



# Proposal for a New Zealand Standard for the Production of Uncooked Comminuted, Fermented Meat

Consultation Process

NZFSA Draft Discussion Document No XX/06

February 2007

## Prelims

Amendment 2

February 2007

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## Disclaimer

### *Important Disclaimer*

Every effort has been made to ensure the information in this report is accurate.

The New Zealand Food Safety Authority (NZFSA) does not accept any responsibility or liability whatsoever for any error of fact, omission, interpretation or opinion that may be present, however it may have occurred.

### **Website**

A copy of this document can be found at: <http://www.nzfsa.govt.nz/animalproducts/index.htm>

# 1 Overview

This discussion document outlines the New Zealand Food Safety Authority's (NZFSA) proposal to develop a New Zealand Standard for the production of Uncooked Comminuted, Fermented Meat (UCFM) that is to be sold for human consumption. NZFSA is seeking comments on the proposed Standard. A draft version of the Standard accompanies this document and the requirements are outlined further in the following sections.

UCFM products primarily contain beef and pork meat, salt, nitrite, glucose, spices, seasonings, and ideally a starter culture (to assist fermentation). The ingredients are mixed and comminuted (reduced in size) to produce a "batter". The mixture is then stuffed into a casing, fermented, dried, and sometimes smoked, to achieve the desired end product. An example of these products is salami.

NZFSA recently completed an assessment of the existing data and information on the pathogen, shiga-like toxin producing *Escherichia coli* (STEC), found in raw meat used in UCFM products. It was identified that the current level of control during production of UCFM products, in some premises in New Zealand, is insufficient to assure safety. This is in regard to the potential consumer health risks associated with the presence of STEC in the raw meat ingredient going into UCFM products.

New Zealand to date has not had any notified human illness cases attributed to the consumption of UCFM products. However, it is more likely that this lack of cases is due to the current low level of STEC in New Zealand raw meat rather than good manufacturing practice. It can not be assumed that the low level of STEC will remain constant into the future. Similarly, in the absence of government regulations for the production of UCFM, there can be no assurance that product made and sold by some UCFM producers does not pose a risk to New Zealand consumers. Therefore it is proposed that a New Zealand Standard for the production of UCFM be developed and implemented.

The proposed draft New Zealand Standard is based on the essential relevant parts of Part 1.6.2 (Australia-only) of the Australia New Zealand Food Standards Code (FSC), the New Zealand Pork Industry Board, Pork Quality Improvement Process (PQIP) 07 Code of Practice, and other elements that NZFSA have identified as essential inclusions.

It is believed that many of the major UCFM producers in New Zealand are already likely to be using either the existing Australian Standard or PQIP Code of Practice. Therefore the implementation of the proposed Standard will most likely affect the smaller producers who may not have a HACCP (Hazard Analysis and Critical Control Point) based system in place.

## 1.1 Consultation

This paper is being distributed for comment to producers of UCFM, including wholesale processors, retail butchers and Dual Operator Butchers, as well as to industry associations and other relevant government agencies. Submissions are invited from any interested party, whether representing organisations or acting as individuals. When sent on behalf of an organisation, the submission should include the position in the organisation of the person signing the submission and the extent of internal consultation undertaken in preparing the submission. All submission formats will be accepted and you are welcome to comment on any matters relating to the proposed Standard.

### **Please send your submission to:**

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### **Closing date for submissions**

The closing date for submissions is 30 March 2007.

### **Official Information Act**

The Official Information Act (OIA) 1982 states that information is to be made available unless there are grounds for withholding it. Grounds for withholding information are in the OIA. Submitters may wish to indicate grounds for withholding information contained in their submission. Reasons for withholding information could include that information is commercially sensitive or that the submitters wish personal information such as names or contact details to be withheld. NZFSA will take such indications into account when determining whether or not to release information. Any decision to withhold information requested under the OIA may be reviewed by the Ombudsman.

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### **Process after submissions close**

After analysing submissions, NZFSA will make recommendations to the Minister for Food Safety. If the Minister agrees, the necessary steps to issue a New Zealand Standard for the production of UCFM, along with relevant guidelines, will be taken, and implementation will commence.

