are defined by the standard in terms of the facility in which they are cared for or as clients of a delivered meals organisation. The facilities listed in the standard include:

- hospital facilities, including acute care, psychiatric, hospice, chemotherapy and renal dialysis facilities
- aged care facilities, including nursing homes, respite care, same-day aged care and low care aged care facilities
- child care facilities, including long day care, occasional day care and employer-sponsored child care.

Food businesses required to comply with this standard have until 5 October 2008 to have a food safety program in place.

Further information on the development of Standard 3.3.1 is provided in the Assessment reports for Proposal P288—Food Safety Programs for Food Service to Vulnerable Populations, available on the FSANZ website at www.foodstandards.gov.au.

Standard 3.3.1

Food Safety Programs for Food Service to

Vulnerable Persons

Standard 3.3.1

Food Safety Programs for Food Service to Vulnerable Persons

(Australia only)

To commence on 5 October 2008

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

- 1 Application
- 2 Interpretation
- 3 Food safety programs

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	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:
	(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	Establishments devoted primarily to the treatment and care of inpatients with psychiatric, mental or behavioural disorders including any:
	(a) Public psychiatric hospital;
	(b) Private psychiatric hospital.
Nursing homes for the aged	Establishments which provide long-term care involving regular basic nursing care to aged persons and including any:
	(a) Private charitable nursing home for the aged;
	(b) Private profit nursing home for the aged;
	(c) Government nursing home for the aged.
Hospices	Freestanding establishments providing palliative care to terminally ill patients, including any:
	(a) Public hospice;
	(b) Private hospice.

Schedule (continued)

Column 1	Column 2
Facility	Definition
Same day establishments for chemotherapy and renal dialysis services	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:
	(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.
	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.
	Freestanding day surgery centres are hospital facilities providing investigation and treatment for acute conditions on a day-only basis.
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	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:
	(a) a service for providing preschool education conducted by a school;
	(b) a service principally conducted to provide:
	(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.

Clause-by-clause explanation of Standard 3.3.1

Introduction to the standard

Standard 3.3.1 requires food businesses that serve or process potentially hazardous food for service to vulnerable persons to comply with Standard 3.2.1 *Food Safety Programs*. It consists of three clauses:

Application The application clause describes the food businesses to which the standard applies. These businesses are described in terms of the food processing activities they undertake, the facilities where or for which these activities are undertaken, the number of vulnerable people to be served, and whether this is the principal activity of the business.

Interpretation The interpretation clause defines the terms used in Standard 3.3.1. Additionally, it specifically applies the definitions used in Part 3.1 and Part 3.2 of the Code to this standard.

Food safety programs This clause contains the requirement for food businesses, as described under the application clause, to have food safety programs.

While the first clause of the standard is the application clause, the clause-by-clause explanation will initially cover the interpretation clause so that all the definitions that apply to the standard are discussed and presented up front.

2 Interpretation

The interpretation clause defines the terms used in Standard 3.3.1.

(1) Unless the contrary intention appears, the definitions in Parts 3.1 and 3.2 of this Code apply in Standard 3.3.1.

Terms used in Standard 3.3.1 (unless defined specifically for use within this standard under subclause 2(2)) are defined in Part 3.1 (Preliminary) and Part 3.2 (Food Safety Requirements) of the *Australia New Zealand Food Standards Code*. In the absence of a definition in these standards, it may be useful to use the *The Macquarie dictionary* (latest edition).

Part 3.1 of the Code contains:

• Standard 3.1.1 *Interpretation and Application*.

Part 3.2 of the Code contains:

- Standard 3.2.1 Food Safety Programs
- Standard 3.2.2 Food Safety Practices and General Requirements
- Standard 3.2.3 Food Premises and Equipment.

The definitions in Parts 3.1 and 3.2 of the Code that apply in Standard 3.3.1 are presented and discussed on the next page.

Food business

A 'food business' is defined in Standard 3.1.1 of the Food Standards Code and means:

a business, enterprise or activity (other than primary production) that involves:

- (a) the handling of food intended for sale, or
- (b) the sale of food;

regardless of whether the business, enterprise or activity concerned is of a commercial, charitable or community nature and whether it involves the handling or sale of food on one occasion only.

Relevance to Standard 3.3.1

This standard only applies to **food businesses**. In order to work out whether a business, enterprise or activity is a food business, the concept of sale is critical. The definition of **sell** is below.

This standard does not apply to food businesses conducting fundraising events (Clause 6 of Standard 3.2.1). This exemption is discussed under subclause 3(2).

Sell

'Sell' is defined in Standard 3.1.1 of the Code and means:

- (a) barter, offer or attempt to sell; or
- (b) receive for sale; or
- (c) have in possession for sale; or
- (d) display for sale; or
- (e) cause or permit to be sold or offered for sale; or
- (f) send, forward or deliver for sale; or
- (g) dispose of by any method for valuable consideration; or
- (h) dispose of to an agent for sale on consignment; or
- (i) provide under a contract of service; or
- (j) supply food as a meal or part of a meal to an employee, in accordance with a term of an award governing the employment of the employee or a term of the employee's contract of service, for consumption by the employee at the employee's place of work:
- (k) dispose of by way of raffle, lottery or other game of chance; or
- (I) offer as a prize or reward; or
- (m) give away for the purpose of advertisement or in furtherance of trade or business; or
- (n) supply food under a contract (whether or not the contract is made with the consumer
 of the food), together with accommodation, service or entertainment, in
 consideration of an inclusive charge for the food supplied and the accommodation,
 service or entertainment; or

- (o) supply food (whether or not for consideration) in the course of providing services to patients or inmates in public institutions, where 'public institution' means 'public institution' as defined in the Act, if it is so defined; or
- (p) sell for the purpose of resale.

For example, a child care centre that only provides food supplied by parents is not food for sale. The definition of sale includes supplying food to patients or inmates in hospitals or prisons.

Process

'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.

This definition has been provided within an editorial note in the standard following clause (1).

Relevance to Standard 3.3.1

Standard 3.3.1 applies to food businesses that **process** or serve food for service within a facility listed in the schedule or a delivered meal organisation. The definition of process does not include an exhaustive list of activities that may be conducted to prepare food. If the business conducts any activities to prepare food for sale, then the business is considered to be processing food.

Potentially hazardous food

'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.

This definition has been provided within an editorial note in the standard following clause (2).

A food may be considered potentially hazardous if it:

- may contain a pathogen that needs to multiply in order to cause illness
- will support the growth of this pathogen.

Standard 3.2.2 specifies food handling controls for potentially hazardous food that keep it under temperature control (for example at 5°C or below or 60°C or above). The intent is to minimise the growth of pathogens and prevent food becoming unsafe.

Foods that are normally potentially hazardous include:

- raw and cooked meats, or foods containing raw or cooked meat, such as casseroles, curries, lasagne and meat pies
- dairy products and foods containing dairy products, such as custard and dairy-based desserts

⁴ Alternative methods of compliance to these temperature requirements are allowed in Standard 3.2.2, providing the microbiological safety of the food is not adversely affected.

- seafood and foods containing seafood
- processed fruits and vegetables, for example salads
- cooked rice and pasta
- foods containing eggs, beans or other protein-rich foods, for example quiche
- foods that contain any of the above, for example sandwiches.

