10/03
16 July 2003

FINAL ASSESSMENT REPORT

PROPOSAL P251

REVIEW OF PROCESSING REQUIREMENTS FOR UNCOOKED COMMINUTED FERMENTED MEAT (UCFM) PRODUCTS
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 Food Standards Code (Code) is prescribed in the Food Standards Australia New Zealand Act 1991 (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.
Final Assessment Stage

The Authority has now completed two stages of the assessment process and held two rounds of public consultation as part of its assessment of this proposal. This Final Assessment Report and its recommendations have been approved by the FSANZ Board and notified to the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council).

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

In New Zealand, the New Zealand Minister for Health gazettes the food standard under the New Zealand Food Act. Following gazetral, the standard takes effect 28 days later.

Further Information

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

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

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

Assessment reports are available for viewing and downloading from the FSANZ website [www.foodstandards.gov.au](http://www.foodstandards.gov.au) or alternatively paper copies of reports can be requested from the Authority’s Information Officer at info@foodstandards.gov.au including other general enquiries and requests for information.
CONTENTS

EXECUTIVE SUMMARY AND STATEMENT OF REASONS ................................................. 6

BACKGROUND .......................................................................................................................... 6
DRAFT ASSESSMENT .................................................................................................................. 6
PUBLIC CONSULTATION ........................................................................................................ 6
FINAL ASSESSMENT .................................................................................................................. 7
STATEMENT OF REASONS ...................................................................................................... 7

1. INTRODUCTION ................................................................................................................ 8

2. REGULATORY PROBLEM ............................................................................................... 9

3. OBJECTIVE ...................................................................................................................... 10

4. BACKGROUND .................................................................................................................... 11
   4.1 PATHOGENIC MICROORGANISMS ASSOCIATED WITH UCFM ............................... 11
   4.2 OUTBREAKS ASSOCIATED WITH EHEC IN UCFM .................................................. 11
   4.3 COMPLIANCE WITH AND ENFORCEMENT OF THE EXISTING STANDARD ............. 12

5. RELEVANT ISSUES ........................................................................................................... 14
   5.1 CONCLUSIONS OF THE MICROBIOLOGICAL RISK ASSESSMENT .......................... 14
   5.2 CONCLUSIONS OF THE FOOD TECHNOLOGY REPORT ........................................... 14
   5.3 ISSUES IDENTIFIED WITH CURRENT CLAUSE 9 OF STANDARD 1.6.2 ...................... 14
   5.4 OTHER ISSUES ............................................................................................................. 15
   5.5 RISK MANAGEMENT ISSUES ...................................................................................... 15

6. REGULATORY OPTIONS .................................................................................................... 16
   6.1 OPTION 1 ...................................................................................................................... 17
   6.2 OPTION 2 (MODIFIED) ............................................................................................... 18
   6.3 MINOR TECHNICAL CHANGES TO E. COLI LIMIT .................................................. 18

7. IMPACT ANALYSIS .......................................................................................................... 19
   7.1 IMPACT OF OPTION 1 .............................................................................................. 19
   7.2 IMPACT OF OPTION 2 (MODIFIED) ......................................................................... 19

8. CONSULTATION .................................................................................................................. 21
   8.1 PUBLIC CONSULTATION AT INITIAL ASSESSMENT ............................................... 21
   8.2 PUBLIC CONSULTATION AT DRAFT ASSESSMENT .................................................. 21
   8.3 OUTCOME OF PUBLIC CONSULTATION ................................................................. 24

9. DRAFT AMENDMENT AT FINAL ASSESSMENT ............................................................ 26

10. CONCLUSION AND RECOMMENDATION ................................................................... 26
    10.1 JUSTIFICATION FOR THE RECOMMENDED REGULATORY MEASURES ............. 26

11. IMPLEMENTATION AND REVIEW ............................................................................... 27

ATTACHMENTS ..................................................................................................................... 28

ATTACHMENT 1 - DRAFT VARIATIONS TO FOOD STANDARDS CODE ...................... 29
Executive Summary and Statement of Reasons

Background

The consumption of uncooked comminuted fermented meat (UCFM), if contaminated by enterohaemorrhagic *Escherichia coli* (EHEC), poses a public health risk. The severity of such a health risk was demonstrated by the 1995 Garibaldi outbreak of food poisoning where more than 35 people were hospitalised, 22 children developed haemolytic uraemic syndrome, one young child died, and a number of people suffered permanent adverse health effects.

A microbiological risk assessment, undertaken by FSANZ, concluded that a very low level of 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, EHEC infection resulting from consumption of EHEC contaminated UCFM can lead to very severe complications, including death.

A review of the existing standard (introduced as an emergency measure in 1996 as Clause 9, Standard 1.6.2 of the *Australia New Zealand Food Standards Code*) found that:

- a key performance criterion in the existing standard, that is the production process must reduce the number of *Escherichia coli* organisms by 99.9% (i.e. a 3-log$_{10}$ reduction) or greater, could not be implemented effectively until recently because of the lack of an objective means to determine industry compliance;
- the requirement of a 3-log reduction is not consistent with the development of outcome based standards because it does not establish a clear correlation with the initial *E. coli* load in the ingoing raw meat ingredients; or a correlation with the end product *E. coli* specification; and
- the performance criterion is unnecessarily prescriptive.

Draft Assessment

Based on the findings of the risk assessment and the review of the current standard, the implementation of hazard analysis critical control point (HACCP) based food safety programs for UCFM production was proposed as an amendment to Standard 1.6.2.

The Draft Assessment also proposed a minor technical change to the minimum permitted level of *E. coli* in finished UCFM specified in Standard 1.6.1 and Standard 1.6.2 of the *Food Standards Code* (Code). The change removed the confusion of two *E. coli* limits being specified for UCFM in the Code.

Public Consultation

All of the submissions received at Draft Assessment supported the introduction of HACCP based food safety programs for UCFM production, to replace the key performance criterion introduced previously, i.e. the 99.9% or greater reduction of *E. coli* organisms.

The proposed end product *E. coli* specification for UCFM was also supported.
A number of submissions opposed the “test and hold” measure proposed in the Draft Assessment as an alternative regulatory measure to HACCP based food safety programs. The “test and hold” refers to “microbiological end product testing for each production lot and holding the lots pending satisfactory compliance of the results with the E. coli limit specified in Standard 1.6.1 of the Code”. This measure was considered detrimental to the consistent uptake of preventative food safety measures embodied in the food safety program.

A number of submissions opposed a proposed maximum E. coli limit of 20 per gram in the ingoing raw meat ingredients, and considered this requirement as highly prescriptive and posing considerable uncertainty in implementation. It was argued that the ingoing raw meat would be monitored for E. coli as a part of the food safety program and therefore the management of this potential hazard was covered elsewhere.

A number of submissions proposed mechanisms for effective implementation of the amended standard, more specifically:

- the need for an independent Expert Advisory Panel to assist the assessment of HACCP based food safety programs for their adequacy in meeting the food safety outcome required in the amended standard; and

- the need for a list of criteria that can be used to measure the competency of an individual’s skill and knowledge on food safety principles and UCFM production.

**Final Assessment**

Resulting from the public consultation at Draft Assessment, a number of minor changes were made to the preferred regulatory option at the Draft Assessment including:

- a refined definition for UCFM which ensures that all heat-treated comminuted fermented meat will be categorised as UCFM;

- a refinement of the phrase associated with the “starter culture” which clarifies that “previously fermented meat or fermenting meat” can NOT be used in UCFM production;

- a whole of food chain approach which requires manufacturers to demonstrate through the food safety programs that their production processes can handle the variations of E. coli contamination in the raw meat ingredients, so as to ensure the end products meet the E. coli specification;

- “E. coli” testing for raw meat ingredients and products in UCFM production is mandated as a part of the validation or verification process of the HACCP based food safety programs; and

- the use of direct-contact pH probes or meters is proposed as additional permissible methods for determining UCFM pH to reflect industry’s current practice.

**Statement of Reasons**

FSANZ recommends a refinement to the existing standard for UCFM production for the following reasons:
• Regulation is required to protect public health and safety from the potentially severe consequences resulting from consumption of EHEC contaminated UCFM products. The proposed amendment to the Code is consistent with the Section 10 objectives of the *Food Standards Australia New Zealand Act 1991* (the Act).

• The risk assessment found that:
  - the EHEC infectious dose is low and ingestion of as little as 1 organism could result in severe adverse health outcomes in susceptible individuals;
  - a very low level of EHEC (0.15 per 100 grams) is likely to be present in approximately 7.2% of UCFM made in Australia; and
  - young children, the frail elderly, and people suffering from chronic diseases, or with depressed immune system, are more susceptible to the development of complications resulting from EHEC infection than the rest of the population, and children under the age of 6 years are most susceptible.

The amendments to Standard 1.6.1 and Standard 1.6.2 proposed in this report are justified by the objectives of the Act in that they provide the minimum effective measure to protect public health and safety. Effective implementation of the amended standard by industry and enforcement authorities will further reduce the risk of EHEC infection from consumption of UCFM.

1. **Introduction**

The existing requirements for the production of uncooked comminuted fermented meat (UCFM) were gazetted in 1996 in response to the Garibaldi outbreak of food poisoning caused by enterohaemorrhagic *Escherichia coli* (EHEC) contaminated mettwurst. The outbreak affected more than 200 people and resulted in the death of a young child. The requirements are specified in Clause 9 of Standard 1.6.2 of the *Australia New Zealand Food Standards Code* (Code). Because the regulatory measure was introduced as an emergency measure, a comprehensive risk assessment to fully identify and characterise the health risk was not undertaken at that time.

The current Clause 9 requires that:

• the production of UCFM products must be initiated with the use of a starter culture;

• previously fermented or fermenting meat products must be cooked prior to use as an ingredient in the production of UCFM products\(^1\);

• the levels of *E. coli* in the ingoing raw meat ingredients and in the product during the production process must be monitored and recorded;

• the pH of UCFM products and fermentation room temperature must be monitored;

• meat for making UCFM products must be stored at 5°C or below prior to fermentation;

---

\(^1\) This is commonly referred to as “no back slopping”.

8
• the fermentation and subsequent processes must reduce by 99.9% (referred as a 3-log\textsubscript{10} reduction) or greater the number of \textit{E. coli} organisms potentially present in a UCFM product; and

• the pH and temperature data be kept for two years.

The Code also contains a minimum permitted level for \textit{E. coli} in UCFM products (Standard 1.6.1 and Standard 1.6.2).

Standard 1.6.2 applies to Australia only. For New Zealand, processing requirements for UCFM are regulated under the New Zealand \textit{Food Act 1981}.