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## 2 Background

### **What are the risks associated with UCFM products?**

UCFM products primarily contain beef and pork meat, salt, nitrite, glucose, spices, seasonings, and ideally a starter culture. The ingredients are mixed and comminuted (reduced in size) to produce a “batter”. The mixture is then stuffed into a casing, fermented, dried, and sometimes smoked, to achieve the desired end product. An example of these products is salami.

It has been established that STEC bacteria can be present in the raw meat going into fermented meat products, and although at low levels, the fact that it is there, and that the dose required to cause infection is very low, means it is a problem for New Zealand. These products rely on a reduced pH and water activity for microbial stability and if the required parameters are not met during production the bacteria won't be controlled and the risk of it being present in the finished product is high.

STEC bacteria are a diverse group of *Escherichia coli* serotypes, the best known of which are *Escherichia coli* O157:H7 and *Escherichia coli* 0111. The clinical consequences of infection may be serious, including kidney and other systemic failures, resulting in long hospitalisations, life-long ongoing illness, and sometimes even death. Between 1998 and 2005, there were between 70 and 100 cases of STEC illness in New Zealand per year (for 2005, the total number of cases (being 92) gave a rate of 2.5 cases/100,000 head of population) (Gilbert et al, 2006).

Over the 1994 Christmas holiday period, the South Australia, Victoria and New South Wales states of Australia experienced an outbreak associated with UCFM products, which is commonly known as the 'Garibaldi Incident'. One 4 year old child died and many were hospitalised after eating Garibaldi brand smallgoods, in particular Garibaldi's fermented meat product mettwurst. Most of the people hospitalised were children, whose immune systems could not cope with the effects of the food poisoning.

The Emergency Management Australia (EMA) Disasters Database, provides information about what the subsequent investigation and court cases identified, it states that the company was found:

- To have failed to adequately sterilise machinery,
- To have mixed older meat with fresh meat,
- To have failed to notify the Health Department (South Australia) of the possible contamination of the product with salmonella after it was detected in their production facility.

As a consequence of the 'Garibaldi Incident' the Australia New Zealand Food Standards Authority (now Food Standards Australia New Zealand – FSANZ) developed a processing and food hygiene standard (Part 1.6.2 of the FSC), this standard is applicable only in Australia as it is outside the scope of the Joint Australia New Zealand Food Standards setting system.

A risk profile on STEC in UCFM products, completed for NZFSA by the Institute of Environmental Science & Research (ESR) (Gilbert et al, 2006), concluded that:

- The current rate of STEC infection in New Zealand is approximately 2 notified cases per 100,000 population (all cases sporadic, no widespread outbreaks),
- There is potential for the presence of pathogenic STEC in raw meat in New Zealand, which could then be used as an ingredient in the production of UCFM,
- The majority of UCFM imported into New Zealand will be from Australia where all UCFM products are required to meet the FSANZ standard,
- The consumption of UCFM is low in comparison with other meat types (both in terms of servings and weight).

The risk profile also stated that:

“As was concluded for Australia [FSANZ risk assessment P251], the risk is low but the consequences, particularly for susceptible groups, such as young children, are severe. Given the potential for exposure, on the basis of the observed prevalence of STEC in red meat in New Zealand, the risk needs to be managed by an appropriate measure.”

A survey in Toronto in 1994-1995 (Gilbert *et al* 2006 quote "Lee and Styliadis, 1996") found that UCFM products made in small deli-type establishments were more likely to be left constantly unrefrigerated, and have a higher pH and water activity than products made at larger commercial plants. This suggested that product from smaller processors of UCFM might pose a greater risk to consumers.

Although there have not been any cases of STEC illness attributed to the consumption of UCFM products in New Zealand to date, NZFSA has identified a potential risk through the lack of understanding by UCFM producers of the controls required during production of UCFM.

### **Why have UCFM products emerged as an issue in New Zealand?**

During assessment and registration of Dual Operator Butchers (DOBs) risk management programmes (RMPs under the Animal Products Act 1999) in 2005, NZFSA identified that in a number of cases essential processing parameters that ensure microbial safety of UCFM products were not being carried out. Further investigations revealed limited technical knowledge and adherence to current available standards. NZFSA has continued to register DOBs RMPs but has put on hold the processing of UCFM products under the programmes until the operators can demonstrate sufficient hazard control.

