

4-05 25 May 2005

DRAFT ASSESSMENT REPORT

PROPOSAL P289

FOOD SAFETY PROGRAMS FOR THE PRODUCERS OF MANUFACTURED & FERMENTED MEATS

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 20 July 2005
SUBMISSIONS RECEIVED AFTER THIS DEADLINE
WILL NOT BE CONSIDERED

(See 'Invitation for Public Submissions' for details)

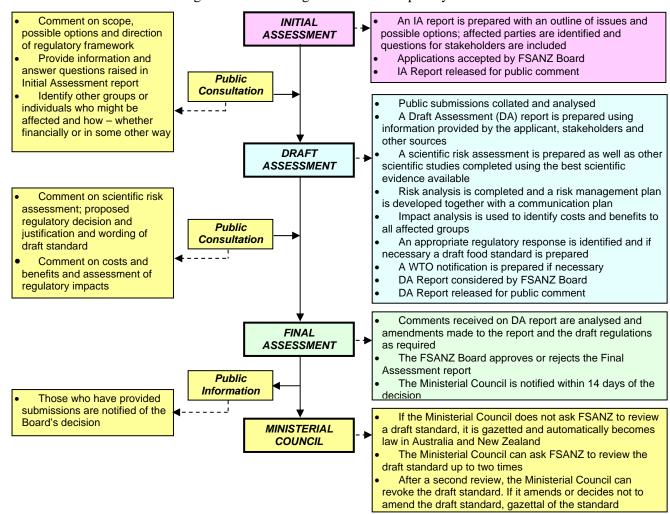
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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

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

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

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



INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared a Draft Assessment Report of Proposal P289; and prepared a draft variation to the *Australia New Zealand Food Standards Code* (the Code).

FSANZ invites public comment on this Draft Assessment Report based on regulation impact principles and the draft variation to the Code for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the Final Assessment for this Proposal. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires FSANZ to treat inconfidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand PO Box 7186 Canberra BC ACT 2610 AUSTRALIA Tel (02) 6271 2222 www.foodstandards.gov.au

Food Standards Australia New Zealand PO Box 10559 The Terrace WELLINGTON 6036 NEW ZEALAND Tel (04) 473 9942 www.foodstandards.govt.nz

Submissions need to be <u>received</u> by FSANZ <u>by 6pm (Canberra time) 20 July 2005</u>.

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

While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Management Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au.

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Executive Summary and Statement of Reasons

In response to a decision of the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) FSANZ is proposing to mandate food safety management systems for producers of manufactured and fermented meats.

The proposed Standard will apply in Australia only. New Zealand has its own legislation in regard to the application of food safety programs and food safety standards are outside the terms of the *Trans Tasman Mutual Recognition Agreement* (TTMRA).

FSANZ established an advisory group in May 2004, consisting of consumer, industry and government representatives, to provide an insight into the current operations of the industry and the role of existing food safety regulations. This group assisted FSANZ in resolving the scope and proposed requirements for businesses covered under the proposed standard.

In accordance with the Ministerial Policy Guidelines¹ the proposed Standard 4.2.3 Primary Production and Processing Standard for Meat (Division 3 – Production of manufactured and fermented meat) and Standard 4.2.2 – Primary Production and Processing Standard for Poultry Meat (Division 3 – Production of manufactured poultry meat) requires producers of manufactured and fermented meats to systematically examine and document all of their operations including identifying food safety hazards and controls, and compliance with specific requirements in a documented food safety management system.

The proposed definition of producers of manufactured and fermented meats is:

Businesses involved in the making, manufacturing, producing, extracting, processing, preparing, treating, preserving, packing, cooking, thawing and/or handling² of readyto-eat meats (product is intended to be consumed without further heating or cooking). Ready-to-meats include:

- *fermented meats (cooked or uncooked);*
- pâtés:
- *dried meat / slow cured meat;*
- *luncheon meat (e.g. devon, pressed chicken) whether whole or not;*
- cooked muscle meat (e.g. ham, roast beef) whether whole or not;
- ready-to-eat meats that have been handled (as defined) after manufacture; and
- ready- to-eat meats that can allow the growth of a pathogen or toxin production.

The definition also includes businesses that dice, shave, slice ready-to-eat meats and pack them in a modified atmosphere package for retail sale.

An Initial Assessment Report was available for public comment for eight weeks in May-June 2004. A total of thirteen submissions were received in response to the Initial Assessment Report and are addressed in this Draft Assessment Report.

Two regulatory options are identified in this Report:

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¹ The Ministerial Policy Guidelines on *Food Safety Management in Australia: Food Safety Programs* can be viewed at www.foodsecretariat.health.gov.au/pdf/food_safety.pdf

² Handling: slicing, shaving, dicing and/or repackaging.

- Option 1 maintain the *status quo* and not adopt Standard 4.2.3 Primary Production and Processing Standard for Meat (Division 3 Production of manufactured and fermented meat) and Standard 4.2.2 Primary Production and Processing Standard for Poultry Meat (Division 3 Production of manufactured poultry meat) to apply a food safety management system to producers of manufactured and fermented meats; or
- Option 2 Adopt Standard 4.2.3 Primary Production and Processing Standard for Meat (Division 3 – Production of manufactured and fermented meat) and Standard 4.2.2 – Primary Production and Processing Standard for Poultry Meat (Division 3 – Production of manufactured poultry meat) to mandate a documented food safety management system for producers of manufactured and fermented meats.

In order to implement the Ministerial Policy Guidelines, Option 2 is the only acceptable outcome. The draft proposed Standard 4.2.3 – Primary Production and Processing Standard for Meat (Division 3 – Production of manufactured and fermented meat) and Standard 4.2.2 – Primary Production and Processing Standard for Poultry Meat (Division 3 – Production of manufactured poultry meat) are provided at Attachment 1.

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

Statement of Reasons

At Draft Assessment, FSANZ recommends that the *Australia New Zealand Food Standards Code* (the Code) be amended to mandate food safety management systems for producers of manufactured and fermented meats for the following reasons:

- The National Risk Validation Project concluded that the production of manufactured and fermented meats was a potentially high risk sector.
- The proposed variations to the Code are consistent with the section 10 objectives of the FSANZ Act to reduce the incidence of food-borne illness in Australia due to manufactured and fermented meat consumption, via a nationally consistent approach that requires producers of manufactured and fermented meats to have a documented food safety management system.
- The proposed variations to the Code provide a preventative approach to food safety management that allows enforcement agencies to establish compliance with the system through audit processes.
- The Allen Report on the costs and efficacy of introducing food safety programs concludes that the benefits for high risk businesses outweigh the costs of implementing, utilising and auditing a food safety management system.

1. Introduction

FSANZ has raised Proposal P289 to amend the Code to mandate the requirements of Standard 3.2.1 – Food Safety Programs for producers of manufactured and fermented meats.

The proposed Standard will apply in Australia only. New Zealand has its own legislation in regard to the application of food safety programs and food safety standards are outside the terms of the *Trans Tasman Mutual Recognition Agreement* (TTMRA). Under the TTMRA product produced in New Zealand or imported through New Zealand is exempt from compliance with Standard 3.2.1 and therefore this Proposal will not affect food businesses or consumers in New Zealand.

FSANZ established an advisory group in May 2004 consisting of consumer, industry and government representatives. The advisory group has provided FSANZ with an insight into the current operations of the industry and the role of existing food safety regulations, and resolved the scope and proposed requirements for businesses covered under the proposed standard.

The Initial Assessment Report, released for public comment from 26 May 2004 until 21 July 2004, summarised our current state of knowledge of the manufactured and fermented meat sectors, with a particular focus on existing food safety regulations and industry and government guidelines and codes of practice initiatives to improve food safety, and sought further information and comment from stakeholders on a broad range of issues. The purpose of this Draft Assessment Report is to inform industry, governments, consumers and other stakeholders of the results of the initial public consultation and provide further detail on the Proposal including the proposed draft amendments to the Code. This Report provides the next formal opportunity for stakeholders to comment on this Proposal and the draft standard.

2. Regulatory Problem

The Food Regulation Standing Committee (FRSC) established a policy committee in 2002 to develop options for food safety management in Australia. The aim of the policy committee was to seek an 'all of government' position on managing food safety risks in Australia. On 12 December 2003, the Ministerial Council approved the Ministerial Policy Guidelines on *Food Safety Management in Australia: Food Safety Programs*³ for national application. These guidelines include overarching principles and recommendations on which food business sectors should develop and implement mandatory food safety programs.

The Ministerial Policy Guidelines specify five overarching principles to apply when addressing particular policy issues of food safety management in Australia:

- 1. That regulations covering food safety management in Australia be based on risk, where the level of legislative requirements and their verification is commensurate with the level of risk.
- 2. That risk profiling be used to classify food businesses or food industry sectors in Australia on the basis of risk.