The Australian UCFM industry is a part of the smallgoods industry. Typical UCFM in the Australian market includes various types of salami, summer sausages, mettwurst and others. Although there are approximately 150 UCFM producers domestically, twenty large producers (producing up to 40 tonnes per week) make up the bulk of the industry. Smaller producers routinely produce less than 100 kilograms a few times per year. The industry is worth approximately $200 million per year in sales (Attachment 5).

FSANZ (formerly Australian New Zealand Food Authority, or ANZFA) raised a proposal in September 2001 to assess the risk to human health from exposure to EHEC in UCFM and to determine effective risk management strategies to mitigate any identified risk. As part of this process, the existing standard was evaluated and implementation issues raised by industry and regulators were examined.

A comprehensive risk assessment of the public health implications of EHEC in UCFM was released at Draft Assessment. FSANZ consulted widely with stakeholders to seek views on the proposed regulatory measures.

2. Regulatory Problem

EHEC contaminated UCFM products, if consumed, pose a potential risk to public health and safety and the consequences to vulnerable subpopulations can be fatal.

The existing standard for the production of UCFM was introduced as an emergency measure in 1996 in response to the Garibaldi outbreak. A review of the efficacy of the standard was foreshadowed at that time.

The conclusion that ‘many UCFM processes currently used, either in Australia or overseas, cannot comply with the 3-Log kill requirement’ in a study\textsuperscript{2} funded by the Meat and Livestock Australia (MLA) raised a question about the ability of the industry to implement the existing standard.

The Meat Standards Committee’s conclusion, at its June 2001 meeting, that a 3-log\textsubscript{10} reduction was ‘incapable of auditor verification’ raised a question about the enforceability of the existing standard.

\textsuperscript{2} Predicting \textit{Escherichia coli} inactivation in uncooked comminuted fermented meat products, Meat & Livestock Australia Limited, 2001
The problems associated with the implementation and enforcement of the requirement of a 3-log$_{10}$ reduction in the existing standard have been largely resolved through the adoption of a predictive model in March 2002 for assessing production protocols submitted by UCFM manufacturers. The active involvement of the industry and the relevant enforcement agencies played an important role in the successful implementation of the requirement of a 3-log$_{10}$ reduction. The UCFM industry however, expressed significant concerns about the applicability of the model as an assessment tool for all types of UCFM (Attachment 6).

FSANZ reviewed the current standard for UCFM production and, as part of this process, undertook a comprehensive risk assessment, which examined the likelihood and public health impact of EHEC contamination in UCFM made in Australia. An amendment to the current standard is recommended.

The FSANZ Board approved the Initial Assessment of this Proposal in February 2002. The first round of public consultation took place during the period of March to May 2002. The FSANZ Board approved the Draft Assessment in December 2002, and the second round of public consultation took place during the period of December 2002 to May 2003. The Proposal is now at Final Assessment.

3. Objective

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

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

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

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

The key objective of this proposal is to protect public health and safety by identifying appropriate regulatory measures that are effective to mitigate the risks of EHEC infection as a result of consumption of UCFM. FSANZ has also had regard to the need for a standard to be appropriate for implementation by industry and enforcement agencies.
4. Background

4.1 Pathogenic microorganisms associated with UCFM

UCFMs are ready-to-eat meat; i.e. the products are consumed without cooking. They are manufactured from principally raw bovine and/or porcine meat together with other ingredients (Attachment 4. Food Technology Report). The production process involves fermentation, maturation/drying and sometimes smoking, but does not involve a cooking step.

Pathogenic microorganisms initially present in the ingredients of UCFM are destroyed during the production process as a result of the reduction in pH and water activity (Attachment 3. Microbiological Risk Assessment). Pathogenic microorganisms, other than EHEC, potentially present in UCFM include *Listeria monocytogenes*, *Salmonella* and enterotoxigenic *Staphylococcus aureus*. Growth of both *Staphylococcus aureus* and *Salmonella* is suppressed at pH 5.3 or below. The fermentation and maturation/drying steps in UCFM production usually result in 10 to 100 fold reductions in numbers of *L. monocytogenes*. A small number of *L. monocytogenes* cells that may be found in finished UCFM cannot multiply because of the low pH and low water activity of the finished UCFM. Microbiological limits for these pathogens in UCFM, other than *L. monocytogenes*, are specified in the Code (Standard 1.6.1).

4.2 Outbreaks associated with EHEC in UCFM

Exposure to EHEC in UCFM can result in severe illnesses (Attachment 3. Microbiological Risk Assessment). In Australia, EHEC contaminated mettwurst, a type of UCFM, was the cause of a major outbreak in 1995, which affected more than 200 people. Of the 200 cases, more than 35 people required hospitalisation, 22 children developed haemolytic uraemic syndrome (HUS), 4 adults developed thrombotic thrombocytopenic purpura and a young child died (Attachment 3. Microbiological Risk Assessment). A recent investigation of a foodborne illness in Western Australia found that consumption of cacciatore, another type of UCFM, contaminated by *E. coli* O157:H7 was the cause of the illness.

A brief review of the impact of the 1995 Garibaldi outbreak of food poisoning on the Australian UCFM industry can be found in Attachment 5.

An EHEC caused outbreak of human illness associated with the consumption of dry-cured salami (a type of UCFM), was reported in the United States in 1994. The outbreak resulted in 24 people falling ill and 3 children developed HUS.

During the period 1997 to 1999, the Canadian Food Inspection Agency issued three Health Hazard Alerts in relation to manufacturers’ recalls for UCFM with possible EHEC contamination.

In the spring of 1998, an *E. coli* O157:H7 outbreak was traced to a naturally fermented Genoa salami product manufactured in Ontario; and in November 1999, another *E. coli* O157:H7

---

3 The cooking process kills microorganisms that may cause human illness. Cooking is defined in the *Food Standards Code* as 65°C for 10 minutes or longer.
4 Goodchild, Department of Health in Western Australia, Per. Communication, 2002
outbreak in Western Canada was traced to a Hungarian-style UCFM. With the latter outbreak, over 150 people became sick and at least five developed HUS.

4.3 Compliance with and enforcement of the existing standard

ANZFA, now FSANZ introduced the existing standard in 1996 as an emergency measure in response to the outbreak of EHEC infection in South Australia. An ANZFA Expert Advisory Panel was established at the commencement of the standard, to assist the State and Territory enforcement agencies to determine industry compliance with the requirement of the $3\log_{10}$ reduction prescribed in the standard.

Despite a significant amount of effort from the Expert Panel, the State enforcement agencies and the industry, a reliable assessment of industry compliance with the requirement of the $3\log_{10}$ reduction was not possible due to a lack of a suitable methodology to objectively determine whether a process met this requirement. UCFM safety was managed by the State enforcement agencies and industry through compliance with the other requirements prescribed in the standard, such as the compulsory use of starter culture and no back slopping, as well as a close adherence with the end product $E. coli$ specification (absence of $Escherichia coli$ in 0.1g) through ‘test and hold’ mechanisms. In addition, the industry and State enforcement agencies made a significant inroad in implementing hazard analysis critical control point (HACCP) in the UCFM production process, assisted by initiatives from the Department of Industry, Science and Tourism, the National Meat Association of Australia and the National Meat Processors Association.

A predictive model of $E. coli$ inactivation, recently developed by the MLA, was adopted in March 2002 to assist the assessment of industry compliance with the requirement of a $3\log_{10}$ reduction. The model uses the temperature and time parameters of the fermentation and maturation/drying steps of the UCFM production process to predict the capacity of the process in destroying $E. coli$ organisms. However, the industry is concerned about the accuracy of the model because the model has a margin of error of $\pm 0.5 \log_{10}$ reduction, and the applicability of the model to predict $E. coli$ inactivation for UCFM products with small diameters. The model is currently being further developed through a MLA funded research.

Despite these limitations, the model is regarded as the most appropriate tool currently available to assess industry compliance by both the joint expert panels and the Meat Standards Committee (MSC).

The ANZFA/FSANZ Expert Advisory Panel, in collaboration with the State and Territory regulators and using the predictive model, assessed 186 production protocols submitted by Australian UCFM manufacturers (Table 1) between April and September 2002.

---


7 Back slopping refers to the use of a previously fermented or fermenting meat without it being cooked, as an ingredient in the production of UCFM.


9 At the joint technical meeting in February 2002 of ANZFA Expert Advisory Panel on UCFM Products, and MLA Expert Panel on Smallgoods.

10 At the Meat Standards Committee’s meeting in March 2002.
Industry compliance with the requirement of a $3\log_{10}$ reduction in the existing standard improved significantly as a result of the above assessment. An example is shown in Figure 1\textsuperscript{11}. Available data indicates 91\% of South Australian UCFM producers are now operating under agreed minimum process parameters that achieve $3\log_{10}$ or greater reduction of \textit{E. coli} organisms\textsuperscript{12}.

**Table 1. Combined assessment outcome of compliance with the requirement of $3\log_{10}$ reduction – Nationwide (FSANZ data, 2002)**

<table>
<thead>
<tr>
<th>Assessed</th>
<th>No. of submissions</th>
<th>Achieving $3\log_{10}$ reduction</th>
<th>Between 2 and $3\log_{10}$ reduction</th>
<th>Less than $2\log_{10}$ reduction</th>
</tr>
</thead>
<tbody>
<tr>
<td>May 2002</td>
<td>96</td>
<td>19%</td>
<td>30%</td>
<td>51%</td>
</tr>
<tr>
<td>Jul. 2002</td>
<td>59</td>
<td>41%</td>
<td>17%</td>
<td>42%</td>
</tr>
<tr>
<td>Sep. 2002</td>
<td>31</td>
<td>39%</td>
<td>16%</td>
<td>42%</td>
</tr>
</tbody>
</table>

Problems with enforcement and implementation of the $3\log_{10}$ reduction requirement in the current standard suggest that the current regulatory measure is not the most effective approach to ensure UCFM safety. A comprehensive assessment of the public health and safety risks posed by EHEC contamination of UCFM is the best tool for informing the most appropriate risk management measures.

FSANZ undertook a microbiological risk assessment (Attachment 3) to determine the public health impact of EHEC in UCFM.

\begin{figure}[h]
\centering
\includegraphics[width=0.5\textwidth]{figure1.png}
\caption{An example of compliance with the requirement of $3\log_{10}$ reduction - Victoria (FSANZ data, 2002)}
\end{figure}

\textsuperscript{11} The compliance change reflects process modifications made in the resubmitted protocols (assessed by the ANZFA/FSANZ Expert Advisory Panel) from UCFM producers in Victoria, who did not meet the requirement of $3\log_{10}$ reduction in the initial round (May) and/or the second round (July) of the protocol assessment. Enforcement agencies in New South Wales, South Australia and Western Australia evaluated industry compliance at the State level on the basis of the outcome of the first assessment carried out by the ANZFA/FSANZ Expert Advisory Panel.