In addition to DOBs, there are other food businesses that may be currently preparing these products. Those that could potentially be involved are likely to fall into the following groups:

- Retail butchers and retail operators who are regulated by the Food Hygiene Regulations,
- Retail butchers and retail operators who are exempt from the Food Hygiene Regulations due to having an approved Food Safety Programme (FSP) in place,
- Secondary processors who have a registered RMP or an approved FSP in place,
- Secondary processors who are regulated by the Food Hygiene Regulations.

NZFSA recognise that many of the secondary processors may already follow the PQIP 07 Code of Practice or FSANZ standard Part 1.6.2 for UCFM production therefore it is likely that the group of operators that present the greatest concern of uncontrolled UCFM production will be those registered under the Food Hygiene Regulations. This may include small boutique delicatessen operations.

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The following list provides examples of the food safety issues identified, which caused concern for NZFSA:

- Starter cultures were not used, nor understood,
- Commercial premixes were used without knowledge of their composition nor was guidance provided from suppliers as to appropriate use and expected final result,
- Premixes containing acidulant, if any, were often used solely for flavouring, not for microbial control, as in fermentation,
- Operators were unaware of critical product or process parameters,
- Fermentation and maturation was often occurring under ambient conditions, with process timing and outcome, dependant on the conditions at that time,
- Operators were not aware of the microbiological conditions of raw materials or final products.

## 3 Current Risk Management Controls

New Zealand does not currently have a specific standard relating to the production of UCFM products. Food businesses in New Zealand currently have to operate in accordance with either the Animal Products Act 1999 or the Food Act 1981.

### 3.1 *Animal Products Act 1999*

The following persons must operate a registered risk management programme (RMP) under the Animal Products Act 1999 for the production or processing of animal material or animal product:

- Primary processors of animal material,
- Secondary processors of animal products intended for human or animal consumption, except to the extent that they are subject to the Food Act regime,
- Retail butchers who are dual operator butchers,
- Other persons required to operate under an RMP as specified by Order in Council under section 15 of the Animal Products Act 1999.

An RMP is a documented programme registered under the Animal Products Act 1999 and is designed to identify and control hazards and other risk factors in relation to the production and processing of certain animal material and animal products. An RMP is put in place to ensure that the resulting animal product is fit for intended purpose.

### 3.2 *Food Act 1981*

Historically food being sold in New Zealand had to be made in premises that were registered and inspected by local authority Environmental Health Officers (EHO's). Food premises were inspected for compliance with the Food Hygiene Regulations 1974. Since 1996 food businesses in New Zealand have had the option to develop a food safety programme (FSP) and be exempt from the Food Hygiene Regulations 1974. The process is applicable to any size and type of food business.

An FSP is a documented programme approved under the Food Act 1981, is based on the HACCP system, and is designed to identify and control food safety risk factors in order to establish and maintain food safety. The food safety risk factors may relate to the production, manufacture, preparation, packaging, storage, handling, transport, distribution or sale of food.

### **3.3 Domestic Food Review**

The Domestic Food Review (DFR) is a significant long term project currently being undertaken by NZFSA. Its purpose is to create a food regulatory programme across all sectors of New Zealand's domestic food industry that promotes and delivers safe and suitable food. It is only the second time in the last 30 years that the Government's role in the New Zealand domestic food sector has been critically examined at an official level. DFR work to date, has developed a comprehensive package of proposals for the future food regulatory regime. In particular the DFR proposes Food Control Plans (FCPs) which will improve and simplify food safety in New Zealand. The DFR proposes that all 'Persons' will have and implement a documented FCP unless agreed alternative mechanisms are in place, e.g. the DFR will accommodate for those businesses that already have HACCP based risk management plans in place, e.g. RMPs.

### **3.4 PQIP 07 Code of Practice and FSANZ Standard Part 1.6.2**

PQIP 07 Code of Practice and FSANZ Standard Part 1.6.2 are the risk management controls most commonly utilised by New Zealand producers of UCFM, but they are not mandatory.

