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INITIAL ASSESSMENT REPORT

PROPOSAL P289

FOOD SAFETY PROGRAMS FOR THE PRODUCERS OF MANUFACTURED & FERMENTED MEATS

DEADLINE FOR PUBLIC SUBMISSIONS to FSANZ in relation to this matter:

21 July 2004

(See 'Invitation for Public Submissions' for details)

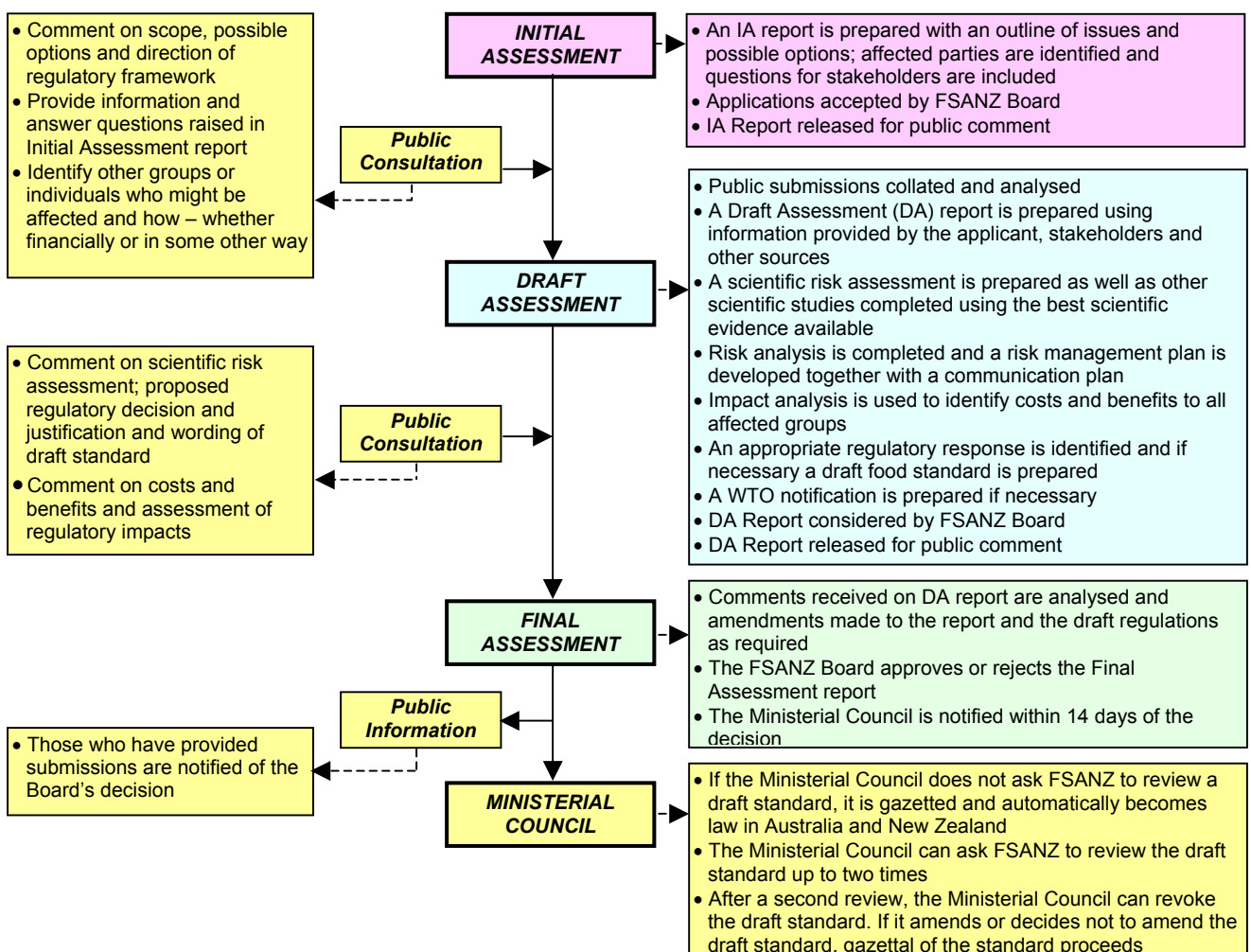
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 Commonwealth; 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 Commonwealth, 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 Commonwealth, 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 an Initial Assessment Report of Proposal P289, which includes the identification and discussion of the key issues.

FSANZ invites public comment on this Initial Assessment Report 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 Draft Assessment/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 in-confidence, 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
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Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
www.foodstandards.govt.nz

Submissions should be received by FSANZ **by 21 July 2004**.

Submissions received after this date may not be considered, unless the Project Manager has given prior agreement for an extension.

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

The Food Regulation Standing Committee (FRSC) has developed Ministerial Policy Guidelines on Food Safety Management in Australia that were endorsed by the Australia and New Zealand Food Regulation Ministerial Council (the Ministerial Council). These guidelines propose that food safety programs be mandatory for four high risk food industry sectors:

- food service, whereby potentially hazardous food is served to vulnerable populations;
- harvesting, processing and distributing raw oysters and other bivalves;
- catering operations serving food to the general public; and
- producing manufactured and fermented meat.