\textsuperscript{12} Data submitted by South Australian Department of Human Services, (2002).
5. Relevant Issues

5.1 Conclusions of the microbiological risk assessment

Based on the available information, the risk assessment (Attachment 3) estimated that a very low level of EHEC organisms (0.15 per 100 grams) is likely to be present in a small proportion of UCFM manufactured in Australia (approximately 7.2%). It was estimated that at this level of contamination, UCFM poses a very low public health risk to the general population. However, while the risk of being exposed to EHEC from UCFM is low, the consequences of an EHEC infection to certain sensitive subpopulations can be very severe. In particular, young children under the age of 6 are likely to develop severe complications such as HUS and kidney failure from EHEC infections. Similarly, the frail elderly may develop thrombotic thrombocytopenic purpura. These complications, if not treated correctly and in time, can lead to death.

5.2 Conclusions of the food technology report

UCFM products have long shelf lives due to a combination of acidification (through fermentation or addition of acidulant), removal of oxygen, addition of compounds that favour the growth of some microorganisms while retarding the growth of others, and ultimately the removal of water.

The stability of the UCFM depends on the extent to which additives or processes are involved, the conditions, and the length of the process. To determine the effectiveness of a UCFM process in controlling pathogens, data such as the product’s final water activity, temperature, pH and undissociated lactic acid content are necessary.

The large number of process variables makes evaluation of UCFM processes for performance against the ‘3-log kill’ criterion difficult to determine.

5.3 Issues identified with current Clause 9 of Standard 1.6.2

- The existing requirements were introduced as an emergency measure in 1996, and have not been reviewed since its introduction.
- The existing requirements were not supported by a comprehensive risk assessment at the time.
- A key performance criterion in the existing requirements, (i.e. the production process must reduce the number of \(E. coli\) organisms by 99.9% or greater), could not be implemented effectively in the past due to the inability to gauge the compliance. A predictive model was adopted in February 2002 to gauge compliance with the key criterion in the current standard, but the model has certain limitations.
- The key performance criterion in the existing requirements is not based on food safety outcomes because it established neither a clear correlation with the \(E. coli\) load in the incoming raw meat ingredients\(^{13}\), nor a clear correlation with the end product \(E. coli\).

\(^{13}\) For example, if raw meat ingredients were contaminated by \(\geq 4\log_{10} \ E. coli\) per gram, ‘reduce the number of \(Escherichia coli\) organisms by 99.9% or greater’ could still leave an unacceptably high level of \(E. coli\) in the end product because the “greater” is not defined here, which may contradict the \(E. coli\) specification for the end product.
specification; and

- The performance criterion is unnecessarily prescriptive\(^{14}\).

### 5.4 Other issues

- The Australian Quarantine and Inspection Service (AQIS) prohibits the importation of UCFM into Australia pending the outcome of an import risk analysis (IRA). An IRA is a quarantine decision-making process where the risks of animal and plant diseases and pests through imported goods are assessed. The lifting of importation restrictions on UCFM depends on the outcome of the IRA, but not the outcome of this proposal. While it is not known when the IRA will be completed, any regulatory measures proposed for the Code will be applied to domestic products as well as future imported products. Upon the lifting of the import restriction, the World Trade Organization will be advised of any proposed regulatory measures as an SPS\(^{15}\) notification.

- There are no existing Codex standards for UCFM.

- Two of Australia’s trading partners, USA and Canada, have comprehensive performance standards for UCFM including the implementation of HACCP systems.

- The review of the existing requirements related to UCFM production identified an unintentional error where two \(E. \text{coli}\) limits are listed in the Code. A technical change is proposed to correct this error.

### 5.5 Risk management issues

The risk assessment indicates that consumption of UCFM, if contaminated by EHEC, poses a potential health risk to consumers, particularly to the susceptible subpopulations. While the risk of being exposed to EHEC is very low, the consequences of EHEC infection can be very severe. Therefore, the risk of EHEC infection must be managed through an appropriate measure. The following countries have introduced processing requirements for the manufacture of UCFM in response to disease outbreaks:

- The USA Food Safety and Inspection Service introduced the USA processing requirements\(^{16}\) for the production of UCFM in 1995 following the 1994 outbreak of illness caused by EHEC (serotype O157:H7) contamination in dry cured salami.

- ANZFA introduced the processing requirements\(^{17}\) for the production of UCFM in product (absence of \(E. \text{coli}\) per 0.1 gram).

---

\(^{14}\) For example, a UCFM product meeting the end product \(E. \text{coli}\) specification could be produced by less than 99.9% reduction of \(E. \text{coli}\) organisms if the raw meat ingredients used contain very little or no \(E. \text{coli}\) organisms. Under the current standard, it must be processed with a process that ‘reduces the number of \(E. \text{coli}\) organisms by 99.9% or greater’.

\(^{15}\) Sanitary and Phytosanitary Measures.

\(^{16}\) Performance standards for the production of processed meat and poultry products; Proposed rule, (February 27, 2001) Food safety and Inspection Service, Department of Agriculture, Federal Register, 9 CFR Parts 301, 303, et al.

\(^{17}\) Clause 9, Standard 1.6.2 of the \textit{Food Standards Code} (1 October 2002), Food Standards Australia New Zealand.
Australia in 1996 in response to the 1995 Garibaldi outbreak of illnesses caused by 
EHEC (serotype O111:H1) contamination in mettwurst.

- The Canadian Food Inspection Agency introduced the Canadian processing 
requirements\textsuperscript{18} for the production of UCFM in 1999 in response to large scale recalls of 
UCFM for possible EHEC (serotype O157:H7) contamination, and the two outbreaks 
caused by \textit{E. coli} O157:H7 contamination in Genoa salami and Hungarian-style UCFM 
in the period of 1997 to 1999.

Processing requirements introduced in the above three countries all focused on the process of 
UCFM production, aiming to reduce the number of EHEC organisms in the products to a safe 
level. The Australian processing requirements aim to achieve a 99.9% or greater reduction of 
generic \textit{E. coli} organisms potentially present in UCFM, i.e. a 3-log\textsubscript{10} or greater than a 3-log\textsubscript{10} 
reduction of \textit{E. coli}. Processing requirements in the USA and Canada are highlighted by a 
99.999% reduction of \textit{E. coli} O157:H7, i.e. a 5-log\textsubscript{10} reduction of \textit{E. coli} O157:H7.

The active involvement of the meat industry, regulators, the scientific community and 
consumers in developing these regulatory measures in Australia and overseas indicates that 
regulation is a desirable approach in managing the health risk of EHEC contamination in 
UCFM.

6. Regulatory Options

Five risk management options\textsuperscript{19} were proposed at the Draft Assessment to mitigate the health 
risk posed by EHEC in UCFM.

Option 1 is the status quo.
Option 2 is a core option containing three regulatory measures (implementation of HACCP 
based food safety programs, or “test and hold”, or “an equivalence measure”).
Option 3 is the same as the core option but without a specified maximum \textit{E. coli} limit.
Option 4 is the same as core option but without an equivalence measure.
Option 5 is the same as the core option but without a specified maximum \textit{E. coli} limit and an 
equivalence measure.

Evaluation of the various risk management measures in the five options at the Draft 
Assessment indicated that regulatory measures contained in Option 2 were the preferred 
approach in managing the risk posed by EHEC in UCFM.

Following consideration of comments received in written submissions and at various face-to- 
face consultations after the release of the Draft Assessment Report, the preferred regulatory 
option at Draft Assessment (Option 2) has been modified.

To avoid repeating what have been presented previously in the Draft Assessment Report, 
only Option 1 and the modified Option 2 are presented here. Full description of regulatory 
measures presented at the Draft Assessment can be found in Attachment 2.

\textsuperscript{18} Control of \textit{E. coli} O157:H7 in dry and semi-dry fermented sausages, (amended 16 December 1999) Canadian 

\textsuperscript{19} A number of other possible options were considered and rejected as not suitable, including developing food 
safety objective based requirements; adapting an international standard, or relying on the implementation of 
Standard 3.2.1 of the \textit{Food Standards Code}.
6.1 Option 1

Status quo – Clause 9, Standard 1.6.2 of the Code.

<table>
<thead>
<tr>
<th>Production of fermented comminuted meat which has not been cooked</th>
</tr>
</thead>
<tbody>
<tr>
<td>(1) Fermentation of a comminuted meat product which will not be cooked must be initiated through the use of a starter culture.</td>
</tr>
<tr>
<td>(2) A previously fermented or fermenting meat product must be cooked prior to use as an ingredient in a fermented comminuted meat product which will not itself be cooked.</td>
</tr>
<tr>
<td>(3) The number of <em>Escherichia coli</em> organisms in a fermented comminuted meat product which will not be cooked must be monitored and recorded for the –</td>
</tr>
<tr>
<td>(a) ingoing raw meat ingredients; and</td>
</tr>
<tr>
<td>(b) product after fermentation and any subsequent process.</td>
</tr>
<tr>
<td>(4) The pH of fermenting comminuted meat products which will not be cooked, measured in accordance with Method 1 in the Schedule, and the fermentation room temperature, must be monitored and recorded during fermentation.</td>
</tr>
<tr>
<td>(5) Measurements recorded under subclauses (3) and (4) must be kept either for 1 year after the end of the minimum durable life of the product, or 2 years, whichever is the greater.</td>
</tr>
<tr>
<td>(6) Meat for a fermented comminuted meat product which will not be cooked must, if stored by the manufacturer, be stored at 5°C or below prior to fermentation.</td>
</tr>
<tr>
<td>(7) The process of fermentation and any other subsequent processes must reduce prior to sale from the processing factory by 99.9% or greater the number of <em>Escherichia coli</em> organisms potentially present in a fermented comminuted meat product which has not been cooked.</td>
</tr>
</tbody>
</table>
6.2 Option 2 (modified)

Key personnel involved in manufacturing of uncooked comminuted fermented meat (UCFM) and food safety auditors must demonstrate to the relevant controlling authorities their competency of food safety matters in UCFM production in accordance with Clause 3, Standard 3.2.2 and Clause 1, Standard 3.2.1 of the Code prior to engaging in manufacturing of UCFM and safety audits. (as an editorial note)

Production of UCFM must comply with one of the following two approaches.

(a) Implement a HACCP based food safety program in accordance with Standard 3.2.1 of the Food Standards Code that has been verified and audited to ensure that the production process effectively renders the number of *Escherichia coli* organisms in the UCFM to a level specified in Standard 1.6.1 of the Code, and satisfies the following requirements.

(1) Fermentation of a UCFM must be initiated through the use of a starter culture; and previously fermented meat or fermenting meat must neither be used as a starter culture of UCFM nor an ingredient of UCFM.