PQIP 07 is an industry devised Code of Practice. The New Zealand Pork Industry Board facilitates PQIP 07 and works closely with the various industry sectors. PQIP 07 involves the application of the international HACCP system and meeting the industry agreed minimum requirements. Manufacturers can obtain a copy and adopt the PQIP 07 Code of Practice by becoming a member of the Pork Processors Association. Accreditation to PQIP 07 requires an independent audit.

FSANZ Standard Part 1.6.2 is applicable only in Australia as it is outside the scope of the Joint Australia New Zealand Food Standards setting system.

Given the ability of STEC to survive in UCFM products, and the suggestion that pathogenic STEC may be more acid tolerant than other strains, FSANZ and the developers of PQIP 07 recognised the importance of understanding and controlling the microbiological quality of ingredient meats, and selecting a process sufficient to kill any STEC present.

Control of pH reduction through the use of starter cultures and the appropriate time/temperature combinations of drying have been shown to be critical for the safe production of UCFM products. These essential requirements result in finished product characteristics that are unfavourable for the growth of harmful pathogens like *Escherichia coli* O157:H7, and indeed, kill any O157 present.

PQIP 07 Code of Practice and FSANZ Standard Part 1.6.2 require that the production of UCFM must include:

- Implementation of a HACCP based food safety programme, in accordance with Part 3.2.1 of the FSC, that has been verified and audited to ensure effective reduction in number of *Escherichia coli* in UCFM product to a level specified in Part 1.6.1 of the FSC,
- Meat for the UCFM must be stored by the manufacturer at 5°C or below prior to fermentation,
- The *Escherichia coli* count of raw material must be known and must be equal to or below the process lethality or validated process. This can be achieved by:
  - National Microbiological Database (NMD) if using New Zealand raw meat ingredients; or
  - Equivalent data source from country of origin if using imported raw meat ingredients; or
  - Adequate data provided by the company supplying the raw meat ingredients; or
  - Adequate data obtained by the manufacturing through own microbiological testing of raw meat ingredients.
- No 'back slopping', i.e. previously fermented meat must not be used as a starter culture or an ingredient in UCFM (FSANZ Standard only),
- The reprocessing of **fully processed compliant** product is allowed (PQIP 07 only),
- Fermentation must be initiated through the use of a starter culture,
- The temperature and time of fermentation (and smoking) and maturation/drying steps must be monitored and recorded,
- The pH of fermenting UCFM together with final *A<sub>w</sub>* (water activity) must be monitored and recorded,
- The microbiological standards in Part 1.6.1 of the FSC must be achieved during fermentation and subsequent processes prior to the sale from processing factory.

## 4 Risk Management Options

Three possible risk management options were developed by NZFSA for the production of UCFM:

1. Take no further action, or
2. Prohibit production of UCFM, or
3. Develop a regulatory standard.

All options were considered and assessed for feasibility, practicality and effectiveness.

NZFSA believes that option 1 is not appropriate because although the risk of STEC illness associated with UCFM consumption is low, the consequences, particularly for susceptible groups such as young children, are severe. Given the potential for STEC to be present in red meat in New Zealand, the risk needs to be managed further by an appropriate measure.

NZFSA believes that prohibition of UCFM production in New Zealand (option 2) is unnecessary at this stage. NZFSA is of the view that the food safety issues associated with the production of UCFM can be managed appropriately without implementing this measure.

Option 3, a regulatory standard, is recognised as being the most feasible, practical and effective measure to manage the risks associated with production of UCFM. There are a number of key reasons that support this decision:

- The food safety issues that arose during assessment of DOB RMPs cannot be ignored,
- The lack of understanding by many operators of the quality of raw meat ingredients being used,
- The presence of unacceptable 'back slopping' in some processes, which was linked to the outbreak in Australia,
- The view that, although New Zealand has had no reported outbreaks, this cannot be attributed to good management but more so due to the low levels of STEC in our raw materials. However, as time goes on this status may not remain,
- The proposal is in line with current international best practice, e.g. Australia and the USA.

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## 5 Implications to Industry

Those businesses not currently appropriately addressing the hazards associated with UCFM, especially those that are registered under the Food Hygiene Regulations 1974 will face increased compliance costs. These will vary according to the nature and size of the existing operation but could include costs relating to:

- Development, approval, registration, verification etc of FSPs or RMPs if not already in place;
- Purchase of equipment and/or facilities;
- Microbiological testing of raw ingredients and finished products; and
- Staff training.