Relevance to Standard 3.3.1

Standard 3.3.1 applies to food businesses that process or serve food that is **potentially hazardous**. The intent is to apply the standard only to food businesses that provide potentially hazardous foods (whether or not the business also serves non-potentially hazardous food). The standard does not apply to businesses that provide only non-potentially hazardous food. For example, a facility that only provides a drink (for example tea or coffee) with biscuits to their clients is not serving food that is potentially hazardous and would not be required to have a food safety program.

(2) In this Standard -

The following definitions are provided specifically for use in Standard 3.3.1.

Milk

milk includes flavoured and modified milk.

Standard 3.3.1 does not apply to businesses that only serve **milk** or soy milk (this exemption is discussed under subclause 3(a)). A definition of milk is included in Standard 2.5.1 of the Code but does not cover modified and flavoured milks. A definition of milk has therefore been provided for the purpose of Standard 3.3.1 to clarify that milk, for the purposes of this standard, includes flavoured milks and modified milks (such as skim milk and low-fat milks).

Ready to eat

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.

Standard 3.3.1 applies to food businesses that, under Activities 2 and 3 in subclause 1(1), process **ready to eat** potentially hazardous food. The definition of 'ready to eat' in Standard 3.3.1 is different from the definition in Standard 3.2.2 to clarify that food is considered ready for consumption even though it may require defrosting, reheating, portioning or garnishing before service.

Vulnerable person

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

Standard 3.3.1 only applies to food businesses that serve or process food for service to six or more **vulnerable persons** in a facility listed in the Schedule or by a delivered meal organisation. For the purpose of the Standard, vulnerable persons are defined by whether they are in care in any of the identified facilities or are clients of a delivered meal organisation. A person is considered

3.3.1

to be in the care of a facility if they receive any services provided by that facility.

For example, vulnerable persons would include aged care recipients, hospital patients (including pregnant women, and nursing mothers and their babies), chemotherapy and dialysis patients, children in child care, respite patients, nursing home residents and psychiatric hospital patients. The definition excludes staff and visitors but includes outpatients.

The standard only applies where food processing or service is for six or more vulnerable people (discussed under clause 1(1)).

1 Application

The application clause describes the food businesses to which the standard applies.

1(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.

Subclause 1(1) applies Standard 3.3.1 to businesses in terms of:

- the food processing activities they undertake (processing or serving potentially hazardous and ready to eat food)
- the facilities or organisations where or for which these activities are undertaken
- the number of vulnerable people to be provided with food service
- whether this is the principal activity of the business
- whether the food is ready to eat, including ready to eat potentially hazardous food.

According to these criteria the food business is described by Activity 1, Activity 2 or Activity 3. A flow diagram showing the application of Standard 3.3.1 to businesses depending on the food handling activities that they undertake is provided in Figure 1 on page 21. Further examples illustrating the application of clause 1(1) to food businesses are provided in Table 1 on page 22. Additional scenarios are included in Appendix 2 to clarify specific issues.

Serve

Activity 1, Activity 2 and Activity 3 refer to the **service** of potentially hazardous food to six or more vulnerable people. Serve is not defined in the Code and has not been defined for the purpose of Standard 3.3.1 as it is a commonly used and understood term referring to the act of setting out or

presenting food for a person who is about to eat. The service of food is considered the final stage of food preparation and is the last step before consumption.

Serving food may involve such activities as:

- portioning food from a bulk tray or container into single serves and placing it on plates
- presenting food in a bain-marie or other bulk food display unit for self-service
- delivery of plated food to patients within a facility.

Serving food would not include activities to help patients eat the food presented to them, such as chopping or cutting food into small pieces on the plate or physically feeding them.

Six or more vulnerable persons

In relation to Activity 1, Activity 2 and Activity 3, the standard only applies to food businesses that serve or process food for **six or more** vulnerable persons at any given time. Businesses that provide food for five or fewer clients are therefore not required by Standard 3.3.1 to have a food safety program. An example of such a business would be a small, possibly remote, aged care facility or hospital that only had the capacity to service five or fewer clients.

The limit of six vulnerable people was determined using a cost–benefit analysis, which found that developing and implementing a food safety program for small businesses servicing five or fewer vulnerable people was not cost effective (that is, the benefit did not justify the cost).

Facility

Activity 1 and Activity 2 apply to food businesses that serve food or process food for service in a **facility** listed and defined in the Schedule to the standard. These facilities include:

- acute care hospitals
- psychiatric hospitals
- nursing homes for the aged
- hospices
- · same-day establishments for chemotherapy and renal dialysis services
- respite care establishments for the aged
- same-day aged care establishments
- low care aged care establishments
- child care centres.

The editorial note following the table to subclause 1(1) outlines that the definitions listed in the Schedule have been adapted from the *National health data dictionary*. Further discussion of these facilities is provided in this guide under Schedule. As discussed previously, the definition of vulnerable people in the standard is provided in terms of people receiving care in these facilities.

The *National health data dictionary* is a national resource that health jurisdictions use to ensure the consistency and comparability of all data collected under the National Health Information Agreement. It is published by the Australian Institute of Health and Welfare (AIHW) and the latest version can be accessed from the AIHW website at www.aihw.gov.au/publications/index.cfm/title/10326.

Principal activity

Activity 2 and Activity 3 refer to the **principal activity** of the business. The intent of using the term 'principal activity' is to capture only food businesses that primarily operate to process food **for service** to vulnerable people in the facilities identified in the Schedule to the standard or a delivered meal organisation.

Not all food businesses principally process food for service to the identified facilities or delivered meal organisations. For example, a business may process food for service to the general community as well as providing meals to the local aged care facility or delivered meals organisation. Such an example may occur in rural areas where the local club restaurant, in addition to providing meals to its patrons, processes meals for delivery by the local delivered meals organisation. This would not be, however, the principal activity of the business and it would not need to comply with Standard 3.3.1.

'Principal activity' also clarifies that food businesses manufacturing foods that are for general distribution (for example, packaged juices and dairy foods such as cheese) and that may also be distributed to hospitals, residential care facilities, child care facilities and the like, are not intended to be captured.

To determine the principal activity of the business it may be necessary to make an assessment of all the food business's operations to determine the primary reason for establishing the food business. In the example of the club restaurant, providing meals to a delivered meals organisation is not its principal activity and this business would not be captured by the standard.

In accordance with clause (4) of Standard 3.2.2, a food business is required to notify the appropriate enforcement agency of certain information, including a description of the nature of the food business. This description may provide the enforcement agency with sufficient information to establish the principal activity of the business.

Delivered meal organisation

Activity 3 refers to a **delivered meal organisation**. Delivered meal organisations are not defined in the standard. However, they generally include meals-on-wheels and like organisations that deliver food to people in their own homes, including the elderly or people with disabilities who cannot cater for themselves. Food businesses that process and supply ready to eat food to delivered meal organisations for delivery are captured by Activity 3 where:

- this is the principal activity of the business
- the food processed is for six or more people.

Activity 3 does not require the delivered meal organisation to have a food safety program. Subclause 1(2) of Standard 3.3.1 describes when a delivered meal organisation is required to have a food safety program and this is discussed further under that clause.