The Commonwealth Department of Health and Ageing (DoHA) undertook key projects to determine the incidence and causes of food-borne illness in Australia and to assess the costs, benefits and justification for food safety programs. The findings of these projects were published in two reports, the *National Risk Validation Project* report and the *Food Safety Management Systems – Costs, Benefits and Alternatives* report. The evidence presented in these reports supported the recommendation that food safety programs be made mandatory for the high risk food industry sectors identified. This Initial Assessment Report is concerned with proposing food safety programs for producers of manufactured and fermented meats. Food safety plans for the other sectors are being addressed through separate processes.

Food safety within the manufactured and fermented meat industry is currently regulated through a combination of State/Territory regulations and voluntary industry guidelines and codes of practice. Current State and Territory regulations draw on a combination of the *Australia New Zealand Food Standards Code* (the Code) and *Australian Standard for the Hygienic Production and Transportation of Meat and Meat Products for Human Consumption*. However there are inconsistencies across States and Territories with respect to implementation of the existing regulatory framework. The current proposal to amend Standard 3.2.1 will require all producers of manufactured and fermented meats to implement food safety programs.

This Initial Assessment Report summarises our current state of knowledge of the manufactured and fermented meat industry in Australia, with a particular focus on food safety regulations and initiatives, and seeks further information and comment from stakeholders on a broad range of issues. The report raises a number of questions in relation to:

- the definition of manufactured and fermented meat - including its relation to the term smallgoods and to other definitions currently in use in various States/Territories, internationally, or within industry;
- implementation issues – including factors effecting industry compliance, enforcement concerns, audits and the development of tools for assisting these processes, such as guidelines; and
- the application and enforcement of Standard 3.2.1 to imported manufactured meats.

Identification of additional relevant issues by stakeholders is also welcomed. The comments, information and data provided during this consultation will be considered during the development of the Draft Assessment Report, which will be released for consultation towards the end of this year.

1. Introduction

In response to the decision in December 2003 by the Ministerial Council, FSANZ is proposing to amend Standard 3.2.1 – Food Safety Programs in Chapter 3 of the Code. This Standard will apply in Australia only and does not apply in New Zealand. The Proposal is to apply the requirements of the standard to producing manufactured and fermented meat.

Consistent with the Ministerial decision, the amendments to the Standard will require businesses in this sector of the food industry to develop and implement audited food safety programs as defined in the standard.

The purpose of the Initial Assessment Report is to inform the food industry, Governments, consumers and other stakeholders of the proposal to apply Standard 3.2.1 – Food Safety Programs to the manufactured and fermented meat sector and to raise issues that FSANZ will address during its assessment of the proposal. The Report may not cover all issues necessary for consideration in mandating Standard 3.2.1 for this sector and further issues may be identified during this public consultation. Through this Report, FSANZ invites stakeholders to comment on the issues raised and asks whether there are additional issues that should be considered.

2. Background

2.1 Regulatory Framework for mandating Standard 3.2.1

2.1.1 Introduction of national food safety standards

In August 2000, the Code was amended to include a new chapter of food safety standards, for application in Australia only, for the safe production of food, the structure of food premises, and equipment and vehicles used by food businesses. The Standards also introduced a notification system for food businesses and a requirement that food handlers and their supervisors have food safety skills and knowledge. These new Food Safety Standards have been progressively introduced into State and Territory legislation and provide a nationally consistent set of food safety requirements for food businesses. They replace inconsistent, outdated and unduly prescriptive State and Territory hygiene regulations. These Standards are:

Standard 3.1.1 – Interpretation and application
Standard 3.2.2 – Food safety practices and general requirements
Standard 3.2.3 – Food premises and equipment¹

State and Territory Governments also agreed to the introduction of a model fourth standard, Standard 3.2.1 – Food Safety Programs, which was included in the Code in December 2000. This Standard requires food businesses, as determined by State and Territory governments, to demonstrate that they are controlling food safety hazards in their businesses by developing and complying with food safety programs.

¹ Copies of the standards and a guide to their interpretation are available on www.foodstandards.gov.au.

The Ministerial Council², made the application of Standard 3.2.1 to food businesses voluntary until sound data on food-borne illness in Australia and more information on costs and efficacy of food safety programs were available. The intention of including the Standard in the Code was to promote national consistency by providing a model for States such as Victoria, which was introducing food safety programs ahead of a national requirement.

DoHA and State and Territory Governments, in cooperation with the food industry and other interested parties, undertook a comprehensive range of studies to provide Governments with data on food borne illness and an analysis of the costs and benefits of introducing mandatory food safety programs.

The results of three projects, in particular, have been important in assisting the Food Regulation Standing Committee to develop options for managing food safety in Australia. These projects are:

- a study into the costs and efficacy of introducing food safety programs in Australia, prepared by the Allen Consulting Group (the Allen Report);
- the National Risk Validation Project which identified the highest risk sectors of the food industry and undertook specific cost and benefit analysis of these sectors; and
- the establishment of OzFoodNet to provide data on the incidence and causes of food-borne illness in Australia.

OzFoodNet reports and Final Reports of the other two studies are available from DoHA³.

Evidence from these projects has supported the development of Policy Guidelines on Management of Food Safety in Australia.