³ The Ministerial Policy Guidelines on *Food Safety Management in Australia: Food Safety Programs* can be viewed at www.foodsecretariat.health.gov.au/pdf/food_safety.pdf

- 3. At a minimum, Food Safety Standard 3.2.1 should be implemented in those businesses/sectors involved in operations identified as high risk **and** where the benefit to cost ratio justifies the implementation of food safety programs.
- 4. That the risk classification of a business or an industry sector may change when new data on the causes and incidence of food-borne illness become available for updating the risk profile, or when the specific circumstances of an individual business can be considered and such change is justified.
- 5. That support is made available to community groups and small businesses to assist them meet their legislative requirements.

Data from OzFoodNet, findings from the Food Safety Management Systems – Costs, Benefits *and Alternatives* report and the National Risk Validation Project⁴, provided a strong case for the producers of manufactured and fermented meats to introduce food safety programs. Consistent with the concept of basing food safety requirements commensurate to the risk based evidence, the Ministerial Council recommended that Standard 3.2.1 be a mandatory requirement for the producers of manufactured and fermented meats.

3. Objective

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 10 of the FSANZ Act. These are:

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

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

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

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⁴ The National Risk Validation Project was undertaken in 2001 to, in Part 1, identify potentially high risk food industry sectors and to use risk assessment principles to validate the categorisation of selected sectors as high risk. Part 2 of the project had two objectives; to determine the potential cost to the food industry, public and Government of food-borne illness associated with high risk businesses and to determine the costs and benefits of implementing food safety programs in high risk food industry sectors.

The specific objective of this Proposal is to reduce the incidence of food-borne illness in Australia due to manufactured and fermented meat consumption, via a nationally consistent approach that requires producers of manufactured and fermented meats to have a documented food safety management system.

4. Background

4.1 Scientific Assessment

The National Risk Validation Project identified potentially high risk food businesses through a review of both Australian and overseas data on food-borne disease outbreaks and examined the factors contributing to these outbreaks.

Although the term 'manufactured meat' was not specifically defined in the National Risk Validation Project, the product categories investigated comprised smallgoods (including fermented meats).

Eight outbreaks of food-borne illness relating to manufactured meats were identified from the Australian outbreak data over the period 1990 - 2001, and a more detailed case study was examined for one of the outbreaks, which was associated with uncooked comminuted fermented meat (UCFM)⁵.

The National Risk Validation Project concluded that the production of manufactured and fermented meats was a potentially high risk sector.

4.2 The Requirements of Standard 3.2.1 – Food Safety Programs

Standard 3.2.1 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.

A food safety program is a documented food safety management system. It is defined by Standard 3.2.1 as a written document which:

- (a) systematically identifies the potential hazards that may be reasonably expected to occur in all food handling operations of the food business;
- (b) identifies where, in a food handling operation, each hazard identified under paragraph (a) can be controlled and the means of control;
- (c) provides for the systematic monitoring of those controls;
- (d) provides for appropriate corrective action when that hazard, or each of those hazards, is found not to be under control:

⁵ Typical UCFM includes various types of salami, summer sausage and mettwurst. As indicated by its name, production of UCFM involves no cooking step. Microbiological pathogens in the raw meat ingredients, such as enterohaemorrhagic *Escherichia coli*, *Salmonella* species and *Listeria monocytogenes* are killed by the fermentation, maturation/drying steps employed in UCFM production.

- (e) provides for the regular review of the program by the food business to ensure its adequacy; and
- (f) provides for appropriate records to be made and kept by the food business demonstrating action in relation to, or in compliances with, the food safety program.

The amount and type of information needed in a food business' food safety program will depend on the type and complexity of the food business, as well as the hazards being addressed. In a food safety program, the business is also demonstrating how it is complying with Standard 3.2.2 - Food Safety Practices and General Requirements and Standard 3.2.3 - Premises and Equipment.

4.3 Existing Food Safety Management Practices in the Manufactured and Fermented Meat Industry

Food safety within the manufactured and fermented meat sector is currently regulated through a combination of State/Territory regulations and voluntary industry guidelines and codes of practice.

4.3.1 Regulatory Measures

4.3.1.1 Australia New Zealand Food Standards Code

Some aspects of the manufactured and fermented meat supply chain are covered by Chapters 1, 2 and 3 of the Code. These general standards apply to all food, including manufactured and fermented meat products, sold or traded at retail or wholesale level in Australia. Such general standards include labelling requirements and compositional standards. The labelling requirements in Chapter 1 provide general product information such as food identification, date markings, nutrition information panels and directions for use and storage. Additional labelling requirements for comminuted fermented meat products are included in Chapter 2 – Product Standards of the Code.

The compositional standards in Chapter 1 define the additives, vitamins, minerals and processing aids permitted to be added to food products, as well as defining chemical and microbiological limits for manufactured and fermented meat products.

The Food Safety Standards in Chapter 3 of the Code set out the general food safety requirements for food premises, equipment and for handling practices that food businesses and food handlers must follow to provide a safe and hygienic food product.

FSANZ recently completed a review of processing requirements for UCFM products and revised the relevant standards in the Code to include a mandatory requirement for developing and implementing food safety programs for the production of UCFM, through reference to Standard 3.2.1. The revised clause 9 of Standard 1.6.2, gazetted on 18 September 2003, requires a UCFM product to be produced in accordance with a food safety program, which has been validated by the producer. This standard also identifies specific steps in the production process, which must be monitored and recorded at suitable frequencies (Attachment 2).

These steps were identified through a risk assessment process which analysed potential hazards in the production process. For producers of UCFM, requirements under Standard 3.2.1 are already adequately included. However UCFM are only one type of product within the scope of manufactured and fermented meats.

4.3.1.2 State/Territory Government regulations

Current State and Territory meat regulation specific to food safety covers the slaughter of meat animals and the processing, transport, and retail (including food service) of manufactured and fermented meat products. Jurisdictions require the licensing and/or accreditation of manufactured meat processing plants and mandate compliance with the *Australian Standard for the Hygienic Production and Transportation of Meat and Meat Products for Human Consumption [AS 4696:2002* (the Australian Standard)]⁶. This includes a requirement for a documented food safety management system.

The current requirements of the Australian Standard (AS 4696:2002) control food safety by requiring an approved arrangement.

The proprietor of a meat business must have an 'approved arrangement' based on management and production practices and the implementation of a HACCP plan that:

- (a) covers each stage of the production of all meat and meat products produced by the business at the premises at which the meat and meat products are produced; and
- (b) contains controls that ensure that meat and meat products for human consumption do not leave the premises unless they are wholesome and accurately identified in accordance with this Standard; and
- (c) contains controls that ensure that meat and meat products unfit for human consumption and meat and meat products not intended for human consumption are removed from the food chain and dealt with separately from meat and meat products for human consumption; and
- (d) specifies how each of the matters specified in this Standard that apply in relation to the operations for the production undertaken at the premises will be met by the proprietor; and
- (e) provides for the implementation of a HACCP Plan for each stage of the production at the premises (details at Attachment 3).

Jurisdictions also mandate compliance with the Standard 1.6.1 of the Code, which defines the microbiological limits for specific commodities and Clause 9 of Standard 1.6.2 for the production of UCFM products.

4.3.1.3 Manufactured meat import and export regulations

The Australian Quarantine and Inspection Service (AQIS) has regulatory responsibility for the monitoring of imported food. Imported manufactured and fermented meat products and their ingredients must meet the requirements of the Code. Exported manufactured and fermented meat products and their ingredients must also meet specific requirements of the importing countries.

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⁶ Available at the Standards Australia website: http://www.standards.com.au/catalogue/script/search.asp

4.3.2 Voluntary industry food safety management strategies

There are a limited number of guidelines specific to manufactured meats for the industry to use. These guidelines provide comprehensive assistance that enable producers to use practises and procedures that ensure the manufacture of safe products.

The most recent of these guidelines, produced by Meat and Livestock Australia (MLA), and titled 'Guidelines for the Safe manufacture of Smallgoods' provides a valuable resource for assisting businesses to achieve the outcome of this Proposal. This guideline describes HACCP plans, Good Manufacturing Practices (GMP) and Standard Sanitation Operating Procedures (SSOPs) for UCFM, cooked fermented meats (CFM), salami-like sausages, fresh sausage, cured/cooked products, bacon, sliced smallgoods, slow cured meats, dried meats such as jerky, pate and roast meats. These guidelines are designed to minimise microbial and chemical contamination of manufactured and fermented meat products. They also draw on, and are consistent with, the UCFM production requirements within Standard 1.6.2 in the Code.

The National Expert Advisory Panel on UCFM Safety developed two guidelines in 2004-2005. A protocol for assessing HACCP-based food safety programs in the UCFM sector and a guideline for UCFM Manufacturers to facilitate compliance with the skills and knowledge requirements of the food safety standards in the Code. The guidelines are implemented under the supervision of the Meat Standards Committee.

5. Relevant Issues

5.1 Definition of Producers of Manufactured and Fermented Meats

The term 'manufactured meat' was not specifically defined in the National Risk Validation Project, however the intention was to cover smallgoods (i.e. not canned meat products) and include fermented meats. The Code defines manufactured meat (Standard 2.2.1) as processed meat containing no less than 660 g/kg of meat. However this is a compositional definition in relation to the meat content in products and not based on food safety considerations.