(2) The number of *Escherichia coli* organisms in the ingoing raw meat ingredients and product after fermentation and any subsequent process must be recorded as part of the validation or verification process of the HACCP based food safety program.

(3) The HACCP based food safety program must demonstrate that the production process handles the variations of *E. coli* contamination in the ingoing raw meat ingredients and ensures the end product meets the *E. coli* level specified in Standard 1.6.1.

(4) The pH of a fermenting UCFM must be measured in accordance with Method 1 in the Schedule of Standard 1.6.2 of the Code.

(5) The pH of a fermenting UCFM; the temperature and time of the fermentation, smoking and maturation/drying steps; and weight loss or water activity of a UCFM must be monitored and recorded during UCFM production at suitable frequencies.

(6) Measurements recorded under subclauses (2) and (5) must be kept for 1 year after the end of the use-by-date or best before date of a UCFM.

(7) Meat and batter mixes for a UCFM, if stored by the manufacturer, their temperature must be maintained at 5°C or below prior to fermentation.

    OR

(b) Implement a new technology or measure that achieves an equivalent food safety outcome as that achieved through the implementation of HACCP based food safety programs as stated in clause a, and this new technology or measure is specified in the Code.

6.3 Minor technical changes to *E. coli* limit

The following *E. coli* limits are proposed to replace the existing *E. coli* limits for UCFM in the Schedule of Standard 1.6.1 of the Code. This minor technical change applies regardless of which regulatory option is chosen. *E. coli* limits referred in the following table correlate to those in the 3-tube MPN\(^{20}\) table with a sample amount of 0.1 g, 0.01 g and 0.001 g per tube.

\(^{20}\) MPN = most probable number.
respectively. They represent the same outcome as “absence of *E. coli* in 0.1 gram” prescribed under the current standard and tested according to the Triplicate Tube method (Australian Standard Method AS 1766.2.3).

<table>
<thead>
<tr>
<th>Column 1 Food</th>
<th>Column 2 Microorganism</th>
<th>Column 3 n</th>
<th>Column 4 c</th>
<th>Column 5 m</th>
<th>Column 6 M</th>
</tr>
</thead>
<tbody>
<tr>
<td>Comminuted fermented meat which has not been cooked</td>
<td><em>Escherichia coli</em>/g</td>
<td>5</td>
<td>1</td>
<td>3.6</td>
<td>9.2</td>
</tr>
</tbody>
</table>

The section on *Escherichia coli* in the Schedule of Methods of Analysis in Standard 1.6.2 of the Code will be removed because it uses a non-numerical expression for *E. coli* limit (“absence of *E. coli* in 0.1 gram”) that is inconsistent with the expression of *E. coli* limits for other foods in the Code. *E. coli* limits for other foods are expressed in MPN numbers.

7. Impact Analysis

7.1 Impact of Option 1

7.1.1 Consumers

Risk management measures in this Option minimise the extent of EHEC contamination in UCFM products, therefore provide a basic level of protection for consumers. No tangible economic benefits could be identified.

7.1.2 Industry

As costs associated with capital injection and implementation to comply with Option 1 have largely occurred (Attachment 5), future cost to the industry will be mainly in the operation area, i.e. additional operating costs to ensure compliance with the existing standard.

The industry itself may have benefited from the requirements in this Option to produce products with a high level of consistency in the long term due to consolidation of production parameters as a result of the protocol assessment (section 4.3). This would minimise operation cost, and have the potential to retain and/or boost the overall sales of those products meeting all the requirements under this option.

7.1.3 Government

Future costs to the government will be those of continuing enforcement. Based on the costs previously incurred (Attachment 5), it is estimated that the total enforcement cost at the State level will be approximately $130,000 a year in total, and FSANZ’s involvement in assisting State and Territory governments to assess industry compliance with the standard will be approximately $93,400 a year. No tangible economic benefits can be identified for government under this option.

7.2 Impact of Option 2 (modified)

7.2.1 Consumers
Option 2 provides a comprehensive level of protection for consumers and hence a greater consumer confidence in the safety of UCFM products is anticipated because HACCP based food safety programs provide systematic and preventive approaches to ensure product safety. A wide range of UCFM product may be available to consumers under Option 2.

As HACCP based food safety systems have already been implemented by the majority of the industry, no tangible economic cost can be identified for consumers under Option 2.

7.2.2 Industry

Under the recommended regulatory measures, the industry will benefit from a reduced compliance cost. Option 2 removes the cost and uncertainty of attempting to comply with the requirement of 3-log_{10} reduction under the current standard where significant outlay of resources may not guarantee compliance. Under Option 2, industry is able to produce a variety of UCFM which may not be possible under the current standard due to the rigidity of the requirement of 3-log_{10} reduction. In addition, the industry will benefit from the flexibility of employing new technology and measures for UCFM production under the “equivalence” provision proposed for Option 2.

Option 2 will impose compliance costs on the industry for the implementation of HACCP based food safety programs, but the costs are expected to be small because the industry has already taken significant steps to implement HACCP based food safety systems. Available information indicates HACCP based food safety systems were introduced into the UCFM industry in 1998. As a result, implementation of HACCP based food safety programs will not result in significant additional costs to the industry. However, new UCFM producers may face a high entry cost because they will have to develop and implement HACCP based food safety programs.

Option 2 may impose a different cost on industry because manufactures will be required to demonstrate that their production processes can handle the variations of *E. coli* contamination in ingoing raw meat ingredients, as well as their competency (key personnel) of skill and knowledge on food safety principles and UCFM production processes.

Maintaining the competency of skill and knowledge will unlikely result in a significant cost because it applies to the key personnel only, but will lead to long-term benefit to the industry as indicated in the report of National Risk Validation Project21.

7.2.3 Government

There will be enforcement costs at the State and Territory level to ensure that HACCP based food safety programs are implemented by the producers through auditing and verification procedures. Because HACCP based food safety systems for the UCFM industry have already been implemented and audited in most of the States, it is anticipated that the additional costs of enforcement will be minimal. State and Territory enforcement authorities will incur a cost for assessing manufacturers’ competency of skill and knowledge on food safety principles

---

21 National Risk Validation Project – Final report (2002) Food Science Australia and Minter Ellison Consulting. The National Risk Validation Project funded by the NSW Department of Health and the Commonwealth Department of Health and Ageing identified potentially high-risk food industries sectors through assessment of potential food safety risks to the public; and determined the potential cost and benefit of food-borne illness associated with the high-risk food industries.
and UCFM production processes under Option 2. Enforcement authorities will incur initial training costs to upgrade their own auditors’ skill and knowledge on food safety principles and UCFM production processes.

FSANZ will incur a cost if it has to evaluate alternative manufacturing processes or measures proposed by the industry and to determine if the proposed processes or measures would achieve the equivalent food safety outcome as that achieved through the implementation of HACCP based food safety programs.

No tangible economic benefit can be identified for government under this option other than the potential health benefit due to reduction of foodborne incidents caused by EHEC in UCFM.

8. Consultation

Two rounds of public consultation were conducted in accordance with the process for amending the Code prescribed in the FSANZ Act, one at the release of the Initial Assessment Report (March 2002), and one at the release of the Draft Assessment Report (December 2002).

8.1 Public Consultation at Initial Assessment

A total of 19 submissions were received from consumers’ organisations, State regulators, individual UCFM producers, the MLA, the National Meat Association of Australia (NMAA), the Australian Food and Grocery Council (AFGC), the Institute of Food Technologists and individual professionals.

Issues raised in the submissions mainly concerned the merit of the likely options proposed for discussion in the Initial Assessment Report.

The consumers’ organisations and regulators expressed an opinion that the requirements in the existing standard played a significant role in ensuring the safety of UCFM in the marketplace.

The regulators, industry and individual professionals expressed an opinion that most of the current processing requirements, including monitoring of pH and fermentation temperature, use of starter culture, ban on the use of fermenting or fermented meat without cooking for making a new batch of UCFM are highly desirable for the purpose of reducing the level of EHEC contamination in UCFM. However submissions state that the component of $3\log_{10}$ reduction in the existing standard is costly to comply with, and difficult to enforce.

The regulators and industry expressed an opinion that HACCP programs are a better alternative to address the issue of UCFM safety. Two industry submissions asked for a “farm to table” approach in addressing the issue of UCFM safety.

A summary of issues raised in these submissions can be found in Attachment 6 of this report.

8.2 Public consultation at Draft Assessment
Four separate face-to-face consultations were held prior to and after the release of the Draft Assessment Report.

- A technical meeting was held on the 17th October 2002 to communicate the findings of the scientific risk assessment to key industry stakeholders, i.e. the MLA, the NMAA, and the AFGC.

- A consultation was held on 14 February 2003 to seek views from regulators on the proposed measures. Participants included enforcement authorities of Victoria, South Australia, Western Australia, New South Wales, Queensland, Tasmania, Australian Quarantine and Inspection Services (AQIS) and the Commonwealth Department of Health and Aging (DOHA).

- A consultation was held on 13 February 2003 to seek views from industry on the proposed measures. Participants included the NMAA, representatives of three UCFM manufacturers, the MLA and the AFGC.

- A final consultation was held on 23 May 2003 to seek views from stakeholders on the refined regulatory measures proposed to be included in this Final Assessment Report. Participants include controlling authorities of New South Wales, Queensland, DOHA, the NMAA, the AFGC and a representative of a UCFM manufacturer.

A total of 18 submissions were received from controlling authorities, regulators of the MSC, individual UCFM producers, the MLA, the NMAA, the AFGC, the Institute of Food Technologists and individual professionals. The submissions focused their discussion on Option 2 (the core option preferred by FSANZ at the Draft Assessment) and to a small degree on Option 3 (the core option without a specified maximum \(E. coli\) limit), but rejected Option 1 (the status quo). No significant support was received for Option 4 (the core option without an equivalence measure) and Option 5 (the core option without a specified maximum \(E. coli\) limit and an equivalence measure) because these are derivatives of Options 2 and 3. A summary of issues raised in the submissions can be found in Attachment 7 of this report.

All the submissions supported the introduction of HACCP based food safety programs for UCFM production, which replaces the key performance criterion in the existing standard, i.e. the 99.9% or greater reduction of \(E. coli\) organisms.

Submissions supported the end product \(E. coli\) limits proposed in this report, other than a minor concern about the \(E. coli\) limits being expressed with a decimal from one submitter.