2.1.2 Ministerial Policy Guidelines on Food Safety Management in Australia

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*⁴ 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:

² State, Territory, Commonwealth and New Zealand Ministers meet as the Australia and New Zealand Food Regulation Ministerial Council to discuss and agree on food safety management in Australia and New Zealand.

³ OzFoodNet website: www.ozfoodnet.org.au

The two reports are The National Risk Validation Project - Final Report (2002) which can be accessed at the following link: www.health.gov.au/pubhlth/strateg/foodpolicy/pdf/validation.htm and The Final Report of *Food Safety Management Systems - Costs, Benefits and Alternatives* is available at: www.health.gov.au/pubhlth/strateg/foodpolicy/pdf/alternatives.htm

⁴ 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

1. That regulations covering food safety management in Australia be based on risk, where the level of legislative requirements and their verification is commensurate with the level of risk.
2. That risk profiling be used to classify food businesses or food industry sectors in Australia on the basis of risk.
3. At a minimum, Food Safety Standard 3.2.1 Food Safety Programs should be implemented in those businesses/sectors involved in operations identified as high risk **and** where the benefit to cost ratio justifies the implementation of food safety programs.
4. That the risk classification of a business or an industry sector may change when new data on the causes and incidence of 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 business to assist them meet their legislative requirements.

The Ministerial Council recommended that Standard 3.2.1 – Food Safety Programs be mandatory for the four highest risk industries identified by the National Risk Validation Project:

- food service, in which potentially hazardous food is served to vulnerable populations;
- producing, harvesting, processing and distributing raw oysters and other bivalves;
- catering operations serving food to the general public; and
- producing manufactured and fermented meat.

The Ministerial Policy Guidelines identify, where appropriate, specific issues for each of these industries including definitional matters and areas of exclusion from the requirement for particular sectors based on a low benefit to cost ratio. These matters are identified later in this report. They have also specified a timeframe for mandating Standard 3.2.1 for the highest risk sectors, which is two years after the amendment to the Code is gazetted.

This Initial Assessment Report applies only to the last of these industries – ‘businesses producing manufactured and fermented meats’.

2.1.3 Food Safety Programs

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;

- (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 3.2.1 - Premises and Equipment.

2.1.4 Support projects for the introduction of food safety programs

FSANZ has commenced work on an interpretive guide to Standard 3.2.1 in consultation with State and Territory enforcement agencies. This guide will be generic to all food businesses, with the purpose of allowing enforcement officers to promote a nationally consistent interpretation of the requirements of Standard 3.2.1. The guide, and additional material produced by FSANZ for food businesses, will aid enforcement officers in their role of assisting businesses understand their legal obligations.

Comment on the format, style and content or other issues related to the interpretive guide may be made in response to this Initial Assessment Report.

2.2 Overview of the Manufactured and Fermented Meat Industry

The term 'manufactured meat' can encompass a broad range of products and the term 'smallgoods' is also commonly used to describe a similar range of products. The fermented meat industry is a part of the smallgoods industry. A specific definition, and the product categories covered within the ambit of the term 'manufactured and fermented meats' will be required to identify the size of the sector affected by this proposal. This will be examined in detail as part of the draft assessment of the proposal. These definitional issues, further explored in section 5.1, are problematic in providing an overview of the industry. Consequently, the information in this section is based on a survey of the smallgoods industry in Queensland undertaken in 2003⁵. In this survey, smallgoods were defined as manufactured meat or meat products intended for human consumption and included 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).

In 2003, 49,700 tonnes of smallgoods were estimated to have been produced within Queensland for the local market. The greatest volume of smallgoods was within the category of cooked, comminuted meats ('in skin' products e.g. frankfurters, Strasburg). There is likely to be some seasonal variation in the course of a year in the production volume for various smallgoods categories, for example, increased ham production is expected over the Christmas period. The most valuable category of smallgoods produced in Queensland on a dollar per kilogram basis during 2003 was dried meat product, such as jerky. During 2003, an estimated 5,000 tonnes of smallgoods were brought into Queensland from other States/Territories, most notably New South Wales.

⁵ Queensland Smallgoods Profile and Production Report 2003, Safefood Queensland 2003.

Manufactured meat products are produced in Australia for both the domestic and export markets. In addition, a small quantity of manufactured meat products are imported into Australia. Again, it is difficult to accurately determine the quantity of manufactured meats imported and exported, as the definition for the purpose of this standard has not been determined. The following figures are provided as an estimate of the size of the import and export markets for these products.

The total amount of manufactured meats and such products imported in 2001 was 3,761 tonnes and included such products as pate/pastes/spreads/ livers, luncheon meats, black pudding, dried meats, hams and canned products. A proportion of these products were canned (18.5%). The quantity of meat products exported is significantly greater than the quantity imported with export figures of 30,763 tonnes for 2003⁶.

2.2.1 Existing food safety management strategies

Government and industry currently manage food safety in the manufactured and fermented meat industry in a variety of ways, as briefly described in the following sections.

2.2.1.1 Regulatory measures

Australia New Zealand Food Standards Code

FSANZ is responsible for developing, varying and reviewing standards in the Code. State and Territory governments are responsible for the enforcement of these standards.