In 2003, MLA published a through chain risk profile for the red meat industry that rated hazards using a semi-quantitative risk assessment tool. During the public consultation for the Initial Assessment Report, MLA provided this risk profile for consideration in defining products that might be considered to present a high public health and safety risk to consumers due to manufacturing, storage and handling operations. A number of smallgoods products were ranked according to risk using this method and since that time, assessments have been prepared for the cooling of cooked meats, including both cooked/cured products and roast meats. 8

Defining 'producers of manufactured meat and fermented meat' is essential for identifying the products or categories of products, and the types of businesses, that are required to implement food safety programs. The development of a definition for manufactured meat (including fermented meat) based on characteristics that will enable specific product categories to be identified will facilitate industry compliance and government enforcement of food safety programs.

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⁷ Ross, T. and Sumner, J. (2002) A simple, spreadsheet-based risk assessment tool. Int. J. Food Microbiol. 77:39-53.

⁸ Sumner, J., Jensen, I., Pointon, A. and Ross, T. (2004) Risk ranger, a food safety risk assessment tool. Proc. 5th World Congress on Foodborne infections and intoxications. in press

A definition of 'producers of manufactured and fermented meats' for this Proposal was developed by a Working Group⁹ of the Advisory Group and subsequently agreed to by the Advisory Group. Available data from the National Risk Validation Project, MLA 'Through Chain Risk Profile for the Australian Red Meat Industry' and submissions provided during the public consultation period on the Initial Assessment Report (IAR) were considered by the Working Group in developing the proposed definition. A summary of available information considered is at Attachment 4.

The proposed definition identifies food businesses that will be required to implement a documented food safety management system based upon the types of products they produce and the activities they perform. This definition reflects the policy principle that food safety management in Australia be based on risk.¹⁰

The following definition will apply in Standard 4.2.2 and Standard 4.2.3 of the Code and will not apply in other standards within the Code.

Producers of manufactured and fermented meats are businesses involved in the making, manufacturing, producing, extracting, processing, preparing, treating, preserving, packing, cooking, thawing and/or handling¹¹ of ready-to-eat meats (product is intended to be consumed without further heating or cooking). Ready-to-eat meats include:

- *fermented meats (cooked or uncooked);*
- pâtés;
- *dried meat / slow cured meat;*
- *luncheon meat (e.g. devon, pressed chicken) whether whole or not;*
- cooked muscle meat (e.g. ham, roast beef) whether whole or not;
- ready-to-eat meats that have been handled (as defined) after manufacture; and
- ready- to-eat meats that can allow the growth of a pathogen or toxin production.

The definition also includes businesses that dice, shave or slice ready-to-eat meats and pack it in a modified atmosphere package for retail sale.

5.3 Proposed Requirements for Producers of Manufactured and Fermented Meats to Protect Public Health and Safety

As described in section 4.3.1.2, the majority of producers of manufactured and fermented meats are currently regulated by State and Territory Governments under the Australian Standard which contains additional food safety requirements not specifically required in the current Standard 3.2.1. These are detailed in Table 1.

⁹ A Working Group consisting of DoHA, NSW Food Authority, PIRSA and AMIC was established at the June 2004 Advisory Group meeting to assist in the development of a definition for producers of manufactured and fermented meat. The Working Group reported their findings to the Advisory Group at the 2 December 2004 meeting.

¹⁰ The Ministerial Policy Guidelines on Food Safety Management in Australia: Food Safety Programs states that 'regulations covering food safety management in Australia be based on risk, where the level of legislative requirements and their verification is commensurate with the level of risk.'

¹¹ Handling: slicing, shaving, dicing and/or repackaging.

Table 1: Australian Standard (AS 4696:2002) HACCP based food safety requirements to be specifically included into the standard in the Code for producers of manufactured and fermented meat.

Clause		
3.11 (a)	HACCP plan – potential hazards are identified as a result of a hazard analysis and a risk	
	assessment of each hazard.	
(c)	HACCP plan – lists the critical control points (CCP) for each hazard identified.	
(d)	HACCP plan – lists the critical limits that must be met at each of the critical control	
	points.	
(e)	HACCP plan – documents:	
	(i) The procedures that will be used to monitor each of the critical control points	
	to ensure compliance with the critical limits; and	
	(ii) The frequency with which these procedures will be performed; and	
	(iii) The person, or persons included in a class of persons, who will carry out these	
	procedures.	
(f)	HACCP plan documents all corrective action to be taken when monitoring indicates that a	
	critical control point is not under control	
(g)	HACCP plan – documents the procedures that the business will use to:	
	(i) Validate that the HACCP plan is working effectively.	

These requirements should be specified as part of the documented food safety management system for producers of manufactured and fermented meat to protect public health and safety and ensure consistency with the current industry practices. Therefore, producers of manufactured and fermented meats must systematically examine and document all of their operations, including identifying food safety hazards and controls and compliance with specific requirements of Standard 3.2.2¹² in a documented food safety management system. This documented food safety management system will cover:

- 1. documenting all stages of production;
- 2. identifying food safety hazards and controls through the use of a HACCP plan¹³;
- 3. documenting compliance with Standard 3.2.2 of the Code; and
- 4. documenting a management system¹⁴.

In summary, the food safety management system requirements in the Code for producers of manufactured and fermented meat would be located in Standard 4.2.3 –Primary Production and Processing Standard for Meat (Division 3 – Production of manufactured and fermented meat) and in Standard 4.2.2 – Primary Production and Processing Standard for Poultry Meat (Division 3 – Production of manufactured poultry meat). The current requirements in clause 9 of Standard 1.6.2 for the production of UCFM would be additional requirements in the documented food safety management system for the producers of UCFM products in Standard 4.2.3 – Primary Production and Processing Standard for Meat (Division 3 – Production of manufactured and fermented meat).

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¹² Standard 3.2.2 specifies process control requirements to be satisfied at each step of the food handling process. Some requirements relate to the receipt, storage, processing, display, packaging, distribution, 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 premises and equipment.

¹³Codex HACCP or the Australian Standard HACCP plan.

¹⁴ Detailed in Clauses 3.3 – 3.10 of the Australian Standard.

6. Regulatory Options

At Initial Assessment, two regulatory options were proposed – to either maintain the status quo or amend Standard 3.2.1 to mandate food safety programs for producers of manufactured and fermented meats. These two options have been amended to reflect the adoption of the proposed Standard 4.2.3 – Primary Production and Processing Standard for Meat (Division 3 – Production of manufactured and fermented meat) and Standard 4.2.2 – Primary Production and Processing Standard for Poultry Meat (Division 3 – Production of manufactured poultry meat). This approach is consistent with the model developed for the structural approach to the Primary Production and Processing Standards. The new options read as follows:

- Option 1 to maintain the status quo and not adopt Standard 4.2.3 Primary Production and Processing Standard for Meat (Division 3 Production of manufactured and fermented meat) and Standard 4.2.2 Primary Production and Processing Standard for Poultry Meat (Division 3 Production of manufactured poultry meat) to apply a food safety management system to producers of manufactured and fermented meats.
- Option 2 to adopt Standard 4.2.3 Primary Production and Processing Standard for Meat (Division 3 – Production of manufactured and fermented meat) and Standard 4.2.2 – Primary Production and Processing Standard for Poultry Meat (Division 3 – Production of manufactured poultry meat) to apply a food safety management system to producers of manufactured and fermented meats.

6.1 Option 1 – maintain the status quo

In maintaining the status quo there would be no amendment to the Code to apply food safety management systems to all producers of manufactured and fermented meats (i.e. there will be no national requirement for producers of manufactured and fermented meats, as defined within this Proposal, to have documented food safety programs as defined in section 5.3). This option would not be consistent with the Ministerial Guidelines to require food safety programs for businesses engaged in producing manufactured and fermented meats.

6.2 Option 2 – Adopt Standard 4.2.3 – Primary Production and Processing Standard for Meat and Standard 4.2.2 – Primary Production and Processing Standard for Poultry Meat

Adoption of Standard 4.2.3 – Primary Production and Processing Standard for Meat and Standard 4.2.2 – Primary Production and Processing Standard for Poultry Meat would mean that a documented food safety management system would be a national requirement for producers of manufactured and fermented meats.

Compliance with Standard 4.2.3 – Primary Production and Processing Standard for Meat (Division 3 – Production of manufactured and fermented meat) and Standard 4.2.2 – Primary Production and Processing Standard for Poultry Meat (Division 3 – Production of manufactured poultry meat) would be achieved through a documented food safety management system that includes the following components:

• documents all stages of production;

- identifies food safety hazards and controls through the use of a HACCP plan that includes the requirements in table 1¹⁵;
- documents compliance with Standard 3.2.2 of the Code; and
- documents management system ¹⁶;

OR

• documents compliance with a recognised food safety management system such as that required by the Export Control (Meat and Meat Products) Orders 2005 or the Australian Standard (AS 4696:2002).