8.2.1 Issues raised in the submissions

Test and hold as a regulatory measure

A number of submissions opposed the inclusion of “test and hold” as an alternative regulatory measure to the HACCP based food safety programs. The “test and hold” measure refers to “microbiological end product testing for each production lot and holding the lots pending satisfactory compliance of the results with the \(Escherichia coli\) limits specified in Standard 1.6.1 of the Code”. Some of the submissions supported the inclusion of “test and hold” measure provided that the measure is combined with the implementation of HACCP based food safety programs.
Prescribed requirements under the HACCP based food safety program

Submissions from the AGFC, the Department of Human Services (DHS) in South Australia and George Weston Foods (GWF) considered that outcome based standard such as HACCP based food safety programs ideally should not specify requirements such as monitoring temperature, time, pH in UCFM production. Regulators of the MSC, SafeFood NSW and Department of Health (DOH) in Western Australia on the other hand, considered that important parameters such as those prescribed under the HACCP based food safety program must be defined in the standard. At the final consultation involving both industry and regulators, it was considered appropriate to review the need to retain the prescribed requirements at an appropriate time in the future, such as 3 years after the full implementation of the amended standard.

Mandatory training for UCFM businesses and food safety auditors

A submission from regulators requested that “mandatory training of UCFM business and food safety auditors” on HACCP, food safety principles and UCFM production processes be specified in the amended standard. The view was supported by industry at the final consultation.

A maximum *E. coli* limit in the raw meat ingredients

Both industry and regulators opposed a proposed maximum *E. coli* limit of 20 per gram in the ingoing raw meat ingredients and considered the maximum limit is highly prescriptive and poses considerable uncertainty in implementation. The regulators of the MSC, SafeFood NSW and DOH in Western Australia supported the requirement for establishing a maximum *E. coli* limit in the ingoing raw meat ingredients by UCFM manufacturers as part of their HACCP based food safety programs.

Key implementation issues

A number of submissions proposed various solutions that would assist the implementation of the amended standard proposed in this report. The key recommendations are:

- the need for an independent Expert Advisory Panel to assist the assessment of HACCP based food safety programs for their adequacy in meeting the food safety outcome required in the amended standard, and the need for retaining such an expert advisory panel should be reviewed at the end of three years;

- the need for a list of criteria that can be used to measure the competency of an individual’s skill and knowledge on food safety principles and UCFM production;

- the need for national consistency in the implementation of amended standard; and

- the need for a guideline material to assist the implementation of the amended standard including specifically: interpretation of the amended standard; guidance on appropriate sampling plan and testing frequency for *E. coli*, pH, temperature, time, and weight loss or water activity; steps involved in establishing a HACCP based food safety program; competency requirement of skills and knowledge for UCFM producers and food safety auditors; description of “batter mixes”; and that validation and verification of a food
safety program should consider all the possible food safety hazards, not just EHEC.

**Other issues**

- A submission from DHS in South Australia commented on the technicality of referencing Standard 3.2.1 (the food safety program standard) in the proposed amendment. It refers to Standard 3.2.1 being a “voluntary” standard in the Code, and a number of jurisdictions may need to enact a regulation to call up this “voluntary” standard.

- Two submissions recommended a modification of the definition for UCFM, and considered that the UCFM definition needs to take away any confusion about heat-treated comminuted fermented meat being a part of the UCFM.

- Both industry and regulators requested a clear statement in the amended standard that *E. coli* testing for ingoing raw ingredients and end product is a part of the validation or verification process of HACCP based food safety program.

- A submission from DOH of Western Australia recommended an adjustment of the wording in the amended standard to ensure that a previous fermented meat or fermenting meat will not be used in making a new batch of UCFM, either as an ingredient or as a starter culture.

- Submissions from DOH of Western Australia and GWF recommended the inclusion of the use of direct contact pH probes or meters as acceptable methods for determining UCFM pH.

- A submission from the AFGC recommended a modification of record keeping from the current two dates (1 year after the end of the minimum durable life of the product, or 2 years, whichever is greater) to 1 year after the end of the use-by-date or best before date.

- Submissions from the NMAA, the AFGC and the MLA recommended any equivalent method should be permitted for routine *E. coli* testing.

- A submission from DOH of Western Australia requested a review of microbiological limits of other identified microbiological hazards in UCFM, namely, *Listeria monocytogenes*, *Salmonella* and coagulase-positive staphylococci.

- A submission from the MLA critically reviewed the microbiological risk assessment attached to the Draft Assessment Report, and expressed a different opinion on the way the risk assessment was conducted, despite these issues having no impact on the Proposal. The issues raised include the use of available data, basis of assumptions, data treatment and expression and others. It questioned how the content of the microbiological assessment report is used to formulate the proposed standard.

8.3 **Outcome of public consultation**

A number of minor changes have now been made to the regulatory option that was preferred at the Draft Assessment stage as a consequence of evaluation of submissions. The changes include:
• a refined definition for UCFM which places heat treated comminuted fermented meat under the UCFM category unequivocally;

• a refinement of the phrase associated with the “starter culture” which clarifies that “previously fermented meat or fermenting meat” can NOT be used in UCFM production;

• a whole of food chain approach which requires manufacturers to demonstrate through the food safety programs that their production processes can handle the variations of *E. coli* contamination in the raw meat ingredients, so as to ensure the end products meet the *E. coli* specification;

• “*E. coli*” testing for raw meat ingredients and products in UCFM production is mandated as a part of the validation or verification process of the HACCP based food safety programs;

• the inclusion of the use of direct-contact pH probes or meters as additional permissible methods for determining UCFM pH; and

• the “test and hold” no longer being included in the amended standard proposed in this report.

In response to concerns from stakeholders regarding effective implementation of the amended standard, FSANZ will raise the following issues with the Development and Implementation Sub-Committee (DISC) of the Food Regulation Standing Committee (FRSC). The first issue relates to the need for a list of criteria to enable a nationally consistent measurement of competency of skill and knowledge on food safety principles and UCFM production processes. The other issue relates to the establishment of an independent national Expert Advisory Panel to assist in the assessment of HACCP based food safety programs. A process for a review of the continued operation of this panel will be raised in a DISC paper.

In addition, the MLA has agreed to update the section on UCFM in the MLA’s *Guidelines for safe manufacture of smallgoods* to reflect the proposed standard. The Guidelines has been referenced in an Editorial Note in Standard 1.6.2.

In relation to the technicality of referencing Standard 3.2.1 in the proposed amendment as commented by DHS in South Australia, the draft variation to Standard 1.6.2 does not require the “calling up” of Standard 3.2.1 per se. Standard 3.2.1 was adopted by the Ministerial Council and duly gazetted, and accordingly, exists in the legal sense, as a standard. To ensure consistency and avoid unnecessary duplication of text throughout the Code, the draft variation to Standard 1.6.2 “picks up” by reference the text in Standard 3.2.1. The practical effect of the draft variation for enforcement purposes is that it does not require the application of Standard 3.2.1 because any action taken for a breach of the Code regarding the production of UCFM would be pursuant to Standard 1.6.2 not Standard 3.2.1.

In relation to the issue of “any equivalent method should be permitted for routine *E. coli* testing” raised in the submissions from the NMAA, the MLA and the AGFC, such permission is already given in Clause 4 of Standard 1.6.1 of the Code.
DOH of Western Australia suggested a FSANZ review of microbiological limits of other identified microbiological hazards in UCFM, namely, *Listeria monocytogenes*, *Salmonella* and coagulase-positive staphylococci. It is considered that a review of these pathogens is outside the scope of this proposal.

FSANZ has considered the comments and opinions raised in the MLA’s submission on the microbiological risk assessment. It is considered that the risk assessment is based on the current data and that microbiological risk assessment is an iterative process where improvement can be made at each cycle when suitable data become available.

9. **Draft Amendment at Final Assessment**

A draft amendment for the entry of *Escherichia coli* in “Comminuted fermented meat which has not been cooked” in the Schedule of Standard 1.6.1, and Clause 9 in Standard 1.6.2 as well as the Schedule of Standard 1.6.2 in the Code is presented in Attachment 1 of this report.

10. **Conclusion and Recommendation**

The issues raised in the section of the Regulatory Problem have been addressed through the risk assessment, analysis of the regulatory options, and stakeholder consultations in this Proposal. Regulatory measures recommended in Option 2 (modified), and a minor technical change for *E. coli* limit, detailed in Attachment 1 are recommended to minimise the potential risk posed to consumers by EHEC in UCFM.

10.1 **Justification for the recommended regulatory measures**

Option 2 (modified) differs from the existing standard in that it uses a HACCP based food safety program to encapsulate all of the critical control points specified in the existing standard together with the relevant refinements. As the HACCP based food safety programs are preventative and outcome-based in managing the risk of EHEC contamination in UCFM, industry can control product safety through systematic planning in UCFM production to minimise EHEC contamination. It places the responsibility of managing UCFM safety on manufacturers.

Implementation of HACCP based food safety programs for UCFM production is consistent with the recommendation of the National Risk Validation Project that identified UCFM production as one of the five high-risk food production or service industries in Australia.

Option 2 (modified) takes a whole of food chain approach to the management of EHEC contamination in UCFM, requiring UCFM manufacturers to ensure that the production processes can handle the variations of *E. coli* contamination in the raw meat ingredients so as to meet the end products *E. coli* specification.

Option 2 (modified) provides an alternative regulatory measure to the implementation of HACCP based food safety programs. The alternative provides flexibility for regulatory control, and opportunities for the industry to apply new technologies or measures in manufacturing safe UCFM. Such alternative technologies or measures will be evaluated by FSANZ in order to ensure the required food safety outcome is achieved.

The requirement for skill and knowledge on food safety principles and UCFM production refers to those contained in Standard 3.2.2 that has been adopted by State and Territory legislations. The specific reference made in the amendment brings to the reader’s attention that such a requirement applies specifically to UCFM production.

The technical change proposed for *E. coli* limit in UCFM removed the confusion of two separate listings of *E. coli* limit in the Code. The limit proposed is expressed as a most probable number, which is an equivalent to the existing limit of “absence of *E. coli* in 0.1 g” of UCFM that has been successfully implemented in the past 7 years by the industry and enforcement authorities. Expression of the limit as a most probable number removed an inconsistency in specifying microbiological limits in the Code.

Option 1 is not preferred because:

- The key performance criterion in this option, i.e. the production process must reduce the number of *Escherichia coli* organisms by 99.9% or greater, could not be implemented and enforced effectively. Limitations in the predictive model used for assessing industry compliance with the performance criterion, prevent a comprehensive evaluation of all processing protocols.
- The performance criterion in this option is not consistent with the development of outcome based standards based because it correlates neither with the initial *E. coli* load in the ingoing meat ingredients; nor the end product *E. coli* specification; and
- the performance criterion is unnecessarily prescriptive.

Option 3 does meet FSANZ’s objective of protection of public health and safety. However a wide range of maximum *E. coli* limits in the ingoing raw meat ingredients is anticipated with this option. This could result in an increased cost in enforcement. In addition, some UCFM producers, particularly small producers, may have significant difficulty in trying to establish a maximum *E. coli* limit for ingoing raw meat ingredients due to various reasons, for example, inability of assessing scientific data.