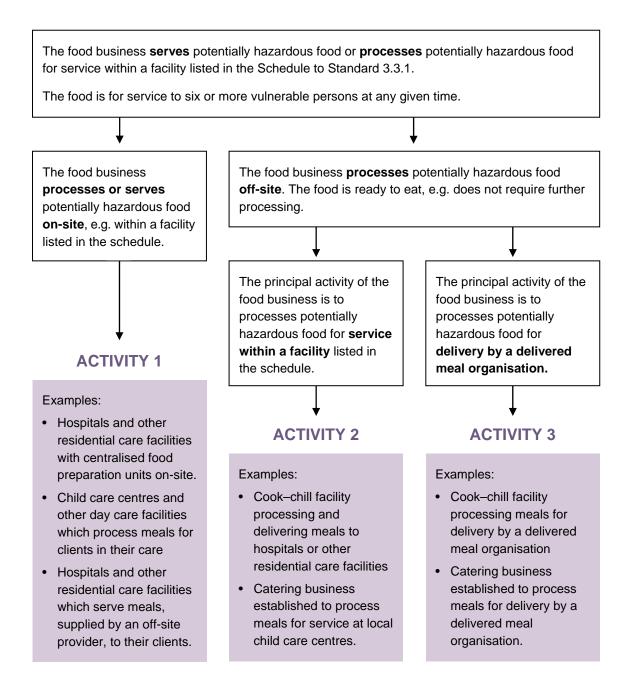


Figure 1: Flow diagram showing the application of subclause 1(1) to food businesses

	Food opfotes was assessed	
Example	Food safety program requirement	Rationale
The kitchen facilities in, and operated by, a hospital process potentially hazardous food for service to those in care (six or more people).	Yes The hospital is captured by Standard 3.3.1 under Activity 1 and must comply with Standard 3.2.1.	Activity 1 the business is processing ready to eat potentially hazardous food for six or more vulnerable persons at any given time the business is in an identified facility (on-site). Under Activity 1 it does not matter whether this is the principal activity of the business.
A business operates a café located in a hospital which processes and serves ready to eat potentially hazardous food to members of the public, staff and patients of the hospital who wish to purchase food from it.	No Standard 3.3.1 does not apply to the café.	The café business is operating in an identified facility (Activity 1) but it is not processing food for six or more vulnerable persons at any one time. That is, the cafe business is not processing food with the intention of serving those in care in the facility (that is, vulnerable people). Its principal activity is to process food for members of the public and hospital staff.
A centralised food preparation unit in a large hospital processes potentially hazardous food for service to those in care in the hospital as well as supplying meals for service at another hospital and for delivery by a delivered meal organisation (DMO).	Yes The food preparation unit (which may or may not be operated separately to the hospital) is captured by Standard 3.3.1 under all activities described and must comply with Standard 3.2.1.	Activity 1, Activity 2 and Activity 3 • the principal activity of the business is processing food for six or more vulnerable persons at any given time • the business is in an identified facility (on-site) (Activity 1) • the business processes food (off-site) for service in anothe facility (Activity 2) • the business processes potentially hazardous food for delivery by a DMO (Activity 3)

Continued

Continued

	Table 1 continued: Exan subclause 1(1) to food b	•	pplication (or not) of	
	Example	Food safety program requirement	Rationale	
	A 30-place child care centre provides long stay care but parents provide their own food (lunches and other snacks) for the children. Centre staff may warm children's meals brought from home. The centre provides milk, fruit juice and biscuits to children at morning and afternoon tea.	No The standard does not apply to the child care centre.	Only non –potentially hazardous food is provided by the child care centre as part of its business. The lunches provided by parents (which may include potentially hazardous food) is not food for sale.	
1	A small business operating from a residential kitchen prepares meals for distribution by a DMO. The DMO collects the meals daily before lunchtime and delivers the meals to its clients (up to 10 people).	Yes The small business is captured by Standard 3.3.1 under Activity 3 and must comply with Standard 3.2.1. The DMO only delivers food and is not required to have a food safety program.	Activity 3 the principal activity of the business is processing food for six or more vulnerable persons at any given time the business processes ready to eat potentially hazardous food for delivery by a DMO.	
	A day centre providing renal dialysis services provides its clients with beverages (tea, coffee, juice, water) and dry snacks such as biscuits (sweet and savoury).	No The standard does not apply to the day centre.	Only non –potentially hazardous food is provided by the centre.	

1(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.

A delivered meal organisation may be involved in producing, organising or delivering food, or all three of these activities. Subclause 1(2) specifically applies Standard 3.3.1 to delivered meal organisations where they are involved in producing, that is, processing food for service to clients.

The standard does not apply to delivered meal organisations that only deliver meals (clarified under subclause 1(3)(b)).

Subclause 1(2)(a) applies the standard only to delivered meal organisations that are food businesses. This subclause has been included to further clarify that Standard 3.3.1 only applies to businesses or enterprises involved in the handling of food intended for sale or the sale of food. Where food is provided by an organisation where no sale is involved, such as a mobile soup kitchen feeding the homeless and disadvantaged, the enterprise is not captured by this standard.

Subclause 1(2)(b) applies the standard to delivered meal organisations according to whether:

- the delivered meal organisation processes food for service
- the food is for six or more vulnerable people
- the food is ready to eat and includes potentially hazardous food.

to delivered meal organisations		
Example	Food safety program requirement	Rationale
A DMO uses a community centre kitchen to prepare meals for delivery to up to 40 elderly residents in the local area. Volunteers organised by the DMO collect the meals daily and deliver them to the recipients on their list. Clients of this service pay a fee for meals provided. The centre kitchen is operated by both volunteers and paid employees of the DMO.	Yes The DMO is required under subclause 1(2) to comply with Standard 3.2.1.	 the DMO is involved in the processing of food for clients—it is a food business (for example it is involved in the sale of food) the centre is involved in the processing of food (including ready to eat potentially hazardous food) for six or more persons.
A meals-on-wheels organisation contracts out the food preparation for its clients to a commercial caterer. It organises volunteers to pick up the meals and deliver them to around 150 clients.	No The standard does not apply to the meals-on-wheels organisation. The commercial caterer may be captured under subclause 1(1) Activity 3 if this is its principal activity.	 The organisation is not involved in the processing of food (as described under subclause 1(2)(b)). An exemption for DMOs that only deliver food is provided under subclause 1(3)(b) (discussed on the next page)

1(3) This Standard does not apply to -

(a) food businesses that only serve milk or soy milk as, or in, a beverage; or

Milk and soy milk are generally considered to be potentially hazardous foods. The intention of subclause 1(3)(a), however, is to exclude food businesses where the **only** potentially hazardous food served is milk or soy milk served either as a beverage or in a beverage such as tea or coffee. In terms of food safety, it is not considered necessary for a business that serves only drinks (such as tea, coffee, milk and juice) with non–potentially hazardous foods such as biscuits or fruit to develop and implement a food safety program.

The exemption for food business serving milk or soy milk does not apply where milk or soy milk are served in any form other than as a beverage, for example foods made with milk or soy milk as an ingredient, such as custards.

As discussed previously under Interpretation, Standard 3.3.1 includes a definition of milk to clarify that, for the purpose of this subclause, milk includes flavoured and modified milks. For clarification, milk does not include infant formula (infant formula is a food for infants and not a 'beverage').