Nine submissions supported the original option 2 to mandate Standard 3.2.1 for all producers of manufactured and fermented meat, with the remaining four submissions making no direct comment. The amended option 2 to adopt Standard 4.2.3 – Primary Production and Processing Standard for Meat (Division 3 – Production of manufactured and fermented meat) and Standard 4.2.2 – Primary Production and Processing Standard for Poultry Meat (Division 3 – Production of manufactured poultry meat) to mandate a documented food safety management system for producers of manufactured and fermented meats will apply the requirements of food safety programs to this sector and is therefore consistent with the intent of the Ministerial Policy Guidelines.

Despite their support for option 2, a number of submissions also raised that the requirements for a food safety management system in the Australian Standard exceed the requirements as specified in Standard 3.2.1, specifically in relation to critical control points, critical limits and validation. The revised option 2 to mandate a documented food safety management systems for producers of manufactured and fermented meats would resolve this issue as the proposed food safety management system contains the essential elements required under the current Australian Standard.

Submissions also raised the issue of consistency within the Code for requirements for food safety programs as currently the production of UCFM products refers to the implementation of food safety programs in clause 9 of Standard 1.6.2. The revised option 2 to adopt Standard 4.2.3 to mandate a documented food safety management system for producers of manufactured and fermented meats would include the additional requirements in clause 9 of Standard 1.6.2 on the producers of UCFM products. Therefore, all of the requirements for a food safety management system for producers of manufactured and fermented meats, including UCFM, would be located within a single standard.

7. Impact Analysis

7.1 Cost/benefit analysis

The Australian Government Department of health and Ageing (DoHA) engaged the Allen Consulting Group to undertake a review of the costs and efficacy of introducing food safety programs, as proposed by Standard 3.2.1, across all food businesses.

¹⁵ Codex HACCP or the Australian Standard HACCP plan.

¹⁶ Detailed in Clauses 3.3 – 3.10 of the Australian Standard.

¹⁷ Approved by the controlling authority.

The Final Report of this project, *Food Safety Management Systems – Costs, Benefits and Alternatives* (the Allen Report), found that the benefits of introducing Standard 3.2.1 outweighed the cost for all but 'low risk' businesses.

The Allen Report considered that the requirements of Standard 3.2.1 involve a fundamentally different approach to food safety management, requiring a proactive evaluation of specific risks compared to a 'rote learning' reactive approach to general risk categories. The costs associated with this approach are largely time-based, though businesses would feel the burden of extra hours of work and related stress. The main cost drivers include implementation costs (training and development) and the ongoing costs of record keeping and review, and audit costs.

The Report concludes that the benefits for high risk businesses outweigh the costs of implementing, utilising and auditing a food safety program.

The main benefits of food safety programs reported by the Allen Report would arise from the reductions in food-borne illness. The extent of this benefit is hard to quantify and relates to judgements around:

- the size of current incidence and associated costs; and
- the size of any decrease in food-borne illness attributable to food safety programs.

The Allen Report calculated a median benefit of \$339 million per annum, based on a 15% reduction in food-borne illness.

Data from the Allen Report was further built on by *The National Risk Validation Report*, which included a cost benefit analysis of implementing food safety programs, specifically for high risk food industries. The total cost of food-borne illness associated with manufactured meats was estimated to be \$77 million per year or 39 cents per meal. A benefit to cost ratio was calculated at 115.9 (for class 1 outbreaks¹⁸) and 165.6 (for class 1 and 2 outbreaks). This cost benefit analysis strongly supports the manufactured meat sector.

Findings from these reports informed the development of the Ministerial Policy Guidelines, which have been assessed by the Office of Regulation Review (ORR). In its assessment the ORR took into account:

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

The ORR considered that these matters have been adequately addressed. 19

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¹⁸ Class 1 outbreaks are defined as those where it is reasonable to assume that the cause of illness could have been detected and remedied by measures put in place under a food safety program as opposed to class 2 outbreaks where the information on the source is insufficient to make a judgment on likely effectiveness of a food safety program.

¹⁹ ORR reference number is 3339.

7.2 Affected Parties

Parties affected by the proposed Standard are businesses involved in the making, manufacturing, producing, extracting, processing, preparing, treating, preserving, packing, cooking, thawing and/or handling²⁰ of ready-to-eat meats (product is intended to be consumed without further heating or cooking)²¹ and also includes businesses that dice, shave, slice ready-to-eat meats and pack them in a modified atmosphere package for retail sale.

The majority of these businesses are already operating under a documented food safety management system and will not be affected by the proposed variation to the Code. There may be some businesses that carry out these processes that are not regulated by the current Australian Standard. These businesses would need to comply with the requirement for a documented food safety management system. The greater impact will be felt by smaller businesses with costs associated with developing, maintaining and auditing food safety programs. The FRSC Implementation Sub-Committee (ISC) is currently progressing a National Food Safety Audit policy, the principles of which include minimising the burden on industry imposed by regulatory food safety audits. Discussions have been progressed with the relevant agencies to enable application and enforcement of the proposed requirements for retail of manufactured meats.

8. Consultation

The Initial Assessment Report was released for an eight-week public comment period from 26 May until 21 July 2004 and subsequently extended until 30 July. Thirteen submissions were received and a summary of these is provided in Attachment 1.

The submissions were received from:

- State and Territory Governments
 - Department of Health Western Australia
 - Health Protection Service, ACT Health
 - Department of Health South Australia
 - NSW Food Authority
 - Environmental Health Unit of Queensland Health
 - Department of Health Government of Western Australia WA Food Advisory Committee (late submission)
 - Tasmanian Working Group* Food Safety Programs for Manufactured & Fermented Meats

o Fermented meats (cooked or uncooked);

Dried meat / slow cured meat;

o Luncheon meat (e.g. devon, pressed chicken) whether whole or not;

o Cooked muscle meat (e.g. ham, roast beef) whether whole or not;

o Ready-to-eat meats that have been handled (as defined) after manufacture; and

Ready- to-eat meats that can allow the growth of a pathogen or toxin production.

²⁰ Handling: slicing, shaving, dicing and/or repackaging.

Ready-to- meats include:

o Pates:

- * Department of Primary Industries, Water and Environment (Meat Hygiene Standards Section), Department of Health and Human Services (Environmental Health Services), Local Government (Clarence City Council).
- New Zealand Food Safety Authority (2 submissions)
- Industry Groups
- Australian Food and Grocery Council
- Food Technology Association of Victoria Inc.
- Australian Meat Industry Council
- Meat & Livestock Australia

Many of the submissions provided valuable information and data that was incorporated into the definition of producers of manufactured and fermented meat and more generally into this Draft Assessment Report.

FSANZ, with the assistance of the advisory group for this proposal, will continue to consult with stakeholders in the development of the Standard through its normal processes.

8.1 Issues raised in submissions

8.1.1 Definition of Manufactured and Fermented Meat

Ten submissions commented on the most appropriate definition of manufactured and fermented meats and provided characteristics to enable specific product categories to be identified. The Advisory Group agreed to form a small working group to assist in the development of a definition for manufactured and fermented meat. The final definition was determined after the working group's report had been considered and agreed to by the Advisory Group.

The majority of submissions supported 'ready-to-eat meats' as the basis of the definition and not a reference to manufactured meat nor a compositionally based definition. A number of submissions provided definitions for smallgoods in State legislation e.g. dried meat, UCFM, cooked offal or minced meat products, cooked whole meat products.

Submissions also advised that the definition should not include bacon, fresh sausages, canned products, raw and part cooked meat products, as the consumer will further cook these products.

This issue has been addressed under section 5.1 of this Report.

8.1.2 Interpretive Guide for Standard 3.2.1 Manufactured and Fermented Meats

A number of submissions supported the development of the interpretive guide to Standard 3.2.1 to explain the extent of the provisions in the Standard on a clause-by-clause basis. The primary purpose of the guide will be to promote nationally consistent interpretation of Standard 3.2.1 by State and Territory enforcement officers and thereby assist them in assessing whether the objectives of the legislation are being achieved.

However, industry associations may find the guide useful to prepare information to assist producers of manufactured and fermented meat, particularly those retail businesses affected by Standard 3.3.2, to comply with the proposed requirements. Although the guide will be generic to all food businesses, an appendix outlining the specific requirements for producers of manufactured and fermented meats will be included.

Submissions also suggested that a range of guides should be developed so that they are specific to a particular sector of the industry (e.g. large and small scale producers). The MLA 'Guidelines for the Safe Manufacture of Smallgoods' provides a resource to industry in the establishment of food safety programs.

Industry and government members have nominated to participate in the development of the appendix specifically relating to producers of manufactured and fermented meats. A draft guide will be trialled with enforcement agencies in mid-2005.

8.1.3 Current Control of Food Safety Risks

A number of submissions confirmed that currently producers of manufactured and fermented meat require HACCP-based food safety programs as part of compliance with the Australian Standard. Compliance with the Australian Standard requires the implementation of a food safety program with requirements that exceed the requirements of Standard 3.2.1 and have to be audited by an approved auditor.

Some states, for example Western Australia, noted that the application of the Australian Standard ends at retail and therefore all retail businesses that produce manufactured and fermented meats do not currently require a food safety program. However, the Australian Standard and therefore the requirement for a food safety program is applied to all producers of UCFM. This issue has been addressed under section 7.2 of this Report.