Option 4 and Option 5 do meet FSANZ’s objective of protection of public health and safety. However, both options do not contain an “equivalence” measure that provides flexibilities in regulation as well as opportunities for industry innovation.

The Office of Regulatory Review has considered the regulatory impact statement for this Proposal and considered it as adequate.

11. Implementation and Review

The proposed amendments have been approved by the FSANZ Board and are being reviewed by the Australia and New Zealand Food Regulation Ministerial Council (ANZFRMC). Once the ANZFRMC process is finalised, an amendment to Standard 1.6.1 and 1.6.2 of the Code may be published in the Commonwealth Gazette and adopted by reference and without amendment under Australian State and Territory food law. This amendment will commence on gazettal subject to the provisions in subclause 1.2 of Standard 1.1.1 of the Code.
A review of the new standard should be under plan in due course, particularly on the need to maintain a range of requirements prescribed under the HACCP based food safety programs in Clause 9 of Standard 1.6.2.

Two key issues arose from these consultations, both pertaining to implementation of the draft standards.

- There is a need for an independent Expert Advisory Panel to assist in the assessment of HACCP based food safety programs for their adequacy in meeting the food safety outcome required in the amended standard.
- There is a need to develop a list of criteria that can be used to measure the competency of an individual’s skill and knowledge on food safety principles and UCFM production.

The Development and Implementation Sub-Committee is the appropriate forum for discussing these issues.

**ATTACHMENTS**

1. Draft variations to *Food Standards Code*
2. Regulatory options proposed at Draft Assessment and the associated impact analysis
3. Microbiological Risk Assessment Report
4. Food Technology Report
5. An overview of the Australian UCFM industry and the impact of Garibaldi outbreak on the Australian Economy
6. Summary of issues raised through public consultation at Initial Assessment
7. Summary of issues raised through public consultation at Draft Assessment
DRAFT VARIATIONS TO FOOD STANDARDS CODE

To commence: On gazettal

[1]  **Standard 1.6.1** of the Australia New Zealand Food Standards Code is varied by omitting from the Schedule the entry for Fermented comminuted meat which has not been cooked, substituting –

<table>
<thead>
<tr>
<th>All comminuted fermented meat which has not been cooked during the production process</th>
<th>Coagulate-positive staphylococci/g</th>
<th>5</th>
<th>1</th>
<th>$10^5$</th>
<th>$10^6$</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><em>Escherichia coli/g</em></td>
<td>5</td>
<td>1</td>
<td>3.6</td>
<td>9.2</td>
</tr>
<tr>
<td></td>
<td><em>Salmonella/25g</em></td>
<td>5</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>

[2]  **Standard 1.6.2** of the Australia New Zealand Food Standards Code is varied by –

[2.1] omitting the Editorial note after subclause 8(4), substituting –

<table>
<thead>
<tr>
<th>Editorial note:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Processed meat in this clause includes processed meat and manufactured meat in accordance with Standard 2.2.1, irrespective of the prescribed names set out in that Standard.</td>
</tr>
</tbody>
</table>

*Guidelines for the Safe Manufacture of Smallgoods* published by Meat and Livestock Australia, will assist manufacturers and appropriate enforcement agencies to give effect to the provisions in this clause and in clause 9.

[2.2] omitting clause 9, substituting –

9  **Production of uncooked comminuted fermented meat (UCFM)**

(1) In this clause –

**Audit** means a review or examination of any, or all requirements of a food safety program which has been conducted by a person approved as being competent in food safety matters relating to UCFM.

**Batter mix** means all the ingredients in the UCFM recipe that have been combined prior to filling a casing.

**Food safety program** means a food safety program in accordance with Division 2 of Standard 3.2.1 and which has been validated by the producer.

**Starter culture** means a preparation of micro-organisms prepared for the purpose of fermenting meat which -

(i) successfully competes for the nutrients in the meat medium; and
(ii) produces microbial inhibitors; and
(iii) is microbiologically safe; and
(iv) produces a controlled reduction of the pH of the meat mix.

**UCFM** means a comminuted fermented meat which has not had its core temperature maintained at 65°C for at least 10 minutes or an equivalent combination of time and higher temperature during production. To avoid doubt, a UCFM includes comminuted fermented meat which has been heat treated.

**validation** means obtaining evidence to confirm that the food safety program is complete and effective and will deliver the expected food safety outcomes.

**verification** means the use of methods, procedures and tests in addition to monitoring to determine compliance with the food safety program.

(2) Unless expressly provided elsewhere in this Code, a UCFM must not be sold unless it is produced in accordance with this clause.

(3) For the purposes of subclause 9(2), a UCFM may be sold where it is produced using an alternative technology or method specified elsewhere in this Code, provided that the equivalent food safety outcome in this clause is achieved.

(4) A UCFM must be produced in accordance with a food safety program which –

(a) has been verified and audited to ensure the number of *Escherichia coli* organisms in the final UCFM comply with the microbiological limits in Standard 1.6.1 in this Code; and

(b) demonstrates that the production process handles the variations of *Escherichia coli* contamination in the ingoing raw meat ingredients.

(5) As part of the validation or verification requirements of the food safety program, the number of *Escherichia coli* organisms must be recorded for the –

(a) raw meat ingredients used to make a UCFM; and
(b) product after fermentation and any subsequent process.

(6) During UCFM production the following matters must be monitored and recorded at suitable frequencies –

(a) the pH of a fermenting UCFM; and
(b) the temperature and time of fermentation of UCFM; and
(c) the temperature and time of maturation/drying of UCFM; and
(d) the temperature and time of smoking of UCFM; and
(e) the weight loss or water activity.

(7) The measurements recorded under subclauses (5) and (6) must be kept for 12 months after the use-by date or best-before date of a UCFM.

(8) The fermentation of a UCFM must be initiated through the use of a starter culture.
(9) A previously fermented or fermenting meat must not be used as –

(a) a starter culture; or
(b) an ingredient in a UCFM.

(10) Meat and batter mix used in the preparation of a UCFM must, if stored by the manufacturer, be stored at 5°C or below prior to fermentation.

(11) The pH of a fermenting UCFM must be measured in accordance with Method 1 in the Schedule.

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

Editorial note for New Zealand:
For New Zealand the processing of UCFM is regulated under the Food Act 1981.

[2.3] omitting from the Schedule, Method 1, substituting –

1 Meat Determination of pH.

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

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

Regulatory Options Proposed at Draft Assessment and the Associated Impact Analysis

1. Regulatory options proposed at Draft Assessment

The proposed risk management options to mitigate the health risk posed by EHEC in UCFM are:

1.1 Option 1

Status quo – Clause 9, Standard 1.6.2 of the Code.

**Production of fermented comminuted meat which has not been cooked**

(1) Fermentation of a comminuted meat product which will not be cooked must be initiated through the use of a starter culture.

(2) A previously fermented or fermenting meat product must be cooked prior to use as an ingredient in a fermented comminuted meat product which will not itself be cooked.

(3) The number of *Escherichia coli* organisms in a fermented comminuted meat product which will not be cooked must be monitored and recorded for the –

(a) ingoing raw meat ingredients; and
(b) product after fermentation and any subsequent process.

(4) The pH of fermenting comminuted meat products which will not be cooked, measured in accordance with Method 1 in the Schedule, and the fermentation room temperature, must be monitored and recorded during fermentation.

(5) Measurements recorded under subclauses (3) and (4) must be kept either for 1 year after the end of the minimum durable life of the product, or 2 years, whichever is the greater.

(6) Meat for a fermented comminuted meat product which will not be cooked must, if stored by the manufacturer, be stored at 5°C or below prior to fermentation.

(7) The process of fermentation and any other subsequent processes must reduce prior to sale from the processing factory by 99.9% or greater the number of *Escherichia coli* organisms potentially present in a fermented comminuted meat product which has not been cooked.

1.2 Option 2

Proposed amendment at draft assessment under Option 2:
Production of UCFM product must:

(a) Implement a HACCP based food safety program in accordance with Standard 3.2.1 of the Code that has been verified and audited to ensure that the production process effectively reduces the number of *Escherichia coli* organisms in the UCFM product to a level specified in Standard 1.6.1 of the Code, and satisfies the following requirements.

1. Fermentation of a comminuted meat product, which will not be cooked, must be initiated through the use of a starter culture.

2. A previously fermented or fermenting meat product must be treated so as to eliminate all the microbial pathogens and toxins prior to use as an ingredient in a comminuted fermented meat product, which will not itself be cooked.

3. The maximum number of *Escherichia coli* organisms in the ingoing raw meat ingredients should not exceed 20 (MPN\(^{23}\)) per gram unless an equivalent food safety outcome can be demonstrated with existing processing protocol(s); and the number of *Escherichia coli* organisms in a comminuted fermented meat product which will not be cooked must be monitored and recorded for the:
   i. ingoing raw meat ingredients; and
   ii. product after fermentation and any subsequent process.

4. The pH of fermenting comminuted meat products which will not be cooked, measured in accordance with Method 1 in the Schedule of Standard 1.6.2 of the Food Standards Code, and the temperature and time of the fermentation and maturation/drying steps must be monitored and recorded.

5. Measurements recorded under subclauses (3) and (4) must be kept either for 1 year after the end of the minimum durable life of the product, or 2 years, whichever is the greater.

6. Meat for a comminuted fermented meat product which will not be cooked must, if stored by the manufacturer, be stored at 5\(^\circ\)C or below prior to fermentation.

(b) Implement a measure that achieves an equivalent food safety outcome as that achieved through the implementation of HACCP based food safety programs, and this measure is specified in the Food Standards Code.

(c) Conduct microbiological end product testing of each production lot (a lot corresponds to products with the same diameter manufactured under the same conditions in a single day) and hold the lots pending satisfactory compliance of the results with the *Escherichia coli* limit specified in Standard 1.6.1 of the Code. If the product has a pH of 5.3 or lower and a water activity of 0.90 or lower\(^{24}\), the sampling plan prescribed in Standard 1.6.1 applies. Otherwise, 30 samples of 25 g each from the finished products must be taken for microbiological testing and none of the samples should exceed the level specified in Column 5 of the Schedule in Standard 1.6.1 of the Code.

1.3 Option 3

---

\(^{23}\) MPN stands for most probable number.

\(^{24}\) Based on Canadian Food Inspection Agency’s publication of ‘Control of *E. coli* O157:H7 in dry and semi-dry fermented sausages’ (Meat Hygiene Directive 1999-57. Chapter 4, 2000), and data collected by ANZFA between 1997 and 2000 (Predicting *Escherichia coli* inactivation in uncooked comminuted fermented meat products, Meat & Livestock Australia Limited, 2001).
Option 3 is the same as Option 2 except for a variation of item 3 under subclause (a). Item 3 under subclause (a) in Option 3 is described below.