Some aspects of the manufactured and fermented meat supply chain are covered by the general standards of the Code. These general standards can be found in Chapter 1 of the Code, and apply to all food, including manufactured 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. The compositional standards in Chapter 1 define the additives, vitamins, minerals and processing aids permitted to be added to food products, as well as define chemical and microbiological limits for manufactured meat products. This chapter also describes the processing requirements for some manufactured meat products, for example dried meat, fermented comminuted processed meat, uncooked comminuted fermented meat (UCFM) and semi-dry heat-treated processed meat (Standard 1.6.2).

⁶ These figures are based on a definition of 'game meat product' which means a food that has been processed beyond boning, slicing or trimming, other than soup, that is suitable for human consumption, being a food that -

- (a) has been prepared from game meat or edible game offal; or
- (b) contains in excess of 5% by mass of game meat or edible game offal;

'poultry meat product' means a food that has been processed beyond boning, slicing or trimming, other than soup, that is suitable for human consumption, being a food that -

- (a) has been prepared from poultry meat; or
- (b) contains in excess of 5% by mass of poultry meat.

FSANZ recently completed a review of processing requirements for UCFM products⁷ and revised the relevant standards in the Code to include a mandatory requirement for developing and implementing HACCP (Hazard Analysis Critical Control Point)-based food safety programs, through reference to Standard 3.2.1. The revised Standard was gazetted on 18 September 2003.

Chapter 2 of the Code defines, for particular classes of foods, the labelling and compositional requirements. In this chapter, the definitions, compositional and labelling requirements for manufactured meats is defined under Standard 2.2.1 Meat and Meat products. The following definitions related to manufactured meat are defined:

- manufactured meat means processed meat containing no less than 660 g/kg of meat;
- processed meat means a meat product containing no less than 300 g/kg meat, where meat either singly or in combination with other ingredients or additives, has undergone a method of processing other than boning, slicing, dicing, mincing or freezing, and includes manufactured meat and cured and/or dried meat flesh in whole cuts or pieces;
- sausage means processed meat that is minced, or comminuted meat or a combination thereof, which may be combined with other foods, encased or formed into discrete units, but does not include meat formed or joined into the semblance of cuts of meat.

Standard 2.2.1 also sets out the declaration requirements for offal and fat in meat products. Clause 8 of this standard sets out the requirements for labelling fermented comminuted processed meat and fermented comminuted manufactured meat both on packaged and unpackaged products.

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

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 4694-2002)* (the Australian Standard)⁸. This includes documentation of a food safety plan. The Australian Standard is based on HACCP principles and covers the production and transportation of meat and meat products for human consumption, and as such is consistent with Chapter 3 of the Food Standards Code.

There are eight parts to the Australian Standard:

⁷ 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.

⁸ Available at the Standards Australia website: <http://www.standards.com.au/catalogue/script/search.asp>

- Part 1 lists the objectives and application of the standard, and defines many of the terms used;
- Part 2 sets out the management and production processes and operational hygiene process controls for the production of a wholesome product;
- Part 3 describes the requirements for slaughter and dressing of animals;
- Part 4 sets out processing requirements for chilling, freezing, thawing, tempering, boning and other raw meat processing, curing, cooking, fermenting, canning and rendering meat and meat products for human consumption;
- Part 5 lists the packaging, storage and handling requirements for meat and meat products;
- Part 6 describes the processes required for product identification, traceability, integrity and record keeping;
- Part 7 sets out requirements for the premises and equipment; and
- Part 8 lists the transport requirements for meat and meat products.

The extent to which the Australian Standard is applied along the production and supply chain varies according to the legislative requirements of each specific State and Territory. Therefore, various States and Territories have different requirements at the retail stage. For example, Victoria enforces compliance with the Australian Standard at the retail end of production, whereas the retail of manufactured meat in Western Australia is regulated through Standards 3.2.2 and 3.2.3 of the Code⁹.

Jurisdictions also mandate compliance with the Standard 1.6.1 of the Code, which defines the microbiological limits for specific commodities.

2.2.1.2 Voluntary industry food safety management strategies

There are a limited number of guidelines specific for manufactured meats for the industry to use. These guidelines provide comprehensive assistance to ensure the manufacture of safe products. The most recent of these guidelines was produced by Meat and Livestock Australia (MLA) and is for the hygienic production of smallgoods products. This guideline describes HACCP plans, Good Manufacturing Practices (GMP) and Standard Sanitation Operating Procedures (SSOPs) for uncooked comminuted fermented meats (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 plans are designed to minimise microbial and chemical contamination of the manufactured meat product.

Other guidelines specific for the manufactured meat industry are the *Code of Hygienic Practice for the Smallgoods Industry*, produced by the Meat and Allied Trades Federation of Australia, *A Guide for the Preparation of the Meat Safety Quality Assurance System* (MSQA), second edition, an AQIS publication, the *Advisory Guidelines for Making Comminuted, Uncooked, Meat Products* produced by the former Australia and New Zealand Food Authority (ANZFA) in 1996 and *The Australian Smallgood Food Safety Guidelines* produced in 1989.

⁹ In Western Australia manufacturers of fermented smallgoods have been required to have HACCP based food safety plans in place for a number of years, including at the retail level.