8.1.4 Potential Changes to Current Regulatory Practices

Individual states noted that the introduction of the requirement for a documented food safety management system would require legislative amendments and entail changes to current regulatory practices. In some States this would not add any further requirements to what is already in place as meat processing plants and butcher shops are currently required to have food safety programs based on HACCP principles.

Requiring a documented food safety management system will not entail changes to Australian Food and Grocery Council members' practices. This issue has been addressed under section 7.2 of this Report.

8.1.5 Scientific Justification

One submission provided additional scientific data on the possible public health and safety risks associated with the production and handling of manufactured and fermented meat. The information has been incorporated into the report of the working group on identifying activities and products to be covered by this Standard. This issue has been addressed under section 5.1 of this Report.

8.1.6 Tools for Implementation

A number of submissions commented on the availability of tools to aid in the implementation of this standard. However, submissions differed on the need for future national templates to be developed as a consequence of introducing this Standard into the manufactured and fermented meat sector.

8.1.7 *Audits*

Submissions raised issues in relation to audit frequency, unnecessary duplication and the availability of resources (skills and costs). These issues are being progressed through ISC. This issue has been addressed under section 7.2 of this Report.

8.1.8 Regulatory options for ensuring compliance of imported manufactured meats with Standard 3.2.1

Comments received focused on enforcement of outcome-based standards at the border. FSANZ is currently in discussions with AQIS on this issue.

8.2 World Trade Organization (WTO)

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

The mandatory application of food safety management systems for manufactured and fermented meats will have implications for imported product in this category. Notification will therefore be made in accordance with Australia's obligations under Sanitary and Phytosanitary Measure (SPS) Agreements. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

10. Conclusion and Recommendation

At Draft Assessment, FSANZ recommends that the Code be amended to mandate food safety management systems for producers of manufactured and fermented meats for the following reasons:

- The National Risk Validation Project concluded that the production of manufactured and fermented meats was a potentially high risk sector.
- The proposed variations to the Code are consistent with the section 10 objectives of the FSANZ Act to reduce the incidence of food-borne illness in Australia due to manufactured and fermented meat consumption, via a nationally consistent approach that requires producers of manufactured and fermented meats to have a documented food safety management system.

- The proposed variations to the Code provide a preventative approach to food safety management that allows enforcement agencies to establish compliance with the system through audit processes.
- The Allen Report on the costs and efficacy of introducing food safety programs concludes that the benefits for high risk businesses outweigh the costs of implementing, utilising and auditing a food safety management system.

The proposed drafting for amendments to the Code is at Attachment 1.

This Draft Assessment Report provides a second and final formal opportunity for stakeholders to comment to FSANZ on the information, data and proposed Standard regarding the mandatory application of food safety management systems for producers of manufactured and fermented meats. FSANZ welcomes and encourages stakeholder input. The comments, information and data provided during consultation will be considered during the development of the Final Assessment Report.

11. Implementation and review

Individual States have developed appropriate template programs to facilitate the implementation of food safety programs into various meat sectors. For example, the New South Wales Food Authority developed 'A guide to food safety programs for retail meat premises'.²²

The Ministerial Policy Guidelines have specified that mandatory food safety programs for the producers of manufactured and fermented meats be nationally implemented in two years after the amendment to the Code is gazetted.

ATTACHMENTS

- 1. Draft variations to the Australia New Zealand Food Standards Code
- 2. Requirements of the *Food Standards Code* for the production of uncooked comminuted fermented meat (UCFM)
- 3. The HACCP requirements within the Australian Standard for the Hygienic Production and Transportation of Meat and Meat Products for Human Consumption (AS4696: 2002).
- 4. Summary of information considered by the 'Food Safety Programs and Manufactured and Fermented Meats' Working Group to develop definition of producers of manufactured and fermented meats.
- 5. Summary of Submissions

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²² The guide is available from the New South Wales Food Authority website at http://www.foodauthority.nsw.au/pdf/Manual-Food-Safety-Gude-Retail.pdf

Draft Variations to the Australia New Zealand Food Standards Code

To commence: 12 months from gazettal

Note on commencement:

Subclause 1(2) of Standard 1.1.1 applies to these amendments to the Code. The effect of this subclause is that a food is taken to comply with Division 3 of Standards 4.2.2 and 4.2.3 (below) for a period of 12 months after the commencement of the Standard, provided the food otherwise complied with the Code. This means that producers of manufactured and fermented meats have 2 years from the gazettal of Standards 4.2.2 and 4.2.3 (Division 3) before they are required to comply with the new requirements.

- [1] Standard 1.6.2 of the Australia New Zealand Food Standards Code is varied by omitting clause 9.
- [2] The Australia New Zealand Food Standards Code is varied by inserting -

STANDARD 4.2.2

PRIMARY PRODUCTION AND PROCESSING STANDARD FOR POULTRY MEAT (AUSTRALIA ONLY)

Purpose and commentary

Reserved

Table of Provisions

Division 1 – Reserved

- 1 Reserved
- 2 Reserved

Division 2 – Reserved

Division 3 – Production of manufactured poultry meat

Requirements for producers of manufactured chicken meat

Clauses

Division 1 – Reserved

- 1 Reserved
- 2 Reserved

Division 2 – Reserved

Division 3 – Production of manufactured poultry meat

3 Requirements for producers of manufactured poultry meat

Division 3 of Standard 4.2.3 (manufactured and fermented meats) applies to the producers of manufactured chicken meat.

[3] The Australia New Zealand Food Standards Code is varied by inserting –

STANDARD 4.2.3

PRODUCTION AND PROCESSING STANDARD FOR MEAT (AUSTRALIA ONLY)

Purpose and commentary

Reserved

Table of Provisions

Division 1 – Preliminary

- 1 Reserved
- 2 Interpretation

Division 2 – Reserved

Division 3 – Production of manufactured and fermented meat

- 3 Interpretation
- 4 Requirements on producers
- 5 Additional requirements for uncooked comminuted fermented meat

Clauses

Division 1 – Preliminary

1 Reserved

2 Interpretation

(1) Unless the contrary intention appears, the definitions in Chapter 3 of this Code apply for the purposes of this Standard.

Division 2 – Reserved

Division 3 – Production of manufactured and fermented meat

3 Interpretation

In this Division -

control means a measure that prevents, eliminates or reduces to an acceptable level, a food safety hazard.

HACCP plan means the -

- (a) Codex HACCP plan, Annex C to CAC/RCPI 1969, Revision 4 (2003); or
- (b) Standards Australia HACCP plan, Australian Standard AS 4696.

handling means slicing, shaving or dicing followed by the packaging of the product in a modified atmosphere package..

producer of manufactured and fermented meats means a food business that engages in the –

- (a) making, manufacturing, producing, extracting, processing, preparing, treating, preserving, packing, cooking, thawing or handling of ready to eat meat; or
- (b) handling of ready to eat meat for retail sale.

ready–to-eat meat means meat products intended to be consumed without further heating or cooking, and includes –

- (a) cooked or uncooked fermented meat; and
- (b) pâté; and
- (c) dried meat; and
- (d) slow cured meat; and
- (e) luncheon meat including devon or pressed chicken; and
- (f) cooked muscle meat including ham and roast beef; and
- (g) other ready-to-eat meat that is susceptible to the growth of pathogens or the production of toxins.

4 Requirements on producers of manufactured and fermented meat

A producer of manufactured and fermented meat must implement a food safety management plan that identifies, evaluates and controls hazards, and meets the requirements in Table 1 or Table 2 to this clause.

Table 1 to clause 4

Document all stages of production	
Identify all food safety hazards and controls through the use of a HACCP plan	
Document compliance with Standard 3.2.2 of this Code	
Document the management system set out in clauses 3.3 to 3.10 of the Australian Standard AS4696: 2002	

Table 2 to clause 4

Comply with a food safety management system recognised by the relevant authority

Editorial note:

'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 an adverse health effect in humans.

'Relevant authority' is defined in Standard 1.1.1.

Examples of a food safety management system that a relevant authority may recognise are the Commonwealth Export Control (Meat and Meat Products) Orders 2005 or the Australian Standard AS4696: 2002.

5 Additional requirements for uncooked comminuted fermented meat

- (1) In this clause
 - **audit** means a review or examination of any, or all requirements of a food safety program which has been conducted by a person approved as being competent in food safety matters relating to UCFM.
 - **batter mix** means all the ingredients in the UCFM recipe that have been combined prior to filling a casing.
 - **food safety program** means a food safety program in accordance with Division 2 of Standard 3.2.1 and which has been validated by the producer.
 - **starter culture** means a preparation of micro-organisms prepared for the purpose of fermenting meat which
 - (i) successfully competes for the nutrients in the meat medium; and
 - (ii) produces microbial inhibitors; and
 - (iii) is microbiologically safe; and
 - (iv) produces a controlled reduction of the pH of the meat mix.
 - **UCFM** means a comminuted fermented meat which has not had its core temperature maintained at 65°C for at least 10 minutes or an equivalent combination of time and higher temperature during production. To avoid doubt, a UCFM includes comminuted fermented meat which has been heat treated.
 - **validation** means obtaining evidence to confirm that the food safety program is complete and effective and will deliver the expected food safety outcomes.
 - **verification** means the use of methods, procedures and tests in addition to monitoring to determine compliance with the food safety program.
- (2) Unless expressly provided elsewhere in this Code, a UCFM must not be sold unless it is produced in accordance with this clause.