It is possible that some UCFM producers may choose to cease production of these products to avoid new compliance costs.

The Business Compliance Cost Statement in Appendix A provides further detail on the potential compliance costs involved.

## 6 Proposed Standard Development

UCFM producers are currently regulated under the Food Act 1981 or the Animal Products Act 1999 therefore the proposed Standard, if accepted, will be enabled by both Acts.

To allow this to happen, criteria or preconditions under each Act must be met. These preconditions (outlined below), and NZFSA's consideration of each, are detailed in Appendix B.

### **Food Act 1981**

#### **Section 11E—Preconditions for issuing food standard**

1. In issuing any food standard, the Minister shall take into account the following:
  - a. The need to protect public health,
  - b. The desirability of avoiding unnecessary restrictions on trade,
  - c. The desirability of maintaining consistency between New Zealand's food standards and those applying internationally,
  - d. New Zealand's obligations under any relevant international treaty, agreement, convention, or protocol, and, in particular, under the Australian-New Zealand Joint Food Standards Agreement, and
  - e. Such other matters as the Minister considers appropriate.
  
2. The Minister shall not issue any food standard unless the Minister is satisfied that appropriate consultation has been carried out with respect to the food standard, including (without limitation)—
  - a. Adequate and appropriate notice of the intention to issue the food standard;
  - b. A reasonable opportunity for interested persons to make submissions; and
  - c. Adequate and appropriate consideration of any such submissions.

## ***Animal Products Act 1999***

### ***Section 44—Regulations may prescribe animal product standards***

44(7) In prescribing any standards under this section, the Minister is to have regard to—

- a. The need to protect the health of consumers and users of animal products,
- b. The desirability of facilitating market access,
- c. The desirability of maintaining consistency between New Zealand animal product standards and any relevant standards, requirements, or recommended practices that apply or are accepted internationally, and
- d. Such other matters as the Minister considers relevant.

### **Section 163(3)—The Director-General must:**

- a. Do everything reasonably practicable on his or her part to consult with the persons or organisations that appear to the Director-General to be representative of the interests of persons likely to be substantially affected by the making of the relevant order or regulations or the setting of the relevant specifications or requirements referred to in subsections (1) and (2); and
- b. In the case of a proposed Order in Council, advise the Minister of the results of any such consultation.

As mentioned previously the proposed New Zealand Standard is likely to be based on the relevant sections of PQIP 07 Code of Practice and FSANZ Standard Part 1.6.2. The development and consultation phases will ensure the Standard is applicable and appropriate to the production of UCFM in New Zealand.

A draft version of the proposed Standard is being issued with this discussion document for comment. Please note that this is a consultation draft only and should the decision be made to introduce a New Zealand Standard for the production of UCFM then the final version may change after the consultation process.

## 7 References

Gilbert, S, Lake, R, Hudson, A, & Cressey, P (2006), 'Risk Profile: Shiga-like toxin producing Escherichia coli in UCFM Products' (unpublished draft), Institute of Environmental Science & Research (ESR), Christchurch, New Zealand.

Food Standards Australia New Zealand (FSANZ), 2006 version, 'Food Standards Code'.

Pork Industry Board, Pork Quality Improvement Process (PQIP) 07 Code of Practice, Part 2.

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# Appendix A – Regulatory Impact Statement and Business Compliance Cost Statement

## **Regulatory Impact Statement**

### **Statement of the nature and magnitude of the problem and the need for government action**

1. Currently, there is no mandatory New Zealand standard controlling the production of uncooked comminuted, fermented meat (UCFM) made for human consumption.
2. The raw meat ingredients used to produce UCFM can contain bacteria, specifically 'shiga-like toxin producing Escherichia coli' (STEC). STEC can cause severe illness, and even death, in vulnerable population groups such as children and the elderly.
3. NZFSA has assessed data and information on STEC found in raw meat used in UCFM products. Although at low levels, STEC is present in the raw meat, which can be a problem if these products are not safely produced. NZFSA has established that current level of control during UCFM production in New Zealand, at some premises, is insufficient to give assurances about the safety of UCFM products. There was evidence by some producers, of a lack of technical knowledge of safe production processes, and also lack of understanding about the quality of the raw ingredients being used.
4. If further measures to control the production of UCFM are not introduced, New Zealand could be vulnerable to a serious outbreak of illness related to the consumption of UCFM products. Such an outbreak could result in long-term treatment and hospitalisations, and even death. It could also threaten New Zealand's domestic and international reputation as a producer and exporter of safe food products.
5. For further information, refer to Section 2 "Background" above.