(d) A maximum level of *Escherichia coli* organisms in the ingoing raw meat ingredients must be established in the HACCP based food safety program.

1.4 Option 4

Option 4 is the same as Option 2 but without subclause (b).

1.5 Option 5

Option 5 is the same as Option 3 but without subclause (b).

The following diagram depicts the five regulatory options proposed in the above section.

<table>
<thead>
<tr>
<th>Option 1</th>
<th>Existing standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>Option 2</td>
<td>A core option proposed to replace the existing standard where the 3-\log_{10} reduction is replaced with HACCP based food safety programs, and a maximum <em>E. coli</em> limit of 20 per gram in raw meat ingredients is proposed. In addition, two alternative regulatory measures are proposed, i.e. an equivalence measure and a “test and hold “ measure.</td>
</tr>
<tr>
<td>Option 3</td>
<td>As Option 2 but without a prescribed maximum <em>E. coli</em> limit of 20 per gram in the raw meat ingredients.</td>
</tr>
<tr>
<td>Option 4</td>
<td>Option 4 is a derivative from Option 2, i.e. the same as Option 2 but without the equivalence measure - subclause (b).</td>
</tr>
<tr>
<td>Option 5</td>
<td>Option 5 is a derivative of Option 3, i.e. the same as Option 3 but without the equivalence measure - subclause (b).</td>
</tr>
</tbody>
</table>

2. **Justification of proposed regulatory options at Draft Assessment**

Option 2 differs from the existing standard in that it uses HACCP based food safety program to encapsulate all of the critical control points specified in the existing standard. As food safety program is an outcome-based approach, industry can control product safety through systematic planning in UCFM production to minimise EHEC contamination.

Option 2 specifies a maximum limit for *E. coli* organisms in the ingoing raw meat ingredients, which is a critical control point in reducing EHEC contamination in UCFM. This maximum limit of 20 *E. coli* organisms per gram was derived from the Australia-wide survey data of the microbiological quality of meat, where the mean value of *E. coli* contamination in
frozen-boxed beef was 8 MPN per gram in less than 21% of the samples surveyed\(^\text{25}\). The HACCP based food safety programs, through defined processing conditions or hazard correction procedures, establish a linkage between the maximum limit of \textit{E. coli} in the ingoing raw meat ingredients and the \textit{E. coli} limit in the end products, i.e. the food safety outcome. In estimation, 20 \textit{E. coli} per gram in the ingoing meat ingredients would lead to 0.04 \textit{E. coli} in 0.1 gram of the end product\(^\text{26}\), if the UCFM production process delivers a 2 log\(_{10}\) reduction of \textit{E. coli} organisms and a 28% weight loss. These two values are the industry average of UCFM processing conditions (Attachment 3).

Option 2 provides two alternative regulatory measures to a HACCP based food safety program. The ‘test and hold’ approach, i.e. clause (c) in option 2, is designed for a situation where audit and verification of HACCP based food safety programs become impossible or impractical for various reasons. This may apply to UCFM imported from overseas production sites or to domestic producers whose HACCP based food safety programs are in the process of development or not fully implemented. The pH and water activity requirement (indicators of the effectiveness of the manufacturing process in inactivating \textit{E. coli} organisms) under (c) sets a two-tiered sampling plan. A sufficient reduction of product pH reflects an effective fermentation that has taken place, and a sufficiently low water activity reflects an effective maturation and drying process that has taken place. This requirement ensures an equivalent level of safety is achieved and is in line with the principle of good manufacturing practice. The 5 samples per lot is a standard sampling plan specified in Standard 1.6.1 of the Code. In those situations where products do not meet the pH and water activity requirement, the number of samples tested will increase from 5 to 30 per production lot. This increased number of samples is consistent with the principles of microbiological sampling described by the International Commission of Microbiological Specification for Foods\(^\text{27}\). The two-tiered sampling plan provides an equivalent food safety outcome as that achieved through the implementation of a HACCP based food safety program.

FSANZ is aware that the current volume of imported UCFM is very small. However this volume may increase pending the completion of an import risk analysis of this food category by Biosecurity Australia. The practicality and cost of auditing HACCP based food safety programs at an overseas UCFM production site would be overcome by the ‘test and hold’ approach described in option 2 which provides a mechanism to ensure an equivalent food safety outcome is achieved for any imported UCFM.

The other alternative, i.e. clause (b), is designed to provide opportunities for industry to apply new technologies or measures in manufacturing safe UCFM. For example irradiation to eliminate EHEC offers a possible technical solution to produce safe UCFM. Such alternative technologies or measures will be evaluated by FSANZ as required by clause (b) in order to ensure an equivalent food safety outcome as that achieved through clause (a), i.e. the implementation of HACCP based food safety programs, will be achieved.

\(^{25}\) From Journal of Food Protection, 1998, 61: 437-443. A second survey of microbiological quality of Australian beef in 1998 reported 5 colony forming units per gram (mean value) in 5.1% of boneless beef (Journal of Food Protection, 2001, 64:692-696). Due to the difference of the measurement units used, figures in the second survey were not used in this report.

\(^{26}\) Calculations were performed according to those in Table X1 in Attachment 3, but without a conversion of \textit{E. coli} to EHEC.

Option 3 is similar to Option 2, but does not specify a maximum *E. coli* limit in ingoing raw meat ingredients. This option requires individual producers to set their own specification of maximum *E. coli* limits in ingoing raw meat ingredients as a compulsory component under the HACCP based food safety programs. The process must be able to reduce the number of *E. coli* organisms in the UCFM to the level specified in Standard 1.6.1 of the Code. In some cases, producers may find establishing such a limit a difficult task due to various reasons, such as inability to evaluate scientific data. Regulators on the other hand, will face a range of maximum *E. coli* limits, which could create additional demand for enforcement resources.

Option 4 is similar to Option 2, but does not provide industry the opportunity to use alternative technologies or measures in manufacturing safe UCFM because clause (b) in Option 2 has been taken out. This is the only difference between Option 2 and Option 4.

Option 5 is similar to Option 3, but does not provide industry the opportunity to use alternative technologies or measures in manufacturing safe UCFM because clause (b) in Option 3 has been taken out. This is the only difference between Option 5 and Option 3.

The above comparison suggests that Option 2 is the preferred regulatory option for its comprehensiveness. It provides a superior level of protection of public health and safety that is achievable by the UCFM industry, future importers and enforcement agencies. The economic analysis in the next section provides additional support to this preference.

3. Impact Analysis at Draft Assessment

3.1 Impact of Option 1

3.1.1 Consumers

Risk management measures in this option minimise the extent of EHEC contamination in UCFM, therefore provide a basic level of protection for consumers. No tangible economic benefits could be identified.

3.1.2 Industry

As costs associated with capital injection and implementation to comply with Option 1 have largely occurred (Attachment 5), future cost to the industry will be primarily spent in routine operation, i.e. additional operating costs to ensure compliance with the existing standard.

The industry itself may have benefited from the requirements in this option to produce products with a high level of consistency in the long term due to consolidation of production parameters as a result of the assessment of production protocols (section 4.3). This would minimise operation cost, and have the potential to retain and/or boost the overall sales of those products meeting all the requirements under this option.

3.1.3 Government

Future costs to the government will be those of continuing enforcement. Based on the costs previously incurred (Attachment 5), it is estimated that the total enforcement cost at the State and Territory level will be approximately $130,000 a year, and the involvement of FSANZ’s Expert Advisory Panel in assisting State and Territory governments to assess industry
compliance with the standard will be approximately $93,400 a year. No tangible economic benefits can be identified for government under this option.

3.2 Impact of Option 2

3.2.1 Consumers

Option 2 provides a comprehensive level of protection for consumers and hence a greater consumer confidence on UCFM safety is anticipated. A wide range of UCFM may be available to consumers under option 2. No tangible economic cost can be identified for consumers under option 2.

3.2.2 Industry

The industry will benefit from a reduced compliance cost under this option. This option removes the cost and uncertainty of attempting to comply with the requirement of a $3-\text{log}_{10}$ reduction (under Option 1) where significant outlay of resources may not guarantee compliance.

This option will impose compliance costs on the industry for the implementation of HACCP based food safety programs, but the additional costs are expected to be small because the industry has taken significant steps in the past to implement HACCP based food safety systems. Available information indicates HACCP based food safety systems were introduced into the UCFM industry as early as in 1998. As a result, implementation of HACCP based food safety programs will not result in significant additional costs to the industry. To assist the industry to implement and regulators to audit HACCP based food safety programs, FSANZ has approached the MLA to update the section of ‘Uncooked fermented comminuted meats’ in the MLA’s ‘Guidelines for the safe manufacture of smallgoods’ upon the release of the amended standard proposed in this report. The Guidelines provides a comprehensive coverage of the HACCP principles and identifies all the critical control points and corrective measures as well as the good manufacturing practice in the production of UCFM.

As indicated in the report of National Risk Validation Project\textsuperscript{28} published recently, the costs of implementation of food safety programs are outweighed significantly by the benefits associated with avoiding the cost of foodborne illness from EHEC in contaminated UCFM.

The alternative measures, i.e. clause (b), under this option offers flexibility for manufacturers to use alternative technologies or measures in manufacturing safe UCFM products, providing that an equivalent food safety outcome is achieved. The cost is dependent on the chosen technology or measure or both. Under the current FSANZ process, a full assessment to verify a proposed technology or measure in achieving the same food safety outcome as that achieved through the implementation of HACCP based food safety programs as in clause (a) will take more than 12 months to complete. Such an assessment process could result in an opportunity cost to the manufacturer because of the delay in applying the proposed technology or measure to produce UCFM. The benefit of this option is that manufacturers can produce products that may not be allowed under the previous option.

\textsuperscript{28} National Risk Validation Project – Final report (2002) Food Science Australia and Minter Ellison Consulting.
The ‘test and hold’, i.e. clause (c), under this option would impose a significant cost to the industry. A microbiological testing requirement similar to the ‘Test and hold’ option is currently used in Australia as a temporary measure for those manufacturers who are yet to demonstrate successfully their compliance with the requirements in the existing standard.

The ‘test and hold’ provides an alternative regulatory mechanism for determining the safety of imported products, and to those domestic producers whose HACCP based food safety programs are in the development stage or yet to be fully implemented. The estimated cost of microbiological testing is $35 or more per sample. For a production lot, the testing cost would be approximately $175 because 5 samples must be taken. For a manufacturer producing 5 lots a week for 48 weeks in a year, the annual microbiological testing cost under the ‘test and hold’ approach would be approximately $42,000. If the product pH and water activity fall outside the range specified under option 2 (c), the microbiological testing cost would be approximately $252,000 a year. It is anticipated that under normal circumstances, domestic producers would prefer to comply with Option 2 (a), i.e. implementation of HACCP based food safety programs to mitigate the risk of EHEC contamination in UCFM.