(b) delivered meals organisations that only deliver food.

Subclause 1(3)(b) further clarifies that Standard 3.3.1 does not apply to delivered meals organisations that **only** deliver food. Such organisations are not required to have a food safety program.

Subclause 1(3)(b) does not, however, exclude the delivery (transport) of food from a delivered meal organisation's food safety program where that delivered meal organisation is required to have a food safety program under subclause 1(2).

Example

A rural meals-on-wheels organisation uses volunteers to pick up prepared meals from the local hospital and deliver them to 15 to 20 elderly residents in the community. This organisation is not involved in any food processing, only the organisation of volunteers and meal delivery. It is not required under Standard 3.3.1 to have a food safety program.

1(4) Subclause 1(2) of Standard 1.1.1 does not apply to this Standard.

Subclause 1(4) clarifies that the usual 12-month lead-in period under subclause 1(2) of Standard 1.1.1 of the *Australia New Zealand Food Standards Code* does not apply to this standard. Instead, Standard 3.3.1 commences two years from gazettal of the standard. Businesses must comply with Standard 3.3.1 from the starting date specified (5 October 2008).

3 Food safety programs

This clause specifies the requirement for food businesses, as described under the application clause, to have a food safety program.

3(1) A food business to which this Standard applies must comply with Standard 3.2.1

Food businesses to which Standard 3.3.1 applies are required by subclause 3(1) to comply with Standard 3.2.1 *Food Safety Programs*. Standard 3.2.1 is based on the principle that food safety is best ensured through the identification and control of hazards in the production, manufacturing and handling of food as described in the Hazard Analysis and Critical Control Points (HACCP) System. A copy of Standard 3.2.1 is provided at Appendix 1.

The requirements on food businesses in Standard 3.2.1 are specified in Division 2 – Food safety programs. Division 2 covers:

- general food safety program requirements (Clause 3)
- auditing of food safety programs (Clause 4)
- content of food safety programs (Clause 5)
- fundraising events (Clause 6).

In general the food business must:

- carefully examine all its food handling operations to identify any potential hazards
- if one or more hazards are identified, develop a food safety program to control the hazard(s)
- have the food safety program as a written document and retained on the premises
- comply with the program
- conduct a review of the program at least annually to make sure it is adequate.

The content of a food safety program is prescribed under clause 5 and essentially provides for the following elements to be documented:

- the food handling operations of the business
- potential food safety hazards
- control measures
- corrective actions
- the review of the program
- · record keeping.

FSANZ has developed *A guide to Standard 3.2.1 Food Safety Programs* to provide an explanation of the legally defined terms and clauses in Standard 3.2.1. This guide is available on the FSANZ website at www.foodstandards.gov.au. A number of industry guides and tools have also been produced to help businesses develop food safety programs (listed at Appendix 3). Some specific considerations for food handling operations, food safety hazards and control measures in food service to vulnerable persons are provided below.

Food handling operations

'Food handling operation' is defined in Standard 3.1.1 as 'any activity involving the handling of food' and can include delivery, storage, preparation, cooking, chilling, reheating, serving, display and transport. To systematically examine all of its food handling operations, the food business should list all the steps in its food processing activities, beginning with receiving food (including ingredients) through to the final step in the process. *A guide to Standard 3.2.1 Food Safety Programs* provides an example of a hospital kitchen and includes a flow diagram identifying the steps in that food business's operation.

A number of steps may need to be identified by the food business depending on whether it assembles cold foods, cooks fresh, cooks and chills, vitamises, transports, serves etc. Standard 3.3.1 applies food safety programs to businesses on the basis of three activities listed in the table to subclause 1(1) or whether they are a delivered meal organisation processing food (subclause 1(2)). The food handling operations that may be expected to fall within each of these activities are outlined below.

Activity 1

Activity 1 describes the processing and serving of food by food businesses within a facility (on-site). For example, an acute care hospital or nursing home for the aged that has centralised food processing facilities would be expected to cover in its food safety program all the food handling steps (covering processing and service) from purchase and receipt of ingredients through to delivery to patients and clean up. The food handling steps covering **processing and service** could include the following:

- purchase/receipt (ingredients)
- storage (frozen, chilled, ambient)
- food preparation
- cooking/assembling
- cooling
- cold storage
- frozen storage
- thawing
- portioning/vitamising
- hot holding
- reheating
- plating (cold or hot serve)
- delivery (to patients, including delivery to ward fridges or to the bedside. At this step, consideration may need to be given to implementing control measures when patients are unable to eat straight away because, for example, they are asleep or undergoing a medical procedure)
- return of leftovers/clean up.

In the case of an acute care hospital or nursing home that does not have its own food processing facilities and meals are delivered by an external provider (off-site), that hospital or nursing home would need to cover only the steps from receipt of meals through to delivery to patients and clean up. Depending on how the food is supplied and particular requirements of the residents, thawing, reheating, portioning, vitamising and so on may be included. In general, food safety programs for

food businesses that only **serve** potentially hazardous food would involve fewer steps and could include:

- food receipt
- storage (chilled, frozen)
- hot holding
- thawing/reheating
- vitamising
- plating (cold or hot serve)
- delivery (to patients)
- return of leftovers/clean up.

Activity 2

Food businesses described under Activity 2 process food off-site for service within a facility. The food handling operations of such businesses would cover all food processing steps up to transport and delivery to the facility. The food processing steps covered by the food safety program could include the following:

- purchase/receipt (ingredients)
- storage (frozen, chilled, ambient)
- food preparation
- cooking/assembling
- cooling
- portioning
- · hot holding
- · cold storage
- frozen storage
- transport
- delivery/handover
- return of containers.

Activity 3

Food businesses under Activity 3 process food for delivery by a delivered meal organisation. The food handling operations of such businesses would be similar to those described by Activity 2. There may or may not be a transport step depending on where the delivered meal organisation takes receipt of the food (for example it may pick up from the processing business).

Delivered meal organisations

Subclause 1(2) applies Standard 3.3.1 to delivered meal organisations that process ready to eat potentially hazardous food for service to more than six clients. Such a food business would undertake the food handling operations as described under Activity 2, covering all food processing steps up to delivery/handover of meals to clients of the delivered meal organisation. A delivered meal organisation that only delivers food is not required to have a food safety program but must comply with the requirements of Standard 3.2.2 Food Safety Practices and General Requirements and Standard 3.2.3 Food Premises and Equipment.

Food safety hazards and control measures

A 'hazard' is defined in Standard 3.1.1 as 'a biological, chemical or physical agent in, or condition of, food that has the potential to cause adverse health effects in humans'. Examples of microbiological, chemical and physical hazards are provided in the guide to Standard 3.2.1 as well as in the industry guides and tools (Appendix 1 in the guide to Standard 3.2.1).

Clause 3(a) of Standard 3.2.1 requires the food business to systematically examine all of its food handling operations in order to identify the potential hazards that may reasonably be expected to occur. In relation to vulnerable persons there are particular hazards (for example *Listeria monocytogenes* and enterohaemorrhagic *Escherichia coli*) that need to be given particular attention in the hazard analysis process, particularly when selecting foods that may be higher risk for these particular pathogens (discussed below under Menu design). Additionally, there may be particular processing steps, such as food vitamising and the preparation of special purpose foods (such as infant formula), where cross-contamination and temperature control issues are critical for vulnerable people and should be given specific consideration (discussed further below).