- (3) For the purposes of subclause 5(2), a UCFM may be sold where it is produced using an alternative technology or method specified elsewhere in this Code, provided that the equivalent food safety outcome in this clause is achieved.
- (4) A UCFM must be produced in accordance with a food safety management plan under clause 4 which
 - (a) has been verified and audited to ensure the number of *Escherichia coli* organisms in the final UCFM comply with the microbiological limits in Standard 1.6.1 in this Code; and
 - (b) demonstrates that the production process handles the variations of *Escherichia coli* contamination in the ingoing raw meat ingredients.
- (5) As part of the validation or verification requirements of the food safety program, the number of *Escherichia coli* organisms must be recorded for the
 - (a) raw meat ingredients used to make a UCFM; and
 - (b) product after fermentation and any subsequent process.
- (6) During UCFM production the following matters must be monitored and recorded at suitable frequencies
 - (a) the pH of a fermenting UCFM; and
 - (b) the temperature and time of fermentation of UCFM; and
 - (c) the temperature and time of maturation/drying of UCFM; and
 - (d) the temperature and time of smoking of UCFM; and
 - (e) the weight loss or water activity.
- (7) The measurements recorded under subclauses (5) and (6) must be kept for 12 months after the use-by date or best-before date of a UCFM.
- (8) The fermentation of a UCFM must be initiated through the use of a starter culture.
- (9) A previously fermented or fermenting meat must not be used as
 - (a) a starter culture; or
 - (b) an ingredient in a UCFM.
- (10) Meat and batter mix used in the preparation of a UCFM must, if stored by the manufacturer, be stored at 5°C or below prior to fermentation.
- (11) The pH of a fermenting UCFM must be measured in accordance with Method 1 in the Schedule.

Editorial note:

UCFM food businesses should note the skills and knowledge requirements in clause 3 of Standard 3.2.2.

Editorial note for New Zealand:

For New Zealand the processing of UCFM is regulated under the *Food Act 1981*.

SCHEDULE

Methods of Analysis

1 Meat Determination of pH.

Mince a representative portion of the sample of the UCFM and place that portion in a stoppered bottle with twice its weight of water. Shake at five-minute intervals for 30 minutes and determine the pH value of the liquid electrometrically at 20°C.

Alternatively, the pH can be determined through the use of calibrated, direct-contact pH probes or meters.

Clause 9 of Standard 1.6.2

- 9 Production of uncooked comminuted fermented meat (UCFM)
- (1) In this clause
 - **audit** means a review or examination of any, or all requirements of a food safety program, which has been conducted by a person approved as being competent in food safety matters relating to UCFM.
 - **batter mix** means all the ingredients in the UCFM recipe that have been combined prior to filling a casing.
 - **food safety program** means a food safety program in accordance with Division 2 of Standard 3.2.1 and which has been validated by the producer.
 - **starter culture** means a preparation of micro-organisms prepared for the purpose of fermenting meat which -
 - (iii) successfully competes for the nutrients in the meat medium; and
 - (iv) produces microbial inhibitors; and
 - (iii) is microbiologically safe; and
 - (iv) produces a controlled reduction of the pH of the meat mix.
 - **UCFM** means a comminuted fermented meat which has not had its core temperature maintained at 65°C for at least 10 minutes or an equivalent combination of time and higher temperature during production. To avoid doubt, a UCFM includes comminuted fermented meat which has been heat treated.
 - **validation** means obtaining evidence to confirm that the food safety program is complete and effective and will deliver the expected food safety outcomes.
 - **verification** means the use of methods, procedures and tests in addition to monitoring to determine compliance with the food safety program.
- (2) Unless expressly provided elsewhere in this Code, a UCFM must not be sold unless it is produced in accordance with this clause.
- (3) For the purposes of subclause 9(2), a UCFM may be sold where it is produced using an alternative technology or method specified elsewhere in this Code, provided that the equivalent food safety outcome in this clause is achieved.
- (4) A UCFM must be produced in accordance with a food safety program which
 - (a) has been verified and audited to ensure the number of *Escherichia coli* organisms in the final UCFM comply with the microbiological limits in Standard 1.6.1 in this Code; and
 - (b) demonstrates that the production process handles the variations of *Escherichia coli* contamination in the ingoing raw meat ingredients.

- (5) As part of the validation or verification requirements of the food safety program, the number of *Escherichia coli* organisms must be recorded for the
 - (a) raw meat ingredients used to make a UCFM; and
 - (b) product after fermentation and any subsequent process.
- (6) During UCFM production the following matters must be monitored and recorded at suitable frequencies
 - (a) the pH of a fermenting UCFM; and
 - (b) the temperature and time of fermentation of UCFM; and
 - (c) the temperature and time of maturation/drying of UCFM; and
 - (d) the temperature and time of smoking of UCFM; and
 - (e) the weight loss or water activity.
- (7) The measurements recorded under subclauses (5) and (6) must be kept for 12 months after the use-by date or best-before date of a UCFM.
- (8) The fermentation of a UCFM must be initiated through the use of a starter culture.
- (9) A previously fermented or fermenting meat must not be used as
 - (a) a starter culture; or
 - (b) an ingredient in a UCFM.
- (10) Meat and batter mix used in the preparation of a UCFM must, if stored by the manufacturer, be stored at 5°C or below prior to fermentation.
- (11) The pH of a fermenting UCFM must be measured in accordance with Method 1 in the Schedule.

Editorial note:

UCFM food businesses should note the skills and knowledge requirements in clause 3 of Standard 3.2.2.

Editorial note for New Zealand:

For New Zealand the processing of UCFM is regulated under the *Food Act 1981*.

The HACCP requirements within the Australian Standard for the Hygienic Production and Transportation of Meat and Meat Products for Human Consumption AS4696: 2002

The HACCP plan:

- (a) lists the potential hazards associated with all stages of the production of meat and meat products undertaken by a meat business that may reasonably expected to occur and that have been identified as a result of a hazard analysis and a risk assessment of each hazard; and
- (b) specifies the preventative measures that can be applied to control each hazard; and
- (c) lists the critical control points for each hazard identified; and
- (d) lists the critical limits that must be met at each of the critical control points; and
- (e) documents:
 - (i) the procedures that will be used to monitor each of the critical control points to ensure compliance with the critical limits; and
 - (ii) the frequency with which these procedures will be performed; and
 - (iii) the person, or persons included in a class of persons, who will carry out these procedures.
- (f) documents all corrective action to be taken when monitoring indicates that a critical control point is not under control; and
- (g) documents the procedures that the business will use to:
 - (i) validate that the HACCP plan is working effectively;
 - (ii) verify that compliance with the HACCP plan by the business; and lists the frequency with which these procedures will be performed; and
- (h) provides for a system for keeping the documents which contain all matters relevant to the effectiveness of the implementation of the HACCP Plan.

Summary of information considered by the 'Food Safety Programs and Manufactured and Fermented Meats' Working Group

to develop definition of producers of manufactured and fermented meats

Results from the *National Risk Validation Project* (NRVP) and Meat & Livestock Australia's (MLA) *Through Chain Risk Profile for the Australian Red Meat Industry* will be used to determine the types of products to be defined as 'manufactured and fermented meat' for the purpose of manufacturey application of Standard 3.2.1 to producers of manufactured and fermented meat.

1. National Risk Validation Project

Food Science Australia's review of both Australian and overseas data on food-borne illness outbreaks and examination of the factors contributing to these outbreaks concluded that the production of manufactured and fermented meats is a potentially high-risk sector as detailed in the NRVP.

Products identified:

- Smallgoods (including fermented meats) were investigated; and
- A more detailed case study associated with uncooked comminuted fermented meat (UCFM) was conducted.

2. Through Chain Risk Profile for the Australian Red Meat Industry

MLA's risk profile also reviewed the food-borne illness outbreak data as reported in the NRVP in addition to more recent OzFoodNet data. Further to the epidemiological data, MLA's generic hazard analysis and assessment of specific products using risk ranger concluded that based on a specific criteria particular meat products are high-risk based. *Products identified:*

- Fermented products;
- Cooked, sliced, ready-to-eat meats; and
- Pates (not cooked in their container but packed following the thermal process).

MEAT PRODUCTS FOR CONSIDERATION

Products that should be covered by the definition

The manufacture of the products listed below is considered to be the cause of eight Australian outbreaks of forborne illness (over the period 1990-2001) (NRVP).

- Salami
- Pork sausages (cooked manufactured meat)
- Mettwurst (uncooked fermented meat)
- Sliced corned beef/silverside
- Ham

The products (product categories) listed below were identified as 'high risk' based on more recent outbreak data from OzFoodNet supplied to MLA (2003) and MLA risk profiling.

- Fermented meat products
- Cooked, sliced, ready-to-eat meats
- Pates that are not cooked in their container but packed following the thermal process.