Some of the major customers of the industry (i.e. supermarkets, take-away chains etc) require that their producers have food safety and quality systems in place. Compliance with these is ensured through third party audits.

Information is requested on the guidelines and codes of practice used by producers of manufactured and fermented meats.

Information is required on how food safety risks are controlled by producers of manufactured and fermented meats.

2.2.1.3 Manufactured meat import and export regulations

The Australian Quarantine and Inspection Service (AQIS) has regulatory responsibility for the monitoring of imported food. Imported manufactured meat products and their ingredients must meet the requirements of Chapters 1 and 2 of the Code as described in Section 2.2.1.1. Exported manufactured meat products and their ingredients must also meet specific requirements of the importing countries.

3. Rationale for Mandating Standard 3.2.1

The Ministerial Council's decision in December 2003 to mandate food safety programs for the sectors identified as potentially high risk in Australia was based on the results of the *National Risk Validation Project*, and the *Food Safety Management Systems, Costs, Benefits and Alternatives* study (the Allen Report). Evidence from OzFoodNet on the incidence of food-borne illness and its causes was also considered. These two reports are drawn on in this section.

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.

3.1 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 UCFM.

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

The risk assessment concluded that a very low level of enterohaemorrhagic *Escherichia coli* (EHEC) is likely to be present in a small proportion of UCFM made in Australia. The risk of developing a clinical EHEC infection through consumption of UCFM was estimated to be very low for the general population. However, for the more susceptible subpopulations (young children - particularly those under the age of 6 years, the frail elderly, and people suffering from chronic diseases, or with depressed immune system), EHEC infection resulting from consumption of EHEC contaminated UCFM can lead to very severe implications, including death. For this reason amendments were made to Standards 1.6.1 and 1.6.2, making reference to Standard 3.2.1, as described above in section 2.2.1.1 of this report.

3.2 Cost/benefit analysis

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. 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 outbreaks¹⁰) and 165.6 (for class 1 and 2 outbreaks). This cost benefit analysis strongly supports the mandating of food safety programs for the manufactured meat sector.

¹⁰ 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 judgement on likely effectiveness of a food safety program.

4. 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 internationally competitive food industry;
- the promotion of fair-trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

The specific objective in amending Standard 3.2.1 is to reduce the incidence of food-borne illness in Australia due to manufactured meat consumption, via a nationally consistent approach that requires producers of manufactured meats to have food safety programs.

5 Relevant Issues

5.1 Scientific justification

The National Risk Validation Project has provided the scientific basis for the Ministers' policy decision to require food safety programs for the producers of manufactured meats. This Project will be an important source of information underpinning the assessment of this Proposal. However, there may be additional information relating to health and safety risks available that updates the National Risk Validation Report or may not have been addressed in this Project.

Stakeholders may provide any additional information relevant to the scientific justification to require food safety programs for the producers of manufactured meats.

5.2 Definition of Manufactured Meat

The National Risk Validation Project identified producers of manufactured meats, including fermented meats, as a 'high risk' food business. Although the term 'manufactured meat' was not specifically defined in the National Risk Validation Project, the intention was that this term equate to smallgoods (i.e. not canned meat products) and include fermented meats.

Defining 'manufactured meat and fermented meat' is a crucial part in identifying the products or categories of products, and the types of businesses, that this Standard will apply to. It must be noted that as there is currently so much variation in definition that the number of businesses affected by this standard will vary accordingly.

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 with and government enforcement of Standard 3.2.1. Industry and State and Territory regulators have provided FSANZ with definitions of manufactured meat that are currently used within the industry and specific State regulations. However, a nationally recognised definition must be developed in order to ensure a national approach to food regulation as a whole.

Examples of the various definitions provided are as follows:

5.2.1 *Australia New Zealand Food Standards Code*

- *Manufactured meat* (Standard 2.2.1): processed meat containing no less than 660 g/kg of meat.
- This is a compositional definition in relation to the meat content in products and not a food safety based definition.
- The Code also contains definitions of processed meat and sausage¹¹.

5.2.2 *Codex Alimentarius (Procedural Manual 13th edition) – as used by New Zealand, the US, Canada and the European Union.*

- *Manufactured meat*: products resulting from the processing from raw meat or from the further processing of such processed products, so when cut, the cut surface shows that the product no longer has the characteristics of fresh meat.

5.2.3 *Meat Industry Act 1993*

- *Manufactured meat*: a processed food product that is a mixture of meat and other food (including water) and in at which at least 66% of the unpacked weight of the product is meat, but does not include unmixed meat (any meat that has not been mixed with any other substance).

5.2.4 *AQIS Meat Exports*

- *Meat Product* (Export Meat Orders 1985): a food that has been processed beyond boning, slicing or trimming (but does not apply to any meat or offal that has been further processed only but wrapping, packing, refrigeration, ageing or the simple addition of surface spices, or any combination of these), other than:
 - soup, soup powder or soup concentrate;
 - refined tallow that contains animal fat;
 - gelatine; and
 - regenerated collagen products,

¹¹ *Processed meat* means a meat product containing no less than 300g/kg meat, where meat either singly or in combination with other ingredients or additives, has undergone a method of processing other than boning, slicing, dicing, mincing or freezing, and includes manufactured meat and cured and/or dried meat in whole cuts or pieces.