### **Statement of the public policy objective(s)**

1. The public policy objectives are to:
  - Reduce and/or prevent the incidence of food borne disease in New Zealand, specifically STEC infection; and

- Maintain and enhance New Zealand's domestic and international reputation as a producer and exporter of safe food products.

***Statement of feasible options (regulatory and/or non-regulatory) that may constitute viable means for achieving the desired objective(s)***

**Status Quo**

1. The default option is for no further action to be taken. However, this option would neither guarantee the public policy objectives nor resolve the problems identified above. This option is considered inappropriate because the risks of human illness related to STEC found in UCFM products are too significant, as is the potential negative impact on New Zealand's reputation as a supplier of safe food.

**Prohibit the Production of UCFM Products**

2. This option would have a detrimental financial impact on UCFM producers. It would also limit choice for New Zealand consumers. It is considered unnecessary because the food safety issues associated with production of UCFM can be addressed through other measures.

**Preferred Option**

3. The preferred option is to develop a regulatory Standard for the production of UCFM sold for human consumption under the Food Act 1981 and the Animal Products Act 1999. The advantages of this option are that:
  - It will meet the public policy objectives stated above and resolve the food safety problems linked to UCFM production,
  - It will resolve the lack of understanding demonstrated by many operators about the safe production processes and quality of raw materials used in UCFM products, and
  - It will be consistent with current international best practice with, for example, similar regulatory standards in place in Australia and the USA.

***Statement of the net benefit of the proposal, including the total regulatory costs (administrative, compliance and economic costs) and benefits (including non-quantifiable benefits) of the proposal, and other feasible options***

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## Government

1. The proposed Standard will benefit Government as it will assist:
  - To achieve Government's desired outcome of reducing the incidence of food borne illness in New Zealand,
  - To maintain and enhance New Zealand's reputation both domestically and internationally as a producer of safe, quality food, and
  - By preventing and/or reducing the incidence of illness related to UCFM consumption, potential government expenditure on health treatment and hospitalisation may be avoided.

The setting of fees/charges will enable the government to appropriately fund any services it provides to UCFM producers as a result of the proposed Standard, e.g. registration, assessment and verification of RMPs or FSPs.

## Industry

2. UCFM products are likely to be produced by the following types of operators:
  - Retail butchers and retail operators regulated by the Food Hygiene Regulations,
  - Retail butchers and retail operators exempt from the Food Hygiene Regulations due to having an approved Food Safety Programme (FSP) in place,
  - Secondary processors (e.g. delicatessens or small goods manufacturers) who are regulated by the Food Hygiene Regulations,
  - Secondary processors who have a registered Risk Management Programme (RMP) or an approved FSP in place, and
  - Dual operator butchers who are required to have a registered RMP in place.
3. If a significant outbreak of illness associated with the consumption of UCFM was to occur, all UCFM producers could be impacted negatively, due to a potential reduction in consumer confidence in, and purchasing of, UCFM products. The proposed Standard will help protect against such risk.
4. Some dual operator butchers (DOBs) are currently not producing UCFM. This is because all DOBs were required to have an RMP registered by 1 July 2005 under the Animal Products Act 1999 but, when assessing and registering these RMPs, it became clear that essential processing parameters that ensured the safety of UCFM products were not being carried out by

some operators. The introduction of the proposed Standard will benefit DOBs who will obtain clarification and guidance around the safe production of these products enabling them to produce these products again.