Products that should not be included under definition

The manufacture of the products listed below is considered to be the cause of two Australian outbreaks of foodborne illness (over the period 1990-2001). However, the outbreak cause of illness cannot be attributed to the meat component of the foods.

- Meat pie
- Bread rolls with meat filling

SUMMARY OF SUBMISSIONS

SUBMITTER	ISSUES
Environmental Health Unit of Queensland Health Kerry Bell / Gary Bielby (enquiries)	 Current definition of smallgoods in the <i>Food Production (Safety) Act 2000</i> should be used. Smallgoods mean – dried meat (e.g. Beef jerky), uncooked and fermented minced meat products (e.g. salami), cooked offal or minced meat products (e.g. chicken liver pate, luncheon sausage), cooked whole meat products (e.g. ham) and bacon. The introduction of Standard 3.2.1 would require legislative amendments and entail significant changes to current regulatory practices. Main concern is that the proposal to require <i>retailers</i> of MFM to have a food safety program. Based on the findings from the NRVP and the Costs, Benefits and Alternatives report the Ministerial Policy Guidelines state that <i>producers</i> of MFM are required to have a food safety program. Believe existing tools available to industry are satisfactory (especially AMIC developing additional tools for smaller operators). More validation work is essential. Supports an initial audit frequency of one every 6 months with an increase or reduction in frequency dependant on compliance and volume of product produced. Auditing frequency should never be less than every 12 months. The current situation of where the duplication of auditing arrangements regularly occurs needs to be addressed.
NSW Food Authority	 Regulatory Options – supports Option 2. Committed to assisting FSANZ in the development of a guide to Standard 3.2.1 by actively participating in the Working Group. Must ensure that a number of ambiguities within the Standard are clarified in the guide. The guide is important to ensuring consistent interpretation of Standard 3.2.1. The guide's timely completion is important. There are 328 'class 1' meat processors and 1872 retail meat premises (butcher shops) licensed to operate in NSW. Meat processors process meat in the form of ham, bacon, sausages or cooked meat, or salted, smoked, pickled or cured abattoir meat. In practice, this definition is extended to cover meat processors producing smallgoods, including fermented and dried products. Retail meat premises (butcher shops) sell meat by retail and process raw meat carcasses or parts of raw meat carcasses are in some way (such as boning, slicing or cutting) – about 1/3 of butcher shops produce smallgoods (seasonal basis). 28 licensed producers of UCFM – considered the highest risk of all smallgoods must have a HACCP based FSP. States that the amendment to 1.6.2 ensures that producers of UCFM must have in place a food safety program, based on Standard 3.2.1.

SUBMITTER	ISSUES
SUBMITTER	 Producers of MFM require HACCP based FSPs as part of compliance with the Australian Standard. This is in line with the national position, as defined by participation in the MCS and NSW Food Authority's own priority classification system which rates producers of MFM as 'priority 1'. This requires the implementation of a food safety program to Standard 3.2.1 or greater and to be audited by an approved auditor. Agree that the NRVP adequately demonstrates the need for the implementation of standard 3.2.1 for the producers of manufactured and fermented meats, due to a number of foodborne outbreaks attributed to those products in recent years. The implementation of 3.2.1 would be more appropriate for those manufactured meat products that are defined as Ready-to-eat (RTE). A Ready-to-eat (RTE) meat or poultry product is defined as one that is in a form that is edible without additional preparation to achieve food safety. The product may or may not receive additional preparation before consumption (such as re-heating) to improve its taste or appearance – NSW Food Authority definition. Meat processing premises producing MFM ('class 1') require compliance with the Australian Standard. Meat retail premises must comply with the New South Wales Standard for Construction and Hygienic Operation of Retail Meat Premises. The implementation of 3.2.1 would not add any further requirements to what is already in place as meat processing plants and butcher shops are currently required to have food safety programs based on HACCP principles. The implementation of food safety programs for butcher shops is aided by template programs in 'A guide to food safety programs for a retail meats premise'. MLA smallgoods guidelines. Documents mentioned have proven to be valuable tools for the initial implementation of FSPs. Does not consider there is a need (at a national level), for development of additional tools that focus on assisting businesses to prepa
Department of Health SA	 within the processing standard, 1.6.2. Regulatory Options – supports Option 2 – queries why proposal covers all fermented meats when the original subject was
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CUDMITTED	ISSUES
SUBMITTER To smarrier Working Group	
Tasmanian Working Group – FSPs for Manufactured &	• Definitions utilised by AMIC and QLD Smallgoods Survey provides a sound basis for defining manufactured meat in the
Fermented Meats	amended Standard. AMIC:
	o Smallgoods are characterised as meat products where the meat, together with other ingredients has undergone a
Chris Lyall (Meat Hygiene Standards)	manufacturing process beyond boning, to form a new product, with different characteristics and flavour from the fresh
Standards)	meat, sold either uncooked or cooked, but not sterilised, and excludes canned shelf-stable meat products.
	o Smallgoods includes ham, bacon, fresh or cooked sausage, fermented sausage, corned beef, pastrami, pate, liver paste, roasted meats and dried meats.
	o UCFM are a subsection of smallgoods. E.g. 'salami' sausage – although not all salamis are uncooked fermented products, chorizo, csabai. QLD Smallgoods Survey:
	o Smallgoods – manufactured meat or meat products intended for human consumption and include meat that has had its
	nature substantially changed and its shelf life markedly increased by processing e.g. salami, ham, bacon, fermented meats and corned, cured and cooked meats.
	• Specific product categories could be determined by risk ranking/rating known products (via Risk Ranger?) and selecting those with CCPs.
	Businesses that currently comply with the Australian Standard will comply with Chapter 3 Standards. Depending on
	jurisdictions' application of the Australian Standard or Standard 3.2.1, producers of MM at the retail level in some States have not operated a FSP.
	• Ag/Primary Industry State agencies responsible for MFM regulation will need to adopt the FSC via relevant legislation.
	Increased government resources will be needed to implement and monitor Standard 3.2.1 requirements.
	• There is demonstrated success in providing QA manual/food safety plan templates to industry.
	• Development of a national template would facilitate uniformity.
	• ISC is currently progressing a National Food Safety audit Policy (principles which minimise the burden on industry imposed by regulatory food safety audits) and the outcomes of this could be complemented by the use of other tools developed for industry and regulators in conjunction with this Standard.
	• Regulatory audits conducted against the Australian Standard could be aligned with Standard 3.2.1 requirements.
	• Recognition of existing customer audits could occur under a reporting arrangement whereby the regulator is advised of audit outcomes pertinent to 3.2.1.
	• Auditing costs will be significant for Tasmania due to a lack of auditors with specific technical skills in meat
	manufacturing.
	• Assurances should be sought regarding the equivalence of overseas food safety programs.
	• Regulatory Options – supports Option 2 – delete 'and fermented' from Option 1.
	• Effective implementation of mandating 3.2.1 for all producers of MFM relies on the construction of the Standard, the use
	of other tools (e.g. templates, guidelines) and the targeting of higher risk products.
	• There are significant training costs (including recognition and certification) for both industry and regulators.
	• Training costs will have a greater impact on small businesses and compounded by costs associated with developing,
	maintaining and auditing food safety programs.

SUBMITTER	ISSUES
Department of Health Government of WA Jim Dodds/Stan Goodchild (enquiries)	 Legislative issues would need to be addressed to enable application and enforcement of food safety plans for retail of manufactured meats. In addition, there may be cost and resource implications for the Standards 3.2.1, 1.6.1, 1.6.2 or 2.2.1 do not require HACCP based food safety programs for production of UCFM. They require a food safety program as distinct from a HACCP based food safety program. Change second line of 2.2.1.2 to 'These guidelines provide comprehensive assistance to ensure the 'process is capable' of manufacturing safe products'. The requirement for 3.2.1 (food safety programs) is enforced via the application of the Australian Standards. The application ends at retail. However it is applied to all producers of UCFM products. Manufactured meat – 'ready to eat' product as determined by the manufacturer. If manufactured meat is included under the term smallgoods, this must include 'cooked' and 'raw' products. Enforcement and Compliance – last paragraph reflects the impact on the Department of Health and local government. introduction of Standard 3.2.1 at this level, particularly if the implementation is to be managed by the Department of Health or local government or both. Regulatory Options – supports Option 2 – but it should be changed from 'The amendment to the standard will require all producers of manufactured meats to develop and implement audited food safety programs as defined in the standard' to
Department of Health Government of WA Paul Van Buynder / Walter Arrow (enquiries)	 Noted that a significant percentage of the meat industry is already operating HACCP or equivalent systems through the adoption of the Australian Standards. Needs to be a clear delineation based on physical state with ready-to-eat manufactured meats requiring a FSP and those not ready-to-eat manufactured meats being exempt (exempt producers must still retain documented GMP and SOP records for future assessment). If definition is not specifically targeted then it will capture simple butcher shops, preparing their own raw sausages etc. This was felt to be inappropriate. No need to redefine manufactured meat in Part 2 of the Code but to clarify the scope of this proposal in Part 4. Supports in principle the development of food safety programs in this sector but also recognises that the proposal must not erode existing initiatives and achievements made in the industry by setting lower industry standards.
ACT Health Melissa Langhorne / Vojkan Stefanovic (enquiries)	 The interpretive guide should be multi-lingual and in plain language. A range of guides should be developed so that they are specific to a particular sector of the industry. For example separate guides for large scale and small-scale smallgoods manufacturers. ACT does not have large-scale producers of manufactured and fermented meat. Therefore codes of practice etc. are undertaken at the retail butcher level and only involves the production of sausages, pickled meat and in some instances the smoking of hams. No additional scientific information to support the justification to require food safety programs for the producers of manufactured meat.