Standard 3.2.1 requires that the business's food safety program must include control measures for each hazard identified by the business for its food handling operations. Hazards that are common across food handling steps are normally controlled within support programs (for example health and hygiene program, pest control program, cleaning and sanitation program). Hazards specific to a food handling step are normally controlled by specific measures applied at that step (for example specific cooking times and temperatures).

Validation of controls

Validation is the action taken by the business to confirm that the control measures are effective in controlling the hazards (that is, they prevent, eliminate or reduce a food safety hazard to an acceptable level). Some controls are specified in legislation (such as the cooling of cooked potentially hazardous food within certain times and temperatures specified under subclause 7(3) of Standard 3.2.2 *Food Safety Practices and General Requirements*). Other controls may be specified in guides or templates. Examples of control measures applicable to the food handling steps generally involved in the processing of food for vulnerable persons (for example in hospital facilities, aged care homes and child care settings) are provided in the industry guides and tools (Appendix 3).

In many instances the business will put in place its own procedures to meet the controls required. All procedures that control food safety hazards must be validated by the business. The guide to Standard 3.2.1 provides further discussion on control measures and their validation.

Menu design

There are certain potentially hazardous foods that are not appropriate to provide to vulnerable people because of the higher risk they present for certain hazards. This means that consideration needs to be given to menu design for vulnerable people. If high risk foods are identified, the food safety program should include the control measures in place to deal with them (for example exclusion, use of alternatives and cooking).

Listeria monocytogenes

There are a number of foods that are considered higher risk for *Listeria monocytogenes*, a bacterium that can cause serious illness (listeriosis) in pregnant women, the elderly and persons whose immune

systems have been weakened by disease or illness (such as those suffering cancer, leukaemia, AIDS, diabetes, liver or kidney disease, or anyone on immune-suppressing drugs). Such foods include:

- sliced ready to eat cold meats (packaged or purchased unpackaged from delicatessen counters)
- purchased ready to eat cold cooked chicken (whole, portions or diced)
- pâté (refrigerated pâté or meat spreads)
- pre-prepared or pre-packaged salads
- raw seafoods (for example oysters, sushi)
- soft and semi-soft surface-ripened cheeses (for example brie, camembert, feta, ricotta, blue cheese)
- unpasteurised dairy products.

Safer alternatives can be incorporated into menus for vulnerable people (such as using freshly cooked meats or freshly prepared salads) and control measures implemented to reduce the risk, such as the washing or sanitising of fresh produce and storage limits (for example, keeping at 5°C or below and using within 24 hours).

Enterohaemorrhagic Escherichia coli

Enterohaemorrhagic *Escherichia coli* (EHEC) is another serious foodborne pathogen that can cause very serious illness in young children (haemolytic uraemic syndrome—HUS). There are particular foods that are considered to be of higher risk for this organism and should not be fed to young children, including:

- uncooked fermented meats, such as salami
- unpasteurised fruit juices
- unpasteurised milk
- · raw or undercooked meat.

Safer alternatives can be used (such as 'heat treated' or 'cooked' fermented meats and pasteurised juices and milks) and control measures implemented to reduce the risk such as cooking meats (particularly minced meat) thoroughly and preventing cross-contamination from raw meat. Cooking controls may include cooking to a specified internal temperature (for example 75°C) or visual examination (for example no pink juices evident).

Vitamised food

Certain vulnerable people require the texture of their food to be modified because they have difficulty in chewing and/or swallowing. For such individuals, the texture of foods is modified in a blender or vitamiser. If such equipment is not adequately cleaned and sanitised, food particles left adhering to blades and other surfaces can harbour pathogenic microorganisms and contaminate vitamised food. Where such operations are undertaken by food businesses, the food safety program needs to include appropriate procedures for cleaning and sanitising the equipment and preventing cross-contamination. For example, the cleaning and sanitising support program may include specific procedures for dismantling, cleaning and sanitising vitamisers and like equipment, including frequency (for example washing or cleaning between uses and sanitising at least daily).

Special purpose foods

Special purpose foods include infant formula products and foods for special medical purposes. They may provide the sole source of nutrition or be a specialised dietary supplement. These products are available as ready to use, commercially sterile liquid foods or as powdered formulas that need to be prepared as required. Because these products are specifically fed to vulnerable people with increased susceptibility to foodborne illness, hygienic preparation and handling of these products is essential, and the areas where they are prepared should be included in the food safety program (for example milk rooms in hospitals).

While powdered formula products undergo heat processing during their manufacture, they are not subjected to high temperatures for sufficient time to make the final packaged product commercially sterile and are subject to environmental contamination in the processing environment. Microorganisms that may be of greatest concern in these powdered products include *Bacillus cereus*, *Salmonella* and *Enterobacter sakazakii*. Young babies in particular are at risk from *Enterobacter sakazakii* infections arising from contaminated powdered formula.⁶

Where formula products are provided by the food business to vulnerable people, the food safety program needs to include appropriate control measures to minimise the growth of potential microbiological hazards and prevent contamination from equipment. Such products should be used immediately they are made up or refrigerated until needed. Made-up formula should not be kept for longer than 24 hours and any leftover product should be immediately discarded. Equipment used for infant feeding, such as bottles, teats and other utensils, should be thoroughly cleaned and sterilised before use.

3(2) Clause 6 of Standard 3.2.1 applies to a food business to which this Standard applies.

Subclause 3(2) has been included in the standard to clarify that clause 6 of Standard 3.2.1 is to apply to food businesses providing food service to vulnerable people. Clause 6 Fundraising events states:

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

Clause 6 of Standard 3.2.1 applies to any fundraising event where there is no resulting personal financial gain. An 'event' can be a regular, irregular or one-off occurrence.

A 'fundraising event' is an event that:

- intends to raise funds
- donates all funds raised solely to a community or charitable cause.

The phrase 'not for personal financial gain' emphasises that proprietors or staff of the business do not receive income or other financial reward from the funds raised at the event, as all the funds are donated to the community or charitable cause.

To qualify for an exemption under this clause, two criteria need to be met.

The World Health Organization has developed a guideline document to address such hazards as *E. sakazakii* in powdered infant formula. It includes guidance and recommendations for care settings such as hospitals and day care: FAO/WHO, 2007, *Safe preparation, storage and handling of powdered infant formula: guidelines.* This guideline is available on the web, <www.who.int/foodsafety/publications/micro/pif_guidelines.pdf>.

- 3.3.1
- The purpose of having the event must be to raise money for community or charitable causes. The event must be a fundraising event for a community or charitable cause. Examples of raising money for a community cause could be moneys raised for schools, child care facilities, sports groups and religious institutions. A charitable cause would be the raising of money for needy persons in the community such as for the sick, people with disabilities, the homeless or other persons who are underprivileged.
- 2 All the funds raised at the event must be used for a community or charitable cause and there must be no personal financial gain made from the running of the event. All the money raised must be used for a community or charitable cause. However, the costs of running the event can be taken from the moneys raised, provided there is no personal financial gain.