5. The proposed New Zealand Standard will be based on an existing Code of Practice (the New Zealand Pork Industry Board, Pork Quality Improvement Process (PQIP) 07 Code of Practice) and the FSANZ Standard Part 1.6.2 (Australia only). Many major New Zealand UCFM producers may already be voluntarily following these and are therefore not expected to face onerous costs when transferring to the requirements in the proposed Standard.
6. Those businesses not currently appropriately addressing the hazards associated with UCFM will face increased compliance costs. These will vary but could include costs relating to:
  - Development, approval, registration, verification of FSPs or RMPs if not already in place;
  - Purchase of equipment and/or facilities;
  - Microbiological testing; and
  - Staff training.

It is possible that some businesses may choose to cease production of UCFM products to avoid new compliance costs.

### **Society**

7. Society could benefit from the proposed Standard as it may:
  - Help prevent the outbreak of potentially serious illness;
  - Increase consumer confidence in UCFM products; and
  - Maintain and enhance New Zealand's reputation as a country that can be relied upon to supply safe food products.

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### ***Statement of consultation undertaken***

#### Stakeholder Consultation

1. NZFSA has been in communication with Retail Meat New Zealand during the review of UCFM production. This public discussion document, outlining the proposed Standard, is now being circulated, with an invitation to industry associations and producers of UCFM products to make submissions.

#### **Government Agencies**

2. Comment has been sought from the Department of Prime Minister and Cabinet, the Ministry of Agriculture and Forestry, the Ministry of Consumer Affairs, the Ministry of Economic Development, the Ministry of Health and the Treasury.

### **Business Compliance Cost Statement**

#### ***Source of Compliance Costs***

To meet the requirements of the proposed Standard, UCFM producers may incur:

- One-off costs such as purchasing new equipment, registration and approval of RMPS and FSPs (where not already in place) and training of staff; and
- Ongoing costs such as verification and auditing of RMPs and FSPs, microbiological testing (of raw ingredients and finished products) and training of staff.

#### ***Parties Likely to be Affected***

The impact of costs relating to the proposed Standard will vary according to the size, complexity and nature of the production operation.

Many producers of UCFM will already be voluntarily meeting the requirements of the PQIP Code of Practice or FSANZ Standard Part 1.6.2 for production of UCFM. They will also have FSPs or RMPs in place. This will minimise the new compliance costs which they will face.

Those businesses currently operating only under the Food Hygiene Regulations 1974, who are most likely to be smaller operators such as boutique delicatessens, will incur the greatest costs. This is because they currently may not meet many of the requirements of the proposed Standard.

### ***Estimated Compliance Costs***

#### a. One-off Costs

<p>Purchase of new equipment/facilities</p> <ul style="list-style-type: none"> <li>- pH meter</li> <li>- thermometer (handheld including probe)</li> <li>- thermometer (wall mounted)</li> <li>- water activity meter</li> <li>- dryer (e.g. bench top or separate room)</li> <li>- smoker (e.g. bench top or separate room)</li> </ul>	<p>Need, type and cost of equipment will vary depending on size, complexity and nature of the operation.</p>
<p>Development of Programmes</p> <p>RMPs</p> <ul style="list-style-type: none"> <li>- a initial evaluation</li> <li>- b application fee</li> <li>- c assessment fee</li> </ul> <p>FSPs</p> <ul style="list-style-type: none"> <li>- d initial approval</li> </ul>	<ul style="list-style-type: none"> <li>- a Costs set on individual basis by evaluator</li> <li>- b \$100</li> <li>- c \$320 on average</li> <li>- d \$65+ GST per hour</li> </ul>
<p>Staff training/competency</p>	<p>Will vary according to requirements of producer and training provider used.</p>

b. Ongoing Costs

<p>Ongoing Programme Costs</p> <p>RMPs</p> <p>- a annual verification</p> <p>FSPs</p> <p>- b audit</p>	<p>- a \$310 approximately + travel costs</p> <p>- b Costs vary according to auditor used</p>
<p>Microbiological Testing</p>	<p>Regular microbiological testing of raw ingredients and finished products, firstly to validate the programme then ongoing as part of verification activities.</p>
<p>Staff training/competency</p>	<p>Will vary according to requirements of producer and training provider used.</p>

***Steps Taken to Minimise Compliance Costs***

These include:

- Basing the proposed Standard on existing PQIP Code of Practice and FSANZ Standard Part 1.6.2 which many producers of UCFM will already be following,
- Ensuring the proposed Standard is enabling and outcomes based,
- Provision of some training by NZFSA to assist businesses to effectively address competency needs, and
- Providing a transition period for those needing to develop RMPs or FSPs, or those with existing RMPs or FSPs, to incorporate any changes required by the proposed Standard.