Sausage means meat that is minced, or comminuted or a combination thereof, which may be combined with other foods, encased or formed into discrete units, but does not include meat formed or joined into the semblance of cuts of meat.

and is suitable for human consumption, being a food that:

- has been prepared from meat, Halal meat or edible offal; and
- contains in excess of 5% by mass of meat, Halal meat or edible offal,

either singly or in combination.

5.2.5 *Australian Meat Industry Council (AMIC)*

- *Manufactured meat* (Standard 2.2.1) – processed meat containing no less than 660 g/kg of meat.
- *Ready-to-eat foods* (Guidelines Dec 2001, FSANZ) – food that is ordinarily consumed in the same state as that in which it is sold or distributed and does not include nuts in the shell and whole, raw fruits and vegetables that are intended for hulling, peeling or washing by the consumer.
- *Smallgoods (or processed meat products)* (Guidelines Oct 1996, FSANZ): – 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, excluding canned shelf-stable meat products. The term ‘smallgoods’ covers a wide range of range of processed meats including ham, bacon, fresh or cooked sausage, fermented sausage, corned beef, pastrami, pate, liver paste, roasted meats and dried meats.

Smallgoods are sold either uncooked or cooked, but not sterilised. Uncooked fermented comminuted meat products are a subsection of smallgoods. The best known example is the ‘salami’ sausage, although not all salamis are uncooked fermented products (some are emulsion-based cooked products). Other uncooked fermented comminuted meat products include csabai, chorizo, landjaeger, braunschweiger, polnische and some cabanossi.

5.2.6 *Meat & Livestock Australia (MLA)*

- MLA provided information as to *small good categories* (MLA guidelines for safe manufacturer):
 - Uncooked Comminuted Fermented Meats (UCFM)
 - Cooked Fermented Meats (CFM)
 - Salami-like sausages (difficult to fit into a particular category)
 - Fresh sausage
 - Cured/cooked products e.g. ham, silverside, frankfurters and Strasburg
 - Bacon
 - Sliced smallgoods (sliced and/or packed under vacuum or modified atmosphere)
 - Slow cured meats e.g. prosciutto
 - Dried meat e.g. jerky
 - Pate
 - Roast meats

5.2.7 *Safefood Queensland*

- *Smallgoods* ((Qld) Food Production (Safety) Act 2000): means:
 - dried meat e.g. beef jerky; or
 - uncooked and fermented minced meat products e.g. salami; or
 - cooked offal or minced meat products e.g. chicken liver pate and luncheon sausage; or
 - cooked whole meat products e.g. ham; or bacon

5.2.8 *Queensland Smallgoods Survey*

- *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.
- *Smallgoods product classes*:
 - bacon e.g. bacon, speck
 - slow, cured uncooked meat products e.g. prosciutto ham, Parma ham
 - cooked, cured whole muscle products e.g. ham, corned beef, pastrami
 - cooked, uncured whole muscle products e.g. roast beef, pork
 - cooked comminuted meat products e.g. all cooked chub meats, cooked in skin sausages (frankfurts, cherries etc.)
 - brawn e.g. brawn, brawn sausage
 - pate e.g. pate, terrine
 - uncooked, fermented, comminuted meat products e.g. dry and semi-dry shelf stable sausage (salami, mettwurst etc.)
 - dried meat products e.g. jerky, biltong, flossed meat
 - other (any other smallgoods products not covered above)

5.2.9 *South Australia Health*

- *Manufactured meat* (Meat Hygiene Regulations 1994): includes the following:
 - smallgoods such as frankfurters, saveloys, brawn, devon, Strasburg, salami, meat paste, chicken roll and similar foods.
 - extended muscle products
 - processed meat product
 - sausage meat
 - sausage

5.2.10 *Department of Health and Human Services (DHHS) Tasmania*

DHHS Tasmania indicated that it does not have State based definitions of manufactured meat or smallgoods that are relevant to this issue. However, the Meat Hygiene Act refers to ‘*meat product*’ which means:

a product –

- (a) that wholly or partially is derived from meat; and
- (b) that is intended for human consumption –

and includes any product which complies with paragraphs (a) and (b) and which is partially processed, prepared for further processing, or fully processed.

As can be seen from the above definitions, the scope of the standard could possibly extend to sausages, manufactured and processed meats. Stakeholder input and advice from the Advisory Group will contribute to determining whether these product categories are included in the scope, during the Draft Assessment stage. Public comment will be sought at Draft Assessment.

Comment is sought on the most appropriate definition of manufactured meat for a national standard.

Comment is sought on consideration of characteristics that will enable specific product categories to be identified (e.g. define foods to be covered by this standard as ready-to-eat)

5.3 Implementation

5.3.1 Industry Compliance

As described in section 2.2.1.1, the majority of producers of manufactured and fermented meats are currently regulated by State and Territory Governments under the Australian Standard which requires the implementation and auditing of food safety plans. The Australian Meat Industry Council (AMIC) provides support through the distribution of a template for businesses to develop their food safety plan. However, there are still inconsistencies in implementation and auditing of State and Territory regulations.

Comment is sought on potential differences between the current regulations and the introduction of Standard 3.2.1.

Are there issues associated with the cost of the current regulations to your business?