It is important to note that even though food businesses to which Standard 3.2.1 applies may not be required to prepare a food safety program for a fundraising event, they are required by the standard to have a food safety program for the service or processing of food for vulnerable people. The business may choose to include the food handling activities involved in preparing food for a fundraising event in its food safety program but it is not required to.

Example

A nursing home conducts an annual fete at which it operates a sausage sizzle and devonshire tea stand. All the proceeds of the fete contribute to the operation of a community bus service for elderly residents in the area. The nursing home processes and serves potentially hazardous food to its residents (30 elderly people) and is required to have a food safety program under Standard 3.2.1. It is not required, however, to have a food safety program for its food handling activities at the annual fete (a fundraising event).

Schedule

The Schedule table in Standard 3.3.1 lists and defines the facilities caring for vulnerable people.

Acute care hospitals

Facility	Definition
Acute care hospitals	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:
	(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.

Acute care hospitals provide diagnosis, medical care and surgery for serious and/or life threatening conditions. Patients are usually admitted to hospital and stay for brief periods of time, receiving around-the-clock health care provided by a variety of clinical personnel. The length of stay can vary according to the level and extensiveness of the treatment required. Meals are provided to the patients in care.

The definition makes reference to four types of acute care hospitals based on how they are funded (for example private, public, veterans) or whether the hospital provides specialised services (for example dental or ophthalmic). The funding base or particular services provided do not affect the application of Standard 3.3.1.

Patients in acute care hospitals are considered to be vulnerable persons according to the definition in the standard. Food businesses serving or processing food (as described under Activity 1 and Activity 2) for service to six or more patients in an acute care hospital will need to develop, implement and regularly monitor a food safety program in compliance with Standard 3.2.1.

Psychiatric hospitals

Facility	Definition	
Psychiatric hospitals	Establishments devoted primarily to the treatment and care of inpatients with psychiatric, mental or behavioural disorders including any:	
	(a) Public psychiatric hospital;(b) Private psychiatric hospital.	

Psychiatric hospitals or wards specialise in treating people experiencing a range of different mental illnesses, including depression, psychoses such as schizophrenia, anxiety and eating disorders. Psychiatric hospitals or wards may be part of a larger hospital or located in a separate dwelling. Commonly, admission is for a short duration (that is, a few days). However, this depends on the nature of the illness and the treatment. Food is generally provided to the patients in care.

The definition of psychiatric hospitals refers to both public and private facilities. The distinction between the two simply reflects how they are funded and does not affect the application of Standard 3.3.1.

Patients in psychiatric hospitals, wards or clinics are considered to be vulnerable persons according to the definition in the standard. Food businesses that serve or process food (as described under Activity 1 and Activity 2) for service to six or more patients in a psychiatric hospital at any given time will need to develop, implement and regularly monitor a food safety program in compliance with Standard 3.2.1.

Nursing homes for the aged

Facility	Definition	
Nursing homes for the aged	Establishments which provide long-term care involving regular basic nursing care to aged persons and including any:	
	(a) Private charitable nursing home for the aged;	
	(b) Private profit nursing home for the aged;	
	(c) Government nursing home for the aged.	

Nursing homes for the aged (residential aged care homes) include high level care facilities that provide 24-hour care. Nursing care is combined with accommodation, support services (cleaning, laundry and meals), personal care services (help with dressing, eating, toileting, bathing and moving around) and allied health services (such as physiotherapy, occupational therapy, recreational therapy and podiatry). Food is always provided and prepared by someone other than the resident in these facilities.

The definition of nursing homes makes reference to government and privately funded homes, including religious and charitable homes. How these facilities are funded does not affect the application of Standard 3.3.1.

Residents of nursing homes for the aged are considered to be vulnerable persons according to the definition in the standard. Food businesses that serve or process food (as described under Activity 1

and Activity 2) for service to six or more patients in a nursing home at any given time will need to develop, implement and regularly monitor a food safety program in compliance with Standard 3.2.1.

Hospices

Facility	Definition
Hospices	Freestanding establishments providing palliative care to terminally ill patients, including any:
	(a) Public hospice
	(b) Private hospice.

Hospices provide medical care and support services to terminally ill people. While hospice care can be provided at home or in hospitals, the definition in the standard refers to freestanding facilities only. Hospice care includes treatment from doctors, nurses, therapists, dietitians, social workers, clergy, volunteers and others. Food is provided to patients in care.

As for other facilities, the definition of hospice makes reference to public (government) and private hospices. The requirements of Standard 3.3.1 apply to hospices regardless of their funding basis.

Residents of hospices are considered to be vulnerable persons according to the definition in the standard. Food businesses that serve or process food (as described under Activity 1 and Activity 2) for service for six or more patients in a hospice at any given time will need to develop, implement and regularly monitor a food safety program in compliance with Standard 3.2.1.

Same-day establishments for chemotherapy and renal dialysis services

Facility	Definition
Same day establishments for chemotherapy and renal dialysis services	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: (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.
	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. Freestanding day surgery centres are hospital facilities providing investigation and treatment for acute conditions on a day-only basis.

Chemotherapy and renal dialysis services are typically conducted in dedicated facilities in a hospital, a clinic or a freestanding centre. Patients attend these facilities on a daily basis (for chemotherapy) or several times per week (for dialysis) for the course of their treatment. Depending on the treatment being provided, treatment sessions may require part-day or full-day care but are not residential. Food may be provided to clients during their attendance at these centres.

The definition refers to both public and private chemotherapy and renal dialysis facilities. The requirements of Standard 3.3.1 apply to these establishments regardless of their funding basis.

Persons receiving treatment within a facility that provides chemotherapy or renal dialysis services are considered to be vulnerable persons under the definition in the standard. Food businesses that serve or process food (as described under Activity 1 and Activity 2) for service for six or more patients at any given time in a same-day establishment for chemotherapy or renal dialysis will need to develop, implement and regularly monitor a food safety program in compliance with Standard 3.2.1.

Respite care establishments for the aged

Facility	Definition
Respite care establishments for the aged	Establishments which provide short-term care including personal care and regular basic nursing care to aged persons.

Short-term respite care for the aged provides the nursing and personal care (help with dressing, eating, toileting, bathing and moving around) that elderly person would normally receive from their carer. Three forms of respite care are generally available:

- home-based care (ranges from a few hours a week to overnight care)
- centre-based day respite care (full- or half-day care)
- residential respite care (for two or three weeks).

The schedule refers to respite care establishments, covering **centre-based** and **residential** facilities. The service provided by these facilities generally includes the provision of meals.

Persons receiving care in a respite care establishment for the aged are considered to be vulnerable persons under the definition in the standard. Food businesses that serve or process food (as described under Activity 1 and Activity 2) for service for six or more persons at any given time in such an establishment will need to develop, implement and regularly monitor a food safety program in compliance with Standard 3.2.1.

Same-day aged care establishments

Facility	Definition
Same-day aged care establishments	Establishments where aged persons attend for day or part- day rehabilitative or therapeutic treatment.

Same-day aged care establishments are generally referred to as day therapy centres. These centres offer a range of rehabilitation and therapeutic treatments including physiotherapy, occupational

therapy, speech therapy, hydrotherapy and podiatry. The treatments aim to help people either maintain or recover a level of independence that will allow them to remain in the community or in low level residential care. Food may be provided to clients during their attendance at these centres.