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## Appendix B – Preconditions for issuing a Standard

### ***Food Act 1981***

#### ***Section 11E—Preconditions for issuing food standard***

1. In issuing any food standard, the Minister shall take into account the following:
  - a. The need to protect public health,
  - b. The desirability of avoiding unnecessary restrictions on trade,
  - c. The desirability of maintaining consistency between New Zealand's food standards and those applying internationally,
  - d. New Zealand's obligations under any relevant international treaty, agreement, convention, or protocol, and, in particular, under the Australian-New Zealand Joint Food Standards Agreement,
  - e. Such other matters as the Minister considers appropriate.
2. The Minister shall not issue any food standard unless the Minister is satisfied that appropriate consultation has been carried out with respect to the food standard, including (without limitation)—
  - a. Adequate and appropriate notice of the intention to issue the food standard; and
  - b. A reasonable opportunity for interested persons to make submissions; and
  - c. Adequate and appropriate consideration of any such submissions.

### ***Animal Products Act 1999***

#### ***Section 44—Regulations may prescribe animal product standards***

- 44(7) In prescribing any standards under this section, the Minister is to have regard to—
- a. The need to protect the health of consumers and users of animal products,
  - b. The desirability of facilitating market access,

- c. The desirability of maintaining consistency between New Zealand animal product standards and any relevant standards, requirements, or recommended practices that apply or are accepted internationally,
- d. Such other matters as the Minister considers relevant.

**Section 163(3)—The Director-General must:**

- a. Do everything reasonably practicable on his or her part to consult with the persons or organisations that appear to the Director-General to be representative of the interests of persons likely to be substantially affected by the making of the relevant order or regulations or the setting of the relevant specifications or requirements referred to in subsections (1) and (2); and
- b. In the case of a proposed Order in Council, advise the Minister of the results of any such consultation.

**Condition 1 – Protect public health**

NZFSA assessments to date show that not all UCFM producers have appropriate control measures in place. Currently there is a risk associated with UCFM production, and consequently a risk to human health. The introduction of the proposed Standard for UCFM production will provide for better controls, increased understanding by producers, therefore safe production of these products, and consequently increased protection of public health.

**Condition 2 – Avoid trade restrictions, facilitate market access**

Australia and the United States currently require New Zealand producers of UCFM to meet recognised requirements or they cannot export these products (e.g. approved FSP or registered RMP, adopt PQIP 07 or FSC Part 1.6.2). These requirements would possibly apply to the export of these products to other countries as well therefore the introduction of the proposed Standard for UCFM products will potentially facilitate access to additional markets for these products. With regards to imports of UCFM-like products into New Zealand, there have been 232 consignments of products so far for 2006, 99.8% were from Australian origin and 0.2% from the European Union. New Zealand has trade agreements with these countries regulatory authorities.

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### **Condition 3 – Consistent with international standards**

Given the current requirements for the production of UCFM products, there is a gap in New Zealand standards for these products in relation to other countries. It is in New Zealand's best interests to remain consistent with food standards applying internationally, in particular, those in Australia. The introduction of the proposed Standard for UCFM products will therefore be more in line with our major trading partners (e.g. Australia and the United States).

### **Condition 4 – New Zealand's obligation under international agreements**

New Zealand and Australia have a joint food standards setting system in place. Currently the FSANZ Standard Part 1.6.2 is applicable to the production of UCFM products in Australia only, therefore is outside the scope of the Joint Food Standards. The implementation of the proposed Standard in New Zealand would better align and harmonise with the Australian food standards system.

### **Condition 5 – Carry out appropriate consultation**

NZFSA will ensure an appropriate consultation period to enable all interested parties to adequately assess the proposed Standard and provide suitable feedback within the required timeframe. Consultation will primarily involve distribution of this discussion document, along with the draft proposed Standard, to producers of UCFM products, industry sector associations and other relevant government agencies. Once feedback, in the form of submissions, have been received and analysed, NZFSA will make further decisions on the way forward.