Comment is sought on other issues regarding compliance with current regulations.

Comment is sought on the extent to which the requirements of Standard 3.2.1 for documented food safety plans will entail changes to current regulatory practices.

5.3.2 Enforcement and Compliance

As described above, Australian State and Territory jurisdictions currently mandate compliance with the Australian Standard for the production and transportation of meat products, including manufactured meats, which requires documentation of a HACCP based food safety plan. As such, the requirement of Standard 3.2.1 for documented food safety plans does not necessarily entail changes to current regulator practices. However, there may be some changes required for enforcement in some States/Territories. For example, in some states, such as Western Australia, application of the Australian Standard ceases before retail level, hence there is currently no requirement for food safety plans at the retail level.

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 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.

5.3.3 *Tools*

The main tool currently available for industry to use is the food safety plan template and is a valuable resource for both industry and regulators. AMIC is currently developing additional tools applicable to the smaller operators in this sector.

Comment is sought on other tools available to industry.

Comment is sought on the effectiveness of the tools available in meeting their intended purpose.

Comment is sought on other tools that may be useful for industry and regulators.

5.3.4 *Audits*

Under the current regulatory framework, auditing is currently done a minimum of twice yearly by State and Territory Governments, after which auditing frequency will depend on the compliance history of the particular processor and volume of product produced. Manufactured meat processors are also audited on a regular basis by their major customers (i.e. supermarkets etc). These extra audits are usually undertaken by the same people and may pose an unnecessary impost on industry.

Standard 3.2.1 requires a food business to ensure that its food safety program is audited by a food safety auditor at the auditing frequency applicable to the food business. The editorial note to the standard states that ANZFA (now FSANZ) has developed food safety auditor approval criteria for food safety auditors in conjunction with States and Territories. Where current auditing arrangements exist, all effort should be made to ensure this is not then duplicated by the amendments made in this proposal.

5.3.4.1 Auditor competency and approval

Competency of auditors will be assessed as part of the auditor approval process. Approval of auditors is the responsibility of States and Territories who may maintain publicly available lists of approved auditors as part of their overall management of the audit process.

In the consultation process for the development of the Ministerial Policy Guidelines, the need for suitable, qualified auditors was raised. As part of the Australian Government's National Food Industry Strategy¹², the Australian Government Department of Agriculture, Fisheries and Forestry established the National Food Safety Auditor Framework Strategy, which, in 2003, initiated a project to improve the integrity of Australia's food safety auditor infrastructure.

¹² Information on the National Food Industry Strategy is available on the website of the Australian Government Department of Agriculture, Forestry and Fisheries www.daff.gov.au

Work is currently under way to assess existing auditing arrangements within the food industry and make recommendations for national food safety auditor competency criteria. In addition, this project will develop options for the adoption of these criteria and for the ongoing management and administration of food safety auditors. This work builds on earlier work by the former ANZFA (now FSANZ) on the food safety auditor approval process, the audit process and audit management systems described in *Food Safety: An Audit System*¹³. An outcome of the project will be to ensure that good training and on-going professional development, assessment and accreditation underpin competency of food safety auditors.

5.3.4.2 Type of audits

States and Territories determine whether the audit system for food businesses in the particular jurisdiction will be second-party or third-party to the food business. Second party auditors are auditors employed by the government and third party auditors are private and independent of the government. First-party audits are internal audits carried out by staff of the business and outcomes of such audits would not be recognized by the enforcement agency for the purpose of compliance with Standard 3.2.1. However, they are useful for the business to assess for itself whether it is complying with its food safety program and would form an important part of the business's review of its food safety program as required by Standard 3.2.1.

5.3.4.3 Auditing frequency

Determining the frequency of auditing food safety programs is also the responsibility of States and Territories. To assist national consistency in this regard, the former ANZFA (now FSANZ), in conjunction with States and Territories, provided guidance on auditing frequency in *Food Safety: An audit system*. Frequency is dependant on the priority rating of the type of business based on the risk posed to public health and safety. A risk-based system to classify food businesses into priority ratings has been developed by FSANZ and is described in *Food Safety: The priority classification for food businesses*¹⁴. Businesses classified as 'high risk' under this system, which includes producers of manufactured meats, are assigned an initial audit frequency of one audit every six months with an increase or reduction in frequency dependant on compliance.

Since the development of the priority classification system for food businesses, the concept of risk profiling is being developed to provide a foundation for food safety management in Australia. Risk profiling is a process of initially evaluating a food safety problem and its context to identify the potential for the problem to impact on public health. Risk profiling was used by the *National Risk Validation Project* to identify the highest risk food business types and further work is currently being undertaken, funded by DoHA, to identify a nationally applicable, valid process to classify all businesses on the basis of risk.¹⁵ This will support decisions on audit frequency for various classifications of businesses and may affect the frequency of auditing for producers of manufactured meats indicated by the priority classification system.

¹³ *Food Safety: An audit system* is available on the FSANZ website www.foodstandards.gov.au

¹⁴ *Food Safety: The priority classification for food businesses* is available on the FSANZ website www.foodstandards.gov.au

¹⁵ Information on risk profiling is available on the website of the department of health and Ageing e.g. www.foodsecretariat.health.gov.au

Other matters relevant to auditing are addressed by the State and Territory Food Acts for example, duties of food safety auditors and reporting requirements¹⁶.