Some aged care services are established to provide social activities such as games (bingo), arts and crafts, education programs and general fitness programs. The facilities providing such activities are not providing rehabilitative or therapeutic treatment and as such are not captured by Standard 3.3.1.

Persons receiving treatment in a same-day aged care establishment (day therapy centre) are considered to be vulnerable persons under the definition in the standard. Food businesses that serve or process food (as described under Activity 1 and Activity 2) for service for six or more persons at any given time in such an establishment will need to develop, implement and regularly monitor a food safety program in compliance with Standard 3.2.1.

Low care aged care establishments

Facility	Definition
Low care aged care establishments	Establishments where aged persons live independently but on-call assistance, including the provision of meals, is provided if needed.

Low care aged care establishments are residential aged care homes that provide accommodation, support services (cleaning, laundry and meals), personal care services (help with dressing, eating, toileting, bathing and moving around) and may provide or have access to some allied health services. Nursing care is provided as required. Most facilities have nurses on staff or at least have access to them. Depending on the residents' level of independence, they may prepare their own meals or be provided with meals by the facility. The provision of meals may be through delivery to the room or through dining facilities, including restaurant or café-style facilities located on-site.

Residents of low care aged care establishments are considered to be vulnerable persons under the definition in the standard. Where meals are provided by the establishment and where the food business is serving or processing the food (as described under Activity 1 and Activity 2) for service for six or more persons at any given time, the establishment will need to develop and implement a food safety program in compliance with Standard 3.2.1.

Child care centres

Facility	Definition	
Child care centres	A facility which is not a private residential dwelling and is designated for the purpose of child care and provides long day care, employer sponsored child care, or occasional care, for children four years of age or less, but does not include the following:	
	(a) a service for providing preschool education conducted by a school;	

Continued

- (b) a service principally conducted to provide:
 - (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.

The definition of child care centres covers facilities which provide:

- long day care
- employer-sponsored child care
- occasional care

for children from birth to four years of age (that is, four years of age or less). Child care centres do not include private residential dwellings, exempting family day care from the requirements of the standard. Out of school hours or after school care, which caters for school-aged children (five years and older) is also excluded from the standard.

Long day care may be privately operated, sponsored by a community organisation, church or local government, or work-based for employees (employer-sponsored child care). They generally open 8 to 12 hours per day, five days per week and enrol children for fixed days (for example two, three or five days per week). Occasional care facilities may also be privately operated or sponsored by a community organisation, church or local government but they have variable hours of operation. Some occasional care facilities may enrol children for one hour onwards; others may enrol children for half or full days using a booking system.

Children in care in either long day care (including employer-sponsored child care) or occasional care centres are considered vulnerable persons under the definition of the standard. Regardless of the system of operation, where such centres provide food (ready to eat potentially hazardous food) to the children as part of the service provided, a food safety program is required. Food businesses that serve or process food (as described under Activity 1 and Activity 2) for service for six or more children at any given time in such an establishment will need to develop, implement and regularly monitor a food safety program in compliance with Standard 3.2.1.

The definition of child care centres also includes a number of exemptions for services that are not intended to be captured under the standard. These are discussed below.

(a) a service for providing preschool education conducted by a school;

Preschools generally enrol children from three to under six years of age, though some may be licensed to take younger children (for example from two years). Where such services are attached to a school they are explicitly exempt from consideration as a child care centre.

Preschools that operate independently of a school may be captured by the standard where they:

provide child care

Long day care or occasional care centres may also provide a preschool education program. In some jurisdictions, businesses may be licensed as preschools but also provide child care services. Irrespective of the education program, if the facility is **designated for the purpose of child care** then it fulfils the definition of a child care centre in the schedule. If its sole purpose is the provision of preschool education it is not covered by the definition.

are a food business

Children attending preschools generally take their own food (for example boxed lunch) if required. Fruit and a drink may be provided but, in general, the preschool is not 'selling' food and is not considered a food business. Preschools that provide meals (ready to eat potentially hazardous food) as part of their service delivery are food businesses. If these preschools are designated for the purpose of child care, for example they notify (in accordance with clause (4)(1)(b) of Standard 3.2.2) that the nature of their business includes child care, then they should be captured by the standard.

- (b) a service principally conducted to provide:
 - (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;

Parents may enrol their young children in a variety of programs or services that operate weekly for one to several hours and provide, for example, music appreciation, sports activities, literacy development and religious education, or therapeutic services such as coordination development or speech therapy. Additionally, some businesses may operate to provide recreational activities such as children's parties or holiday camps. Children attending these facilities may be in care of the service provider while in attendance, but are not considered to be in child care. Such facilities are principally conducting other services (for example music education) and are specifically excluded from the definition of child care centres.

(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.

Shopping centres, holiday resorts, swimming pools, clubs and so on may provide occasional child care services for clients or patrons using their facilities. The use of these services by parents may be one-off or infrequent occurrences and bookings may not be required. Such child care facilities are specifically excluded from the definition of child care centres.

Appendix 1

Standard 3.2.1

Food Safety Programs

(Australia only)

Purpose

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

Contents

Division 1 — Interpretation and application

- 1 Interpretation
- 2 Application

Division 2 — Food safety programs

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

Division 1 — Interpretation and application

1 Interpretation

In this Standard -

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

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

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

Editorial note:

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

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

2 Application of this Standard

- (1) This Standard applies to food businesses in Australia in accordance with Standard 3.1.1 and subclause (2).
- (2) This Standard applies to all food businesses that are determined by the appropriate enforcement agency under the Act to be within a priority classification of food business from the commencement date for that priority classification of food business.

Replacement subclause 2(2) to commence on 26 May 2006

(2) Unless expressly provided elsewhere in this Code, this Standard applies to all food and primary food production businesses that are determined by the appropriate enforcement agency under the Act to be within a priority classification of food business from the commencement date for that priority classification of food business.

Editorial note:

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

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

Division 2 — Food safety programs

3 General food safety program requirements

A food business must:

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

- (d) comply with the food safety program; and
- (e) conduct a review of the food safety program at least annually to ensure its adequacy.

4 **Auditing of food safety programs**

A food business must:

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

Editorial note:

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

5 **Content of food safety programs**

A food safety program must:

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

6 Fund raising events

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

Appendix 2

Further examples illustrating the application (or not) of subclause 1(1) to food businesses

Example	Food safety program requirement	Rationale	
On-site cottages are located in hospital grounds. Patients go into the cottages after they receive treatment to help them readjust to normal life before going home. Patients prepare and serve their own meals.	No Standard 3.3.1 does not apply to the cottages.	Food processing and service is not undertaken by a food business—these activities are conducted by the patients. Food for processing may be provided by the hospital services (for example ingredients) but unless it is: • ready to eat, including ready to eat potentially hazardous food • for six or more vulnerable persons at any one time its provision is not described by any of the activities listed in the table.	
A café has an agreement with a same-day aged care establishment whereby clients get a discount on meals. The client buys a voucher from the establishment for use with a meal purchase at the café. The café then charges the establishment for the vouchers redeemed.	No Standard 3.3.1 does not apply to the café.	The principal activity of the café is not processing ready to eat potentially hazardous food for service in a listed facility. Café or restaurant establishments that provide food service to the general community may have arrangements with identified facilities where clients can regularly purchase meals. However, unless the principal activity of such a business is to process or serve ready to eat food for service within that facility, it is not captured by Standard 3.3.1.	