SUBMITTER	ISSUES
	 Manufactured meat – processed food product that is a mixture of meat and other food (including water) and in which at least 66% of the unpacked weight of the product is meat and manufactured meat products would also be ready to eat foods. Ready to eat food – food that is ordinarily consumed in the same state as that in which it is sold or distributed and includes smallgoods. Manufactured meat products – would not include products that need to be thoroughly cooked by the consumer before eating (not just heating up). E.g. raw sausages. Smallgoods are characterised as meat products where the meat, together with other ingredients has undergone a manufacturing process beyond boning, to form a new product, with different characteristics and flavour from the fresh meat, sold either uncooked or cooked, but not sterilised, and excludes canned shelf-stable meat products. (AMIC definition) Smallgoods includes ham, bacon, fresh or cooked sausage, fermented sausage, corned beef, pastrami, pate, liver paste, roasted meats and dried meats (AMIC definition) UCFM are a subsection of smallgoods. E.g. 'salami' sausage – although not all salamis are uncooked fermented products, chorizo, csabai. (AMIC definition) Tools – no comment as there are no smallgoods manufacturers in the ACT. Suggests that process flow diagrams for the various types of smallgoods or manufactured meats should be developed so that industry and regulators are aware of what is best practice and where the risks are. These flow diagrams would aid in assessing the suitability of a food safety plan. Auditing of food safety plans is currently not required in the ACT. Food businesses are routinely inspected and the frequency of inspection is based on the risk classification. The requirement for developing and auditing food safety plans will place significant extra costs on ACT businesses and the Health Protection Service because of the small size of the food business se
New Zealand Food Safety Authority	 NZFSA approved Risk Management Programmes (RMPs) will deliver the requirements of Food Safety Programmes as listed in clause 2.1.3 (FSPs). RMPs are mandatory for primary processors of animal product, but are mandatory only for secondary processors (which this product group would be classified as) if official assurances are needed. NZFSA would not want to see requirements of a FSP applied in addition to RMP requirements for companies exporting these products to Australia. We would seek assurance that the standard would not be applied to processing of imported products that are physically carried out outside Australia. Do not support 1.6.2 being applied to NZ produced products imported in Australia.

CLIDATIONED	IGGLIEG
SUBMITTER	ISSUES
	• Interpretive guide should be clear, concise and provide for alternatives where acceptable and clarify how to deal with
	alternatives.
	• New Zealand's current FSPs deliver the requirements as outlined in 3.2.1 but are not yet mandatory.
	Mandatory FSPs will be phased in with the risk ranking of food businesses.
	 NZFSA is developing a core regulatory tool – Food Control Plans (FCPs) – which will encompass other risk-based management plans and will be applicable in a variety of forms across the food chain. The current voluntary standards used by NZ processors include: A Guide to HACCP Systems In The Meat Industry Template for Establishing a HACCP Plan for Further Processing of Meat and Meat Products Generic HACCP Plan for the Manufacture of Raw Beef Patties Generic HACCP Plan for the Manufacture of Beef Jerky
	 Industry Agreed Standard 2 – Design and Construction
	 Industry Standard 3 / Industry Agreed Standard 3 – Hygiene and Sanitation
	 Industry Standard 6 – Processing of Edible Product
	 Processors also use international standards such as Codex, Canadian, Australian and US documents.
	Food safety risks are controlled using HACCP based risk management programmes.
	 The PQIP 07 Code of Practice is currently under review by NZFSA and the Pork Processors Association. A draft standard for UCFM will be incorporated into the PQIP 07 CoP.
	• NZFSA wish to see the understanding of the microbiological quality of raw material entering the process, and a link to the FSANZ outcome through a process validated by challenge studies or predictive microbiology.
	 Agree that products listed under 5.2.6 (MLA data) other than fresh sausage and bacon should be included.
	• Agree that products listed under 5.2.8 (QLD smallgoods survey) other than bacon should be included.
	• Use a suite of definitions to define the applicable product groups generally, followed by a comprehensive list of those products to which the standard will apply. Ambiguity must be minimised.
	• Levels of definition should start with ready to eat products (the US definition of ready to eat is a possible starting point). Within this group should be those products defined as smallgoods. A possible further narrowing could involve a reference to hurdle technology.
	Definition should not be compositionally based.
	• Consideration should include the degree of handling after the lethality step.
	• Products such as bacon, fresh sausages, canned products, raw and part cooked meat products should not be included within the definition as these will be further cooked by the consumer.
	• Internationally recognised definitions would be preferable (alignment with Codex definitions preferable, such as the definitions agreed on in the paper on Hygiene Provisions for Processed Meat (CXMH).
	Existing audit system would be equivalent to the proposal.

SUBMITTER	ISSUES
	Agree that product testing is not a viable option.
	Agree with country-to-country certification arrangements and recognition of audit system.
Meat & Livestock Australia Ian Jenson	 Suggests that compliance with the Australian Standard (AS4696-2002) be stated as an option for manufacturers of fermented and manufactured meats. This ensures compliance with Food Standards Code Standards 3.2.1, 3.2.2 and 3.2.3. Suggests that MLA's Guidelines for the Safe Manufacture of Smallgoods covers all of the requirements of Standard
	 3.2.1 and therefore it would be suitable for FSANZ to acknowledge this as an aid to the industry in complying with the requirements of the Standard. Scientific Justification – see Attachment 1(a).
Food Technology Association of Victoria	 Regulatory Options – Supports Option 2 – to require all producers of manufactured meats to develop and implement audited food safety programs as defined in 3.2.1.
Inc. David Gill	
Australian Meat Industry Council Conrad Blaney	 Standard should be referenced to Ready-to-eat meat products rather than manufactured meat. allows for exclusion of bacon, fresh sausages and other lower risk products, as they require cooking. Rejects further defining smallgoods products into a manufactured meat category. Supports the AG sub-group to develop the definitions and products scope required for the standard implementation. Industry expectation is that only one audit be required to review a meat business FSP and that the highest audit be recognised by all regulatory stakeholders for compliance to the standard. Supports (in principle) contestable 3rd party audits – more likely to be acceptable to customers and assist in overcoming the current multiple audit problems. Strongly supports audit frequencies based on the business' risk profile (result of sound science and the performance of its FSP). Supports equivalence compliance protocols for both domestic and imported MFM and understands that compliance to 3.2.1 would be an equivalent measure for imported products. Does not believe end point testing is a sufficient measure to ensure the safety of these products. Regulatory Options – supports Option 2 (with consideration of comments made).
Australian Food & Grocery Council	 Supports the Ministerial Policy Guidelines but considers guideline 3 should be clarified. 'At a minimum, Food Safety Standard 3.2.1 Food Safety Programs should be implemented in those businesses/sectors involved in operations identified as high risk and where the benefit to cost ratio justifies the implementation of food safety programs' Considers all high-risk businesses should be required to operate under a documented FSP (as cost/benefit ratio would automatically be favourable) and that all other businesses should operate under a documented FSP where the cost/benefit ratio justifies the implementation.

SUBMITTER	ISSUES
	• Requests that a copy of the interpretive guide be made available so that comment can be made on it. (FSANZ states that
	it has commenced work on it).
	 Major control of food safety risks is through HACCP FSPs.
	• The Garibaldi experience – result from food poisoning due to processed meat products.
	• The human cost and cost to industry of failing to produce safe food is why they support the requirements for all manufacturers to operate to HACCP FSPs.
	• Supports adopting the Codex definition, which would promote consistency with international/overseas standards.
	• Considers the proposed standard should not be restricted to RTE products.
	• Requiring documented FSP will not entail changes to AFGC members' practices.
	• The MLA Predictive model for <i>E. coli</i> reduction in fermented meats is extremely useful.
	• Complying with 3.2.1 will not change the way AFGC members operate, but its application should not require additional audits.
	• Recommends that FSANZ encourage state/territory authorities responsible for enforcing the Code to recognise audits carried out by AQIS and other independent auditors.
	• Recommends that AQIS inspect and audit overseas producers who export to Australia (in the first instance) or government to government certification should be required.
	 Neither options above should replace finished product testing.
	• Regulatory Options – Supports Option 2 – for all processors of MFM to operate under a documented FSP:
	o but such a requirement should not result in additional auditing where companies are already subject to AQIS and
	State authority auditing.
	• All manufacturers of MFM should be required to operate to a HACCP FSP irrespective of their size.
	• Because of the potential for serious consequences, no preferential treatment should be given to small manufacturers.