5.3.4.4 Auditing costs

Studies into costs and impacts of mandatory food safety programs considered ongoing costs to businesses of second or third party audits and concluded that there is a strong case for mandatory food safety programs for producers of manufactured meats. FSANZ, in *Food Safety: An audit system*, indicated that these costs could be reduced for businesses that have a good compliance history by proposing that the audit frequency be reduced.

Comment is sought in relation to auditing expectations for this sector and State and Territory jurisdictions. In particular, how can existing auditing requirements take into account the requirements of Standard 3.2.1 to avoid duplication?

Information and comments is sought on any other issues surrounding auditing.

5.4 Importation of Manufactured Meat

Currently imported manufactured meats are required to comply with the Code and inspections are based on end point testing. The mandating of Standard 3.2.1 will apply to both domestic and imported manufactured meats and may require auditor-based systems or country-to-country certification arrangements rather than relying on testing the final product.

Comment is sort on regulatory options for ensuring compliance of imported manufactured meats against Standard 3.2.1.

6. Regulatory Options

For this proposal two options are considered - to either amend Standard 3.2.1 to mandate food safety programs for producers of manufactured and fermented meats or to maintain the status quo.

Two regulatory options are under consideration:

1. Maintain the status quo; which means that no amendment is made to Standard 3.2.1 to apply to all producers of manufactured and fermented meats (i.e. there will be no National requirement for producers of manufactured and fermented meats to have documented food safety programs). This option would not be consistent with the Ministerial Guidelines to require food safety plans for businesses engaged in producing manufactured and fermented meats.
2. Mandate Standard 3.2.1 for all producers of manufactured and fermented meat. This will be achieved through amendment of Standard 3.2.1 – Food Safety Programs in Chapter 3 of the Code. 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.

¹⁶ Information and copies of State and Territory food legislation is available on the government websites of the States and Territories.

7. Impact Analysis

The Allen Report made an assessment of :

- the costs and benefits of meeting previous State and territory food safety regulations;
- the incremental costs and benefits of meeting Standards 3.1.1, 3.2.2 and 3.2.3 given current practices (at that time);
- the incremental costs and benefits of meeting Standard 3.2.1 given achievement of Standards 3.1.1, 3.2.2 and 3.2.3;
- the advantages and disadvantages of alternatives to a requirement for Food Safety Programs; and
- ways in which compliance costs of meeting the Standards could be minimised.

The Allen Report found that, while the implementation of Standard 3.2.1 includes significant costs, the benefits outweigh these costs for all but 'low risk' businesses.

As previously discussed, 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 outbreaks¹⁷) and 165.6 (for class 1 and 2 outbreaks). This cost benefit analysis strongly supports the mandating of food safety programs for 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.

Information and comments is sought on any other issues relevant to mandating Standard 3.2.1 for producers of manufactured and fermented meats.

In particular, comment is sought on the impact of Standard 3.2.1. on small businesses within the manufactured and fermented meat sector, and suggestions are sought on how these imposts could be minimised.

¹⁷ 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 judgement on likely effectiveness of a food safety program.

8. Consultation

8.1 Advisory Groups

FSANZ will establish an advisory group in May 2004 to assist with amending Standard 3.2.1 – Food Safety Programs in Chapter 3 of the Code for application to the production of manufactured and fermented meats. The advisory group will provide FSANZ with an insight into the current operations of the industry and the role of existing regulations in food safety matters through representation from affected consumer, industry and government stakeholders. The comments, information and data provided during this consultation will be considered during the development of the Draft Assessment Report, which will be released at the end of this year.

8.2 Broad Consultation

The implementation of the Ministerial Policy Guidelines to require producers of manufactured and fermented meats to have food safety programs will require extensive stakeholder consultation to ensure practical solutions to implementation issues.

Currently within this industry, the majority of producers have implemented food safety programs which are regulated by States and Territories using the Australian Standard. However, as discussed in this report, the extent to which the Australian Standard is applied along the production and supply chain varies according to the legislative requirements of each specific State and Territory. Consequently there are some producers who will be required to develop and implement an audited food safety program. Communicating proposed changes within the industry will be a major consideration during the standards development work.

FSANZ will be developing an Interpretative Guide to Standard 3.2.1 and began work in March in consultation with stakeholders.

The risk profiling work currently being conducted by DoHA will continue to reassure industry and consumers that regulation regarding food safety programs is likely to be implemented beyond the four highest risk sectors only when there is clear evidence that the benefits outweigh the risks.

8.3 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 Standard 3.2.1 to manufactured meats will have implications for imported product in this category. This issue will be fully considered at Draft Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia's and New Zealand's obligations under the WTO Technical Barrier to Trade (TBT) or 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.

9. Closing remarks

This Initial Assessment Report provides the first opportunity for stakeholders to comment on and supply information and data to FSANZ regarding the mandatory application of Standard 3.2.1 to producers of manufactured and fermented meats. FSANZ welcomes and encourages stakeholder input. The comments, information and data provided during this consultation will be considered during the development of the Draft Assessment Report, which will be the next formal opportunity for stakeholders to comment.