Example	Food safety program requirement	Rationale	
A retirement village with all self-care units (the provision of meals, if needed, is not provided as part of the retirement village's service) runs about 20 functions per year (for example a barbecue every fortnight) for residents of the village.	No Standard 3.3.1 does not apply to the retirement village.	Unless the retirement village provides a level of care (for example is a low care aged care establishment) it is not an identified facility under the standard. The functions run do not constitute a provision of meals. A food safety program would not be required for the functions provided. A retirement village where a low level of care is provided may include the provision of meals to some residents if needed. In such a case the facility would be captured by the standard under Activity 1 if it processes or serves potentially hazardous food to six or more vulnerable persons at any given time.	
A home for developmentally disabled children (aged 0–25 years) provides meals for clients in its care.	No Standard 3.3.1 does not apply to the home.	The home is not an identified facility in the Schedule to Standard 3.3.1.	

Appendix 3

Food safety program tools

Australian Government Department of Health and Ageing

For copies of the tools listed below contact the Australian Government Department of Health and Ageing; phone: 02 6289 5131; email: foodsafety@health.gov.au

Tool for the development of a food safety program for delivered meals organisations

Tool for the development of a food safety program for children's services operations

Tool for the development of a food safety program for commercial food service establishments

Tool for the development of a food safety program for aged care homes

Tool for the development of a food safety program for small to medium hospitals

New South Wales

Industry guide to developing a food safety program (hospitals and aged care): NSW Food Authority, PO Box 6682, Silverwater, NSW 1811; phone: 1300 552 406; website: www.foodauthority.nsw.gov.au

South Australia

Food safety program template for hospitals

Food safety program template for aged care facilities

Food safety program template for child care centres

Government of South Australia, Department of Health, PO Box 6 Rundle Mall, Adelaide, SA 5000; phone: 08 8226 7100; website: www.dh.sa.gov.au/pehs/Food/food-safety-programs.htm

Victoria

Food Safety Program Template for Retail and Food Service Businesses

FoodSmart (interactive web-based food safety program template for retail and food services businesses): Government of Victoria, Department of Human Services, GPO Box 1670N, Melbourne, Vic. 3000; phone: 1300 364 352; website: www.health.vic.gov.au/foodsafety/

Western Australia

Templates for hospitals and aged care (interactive web-based food safety program template)

Food safety guide for small hospitals (< 6 clients)

Government of Western Australia, Department of Health, Environmental Health Services, PO Box 8172, Perth Business Centre, WA 6849; phone: 08 9388 4999; website: www.health.wa.gov.au/health_services/e/environmental.cfm

Glossary of terms

Following is a glossary of terms that are legally defined within Standard 3.1.1 *Interpretation and Application* and Standard 3.2.1 *Food Safety Programs* that are of relevance to this standard.

appropriate enforcement agency

An enforcement agency prescribed by the regulations under the Act for the purposes of enforcement of the Act or similar purposes. (Standard 3.1.1)

auditing frequency

The most recently determined frequency of auditing determined by the appropriate enforcement agency, or a food safety auditor, in accordance with the Act. (Standard 3.2.1)

authorised officer

a person authorised or appointed under the Act or other legislation for the purposes of enforcement of the Act, or similar purposes, such as an 'authorised officer', 'environmental health officer' or 'inspector'. (Standard 3.1.1)

contaminant

any biological or chemical agent, foreign matter, or other substances that may compromise food safety or suitability. (Standard 3.1.1)

contamination

the introduction or occurrence of a contaminant in food. (Standard 3.1.1)

food business

a business, enterprise or activity (other than primary food production) that involves –

- (a) the handling of food intended for sale; or
- (b) the sale of food;

regardless of whether the business, enterprise or activity concerned is of a commercial, charitable or community nature or whether it involves the handling or sale of food on one occasion only. (Standard 3.1.1)

food handler

a person who directly engages in the handling of food, or who handles surfaces likely to come into contact with food, for a food business. (Standard 3.1.1)

food handling operation

any activity involving the handling of food. (Standard 3.1.1)

food premises

any premises including land, vehicles, parts of structures, tents, stalls and other temporary structures, boats, pontoons and any other place declared by the relevant authority to be premises under the food Act kept or used for the handling of food for sale, regardless of whether those premises are owned by the proprietor, including premises used principally as a private dwelling, but does not mean food vending machines or vehicles used only to transport food. (Standard 3.1.1)

food safety auditor

a person approved as a food safety auditor under the Act as a person competent to audit the relevant class of food business. Jurisdictions may approve environmental health officers, private contractors, or a mixture of the two as food safety auditors. (Standard 3.2.1)

food safety program

a food safety program that satisfies the requirements of clause 5. (Standard 3.2.1)

food safety standards

the standards contained in Chapter 3 of the *Australia New Zealand Food Standards Code*. (Standard 3.1.1)

handling of food

includes the making, manufacturing, producing, collecting, extracting, processing, storing, transporting, delivering, preparing, treating, preserving, packing, cooking, thawing, serving or displaying of food. (Standard 3.1.1)

hazard

a biological, chemical or physical agent in, or condition of, food that has the potential to cause an adverse health effect in humans. (Standard 3.1.1)

milk

includes flavoured and modified milk. (Standard 3.3.1)

monitoring

includes checking, observing or supervising in order to maintain control. (Standard 3.2.1)

proprietor of a food business

the person carrying on the food business, or if that person cannot be identified – the person in charge of the food business. (Standard 3.1.1)

ready to eat

in relation to food means food that is ready for consumption, but includes food that may be reheated, portioned or garnished or food that undergoes similar finishing prior to service. (Standard 3.3.1)

sell

- (a) barter, offer or attempt to sell; or
- (b) receive for sale; or
- (c) have in possession for sale; or
- (d) display for sale; or
- (e) cause or permit to be sold or offered for sale; or
- (f) send, forward or deliver for sale; or
- (g) dispose of by any method for valuable consideration; or
- (h) dispose of to an agent for sale on consignment; or
- (i) provide under a contract of service; or

- (j) supply food as a meal or part of a meal to an employee, in accordance with a term of an
 award governing the employment of the employee or a term of the employee's contract of
 service, for consumption by the employee at the employee's place of work;
- (k) dispose of by way of raffle, lottery or other game of chance; or
- (l) offer as a prize or reward; or
- (m) give away for the purpose of advertisement or in furtherance of trade or business; or
- (n) supply food under a contract (whether or not the contract is made with the consumer of the food), together with accommodation, service or entertainment, in consideration of an inclusive charge for the food supplied and the accommodation, service or entertainment; or
- (o) supply food (whether or not for consideration) in the course of providing services to patients or inmates in public institutions, where 'public institution' means 'public institution' as defined in the Act, if it is so defined, or
- (p) sell for the purpose of resale. (Standard 3.1.1)

vulnerable person

means a person who is in care in a facility listed in the Schedule or a client of a delivered meals organisation. (Standard 3.3.1)



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