3.2.3 Government

There will be enforcement costs at the State and Territory level as a result of auditing and verification to ensure that HACCP based food safety programs are effectively implemented by UCFM manufacturers. Because HACCP based food safety systems have already been implemented by the UCFM industry and audited in most of the States, additional costs of enforcement are likely to be small. AQIS will incur enforcement costs through testing of imported products for compliance with the requirements if the current importation restriction on UCFM is lifted.

FSANZ will incur a cost if it has to evaluate alternative manufacturing technologies or measures proposed by the industry to determine if the alternative technologies or measures would achieve an equivalent food safety outcome as that achieved through the implementation of HACCP based food safety programs.

No tangible economic benefit can be identified for government under this option.

3.3 Impact of Option 3

Option 3 is similar to Option 2, but requires UCFM manufacturers to establish a maximum limit of *E. coli* organisms in ingoing raw meat ingredients. The impact under this option to consumers is no different from those under Option 2.

3.3.1 Industry

Other than those identified under Option 2, establishing a maximum limit of *E. coli* organisms in ingoing raw meat ingredients is not expected to result in a significant cost to the industry under Option 3. However, some manufacturers, particularly small sized manufacturers may find the task difficult due to various reasons, such as problems with access to scientific publications and ability to evaluate scientific data. Under Option 3, there is a perceived benefit to individual producers, where a self-determined maximum limit of *E. coli* organisms in the ingoing raw meat ingredients will allow a close match with the production parameters used.
3.3.2 Government

Other than those identified under Option 2, different limits set by different UCFM producers may lead to an increased level of complexity in auditing and verification by the State and Territory regulators. This may result in an increased cost in the enforcement of the overall regulatory measure. This additional cost is anticipated to be small because auditing and verification are producer specific process where the maximum E. coli limit set by the manufacturer forms a part of the HACCP based food safety program.

3.4 Impact of Option 4

Option 4 is the same as Option 2, but without the equivalence alternative. The equivalence alternative is designed to offer flexibility for manufacturers to use alternative technologies or measures in manufacturing safe UCFM. The removal of this flexibility would impact mainly on industry.

3.4.1 Industry

In addition to those identified under Option 2, industry is denied an opportunity to apply alternative technologies or systems in producing safe UCFM under option 4. This may translate to a cost to the industry.

3.4.2 Government

In addition to those identified under option 2, there will be a saving to the government under option 4. Government will not incur a cost to assess the alternative technologies or measures proposed by the industry to determine if an equivalent food safety outcome is achieved as that achieved through the implementation of HACCP based food safety programs.

3.5 Impact of Option 5

Option 5 is the same as Option 3, but without the equivalence alternative. Because the equivalence alternative is designed to offer flexibility for manufacturers to apply alternative technologies or measures in manufacturing UCFM to achieve the same food safety outcome achieved through the implementation of HACCP based food safety program, it impacts mainly on industry.

3.5.1 Industry

Other than those identified under Option 3, industry is denied the opportunity of applying alternative technologies or measures in producing safe UCFM under option 5. It may translate to a cost to the industry.

3.5.2 Government

Other than those identified under option 3, there will be a saving to the government under option 5. Government will not incur a cost to assess the alternative technologies or measures proposed by the industry to determine if an equivalent food safety outcome is achieved as that achieved through the implementation of HACCP based food safety programs.
Risk assessment of public health implications of enterohaemorrhagic *Escherichia coli* in uncooked comminuted fermented meat products
Executive Summary

This risk assessment evaluates the public health implications of enterohaemorrhagic Escherichia coli (EHEC) organisms potentially present in uncooked comminuted fermented meat (UCFM) products. It uses the available data to evaluate the likelihood of occurrence of EHEC in UCFM products produced in Australia, and the susceptibility of Australian consumers to complications of EHEC infection through consumption of these products. The risk assessment does not specifically determine whether a UCFM product is ‘safe’ or ‘unsafe’ for human consumption.

Previous outbreaks, such as the Garibaldi outbreak in 1995, the 1994 Washington and California outbreak of foodborne illnesses, the 1998 Ontario outbreak and 1999 Western Canada outbreak demonstrate that UCFM products if contaminated by EHEC present a public health risk to consumers, particularly young children under the age of 6-years. This is because UCFM products are ready-to-eat food made with comminuted raw meat that could be contaminated by EHE organisms and with a process involving little or no thermal inactivation of microorganisms, the EHEC infectious dose is low, and the illness caused by EHEC infection can be severe.

The key findings of the risk assessment are:

- The available information indicates that the EHEC infectious dose is low, and ingestion of as little as one EHEC organism could lead to adverse health effects for susceptible consumers. The infectious dose tends to vary according to an individual’s susceptibility. The consequence of EHEC infection can be severe, ranging from diarrhoea to haemolytic uraemic syndrome (HUS), kidney failure and even death.

- There is evidence to suggest that young children, the frail elderly, and people suffering from chronic diseases, or with depressed immune systems are more susceptible to the development of complications resulting from EHEC infection than the rest of the population. Children under the age of 6-years are most susceptible.

- A very low level of EHEC (0.15 per 100 grams) is likely to be present in a small proportion of UCFM (approximately 7.2%) produced in Australia. To the general public, the risk of getting an EHEC infection through the consumption of UCFM products is small.

- These risk estimates are affected primarily by the following factors:
  a) EHEC levels in the raw meat ingredient;
  b) Reduction in the level of EHEC due to UCFM production process;
  c) the amount of weight loss as a result of UCFM production process; and
  d) the susceptibility of the subpopulations to complications of EHEC infection.
The risk estimates in this assessment are derived from a collection of data including EHEC prevalence in beef and survey results of Australian UCFM production processes. The robustness of the risk estimates may only be assessed when appropriate survey data becomes available.
Introduction

Outbreaks of foodborne illness due to consumption of uncooked comminuted fermented meat (UCFM) contaminated by pathogenic microorganisms have been reported in Australia and other countries. Pathogenic microorganisms found in UCFM products include *Salmonella*, *Listeria monocytogenes*, enterotoxic *Staphylococcus aureus*, and enterohaemorrhagic *Escherichia coli* (EHEC). Illnesses caused by EHEC can be severe and sometimes can lead to death, such as those reported in the Garibaldi outbreak in 1995 (Anon. 1995B).

As part of a review of processing requirements for UCFM production in the *Australia New Zealand Food Standards Code* (Code), this risk assessment evaluates the potential occurrence of EHEC in UCFM products produced in Australia. It assesses the susceptibility of Australian consumers to complications of EHEC infection as a result of consumption of EHEC contaminated UCFM. This report is limited to EHEC contamination of UCFM products, and thus other probable pathogens are not considered in this review.

EHEC is a group of emerging microbial pathogens (IFT, 2002). EHEC organisms produce Shiga-like toxins and a number of virulence factors, and are highly infectious to humans because a low number of EHEC organisms can cause severe illnesses (Griffin, 1998). EHEC association with foods, particularly uncooked or undercooked meat products, such as ground beef and UCFM, can lead to severe food-borne illnesses in humans, and therefore has significant implications for public health.

This risk assessment uses the Codex framework of microbiological risk assessment (Codex, 1999), and is divided into four parts.

Hazard Identification Exposure Assessment
Hazard Characterisation Risk Characterisation

Hazard Identification describes the hazard, i.e. EHEC organisms in UCFM, and the effect of the hazard to public health through a review of microbiological, clinical, epidemiological studies and surveillance data.

Hazard Characterisation establishes a relationship between the magnitude of exposure to EHEC in UCFM and the severity of the associated adverse health effects, i.e. a dose-response relationship. More specifically this section examines the dose-response relationship for the subgroups of the Australian population who may be more susceptible to complications of EHEC infection.

Exposure Assessment establishes the level of EHEC contamination in UCFM through an analysis of the critical steps in UCFM production. Consumption data of specific population groups are used to estimate the exposure to EHEC from consuming UCFM products. The combined measure of these two factors leads to a qualitative measure of the hazard exposure.

---

29 Uncooked comminuted fermented meat (UCFM) products are ready-to-eat food, and do not require a cooking step during the manufacturing process or by consumers before consumption. The principle ingredients of UCFM products are chopped or minced bovine and porcine meats. Production of UCFM involves a fermentation step, a maturation/drying step, and sometimes a smoking step. Typical UCFM products include various types of salami, summer sausage, mettwurst and others. In other parts of the world, equivalent terms for UCFM are semi-dry sausages and dry sausages.
Risk Characterisation identifies the likelihood of adverse health effects, i.e. a risk estimate that the Australian population would experience from exposure to UCFM products that may contain EHEC. The risk characterisation also describes the variability and uncertainty of the risk estimate, and identifies data gaps in this assessment.

Among different EHEC serotypes, *E. coli* O157:H7 is the single most important EHEC serotype that dominates the number of reported foodborne illnesses caused by EHEC (Mead et al., 1999). Because of the scarcity of microbiological and epidemiological data of non-O157:H7 EHEC serotypes, this risk assessment relies heavily on research data on *E. coli* O157:H7. For this reason, the terms of EHEC and *E. coli* O157:H7 are sometimes used interchangeably in this report.

Hazard Identification

The hazard identification describes the hazard, namely EHEC in UCFM products, and the effect of this hazard on human health.

*Enterohaemorrhagic Escherichia coli*

*Campylobacter, Salmonella, EHEC, and Listeria monocytogenes* are the four emerging foodborne microbial pathogens which can cause adverse health effects for humans (IFT, 2002). *E. coli* O157:H7, a serotype responsible for the majority of EHEC caused foodborne illnesses, is estimated to account for 62,459 cases of foodborne illness and 52 deaths per annum in the USA (IFT, 2002).

EHEC is a term used to describe a group of *E. coli* organisms producing Shiga toxins and a number of other virulence factors particularly the adhesion molecule, intimin. The Shiga toxins are closely related or identical to the toxins produced by *Shigella dysenteriae*. Genes of the virulence factors other than Shiga toxins, are located in the locus of enterocyte effacement (LEE). These virulent factors and Shiga toxins allow the organisms to attach tightly to mammalian epithelial cells, disrupting the cytoskeletal structure, signalling pathways and causing effacing lesion (Ismaili et al., 1998).

Many synonyms are used to describe EHEC, including Shiga toxin-producing *E. coli* (STEC), Shiga-like toxin-producing *E. coli* (SLTEC), verotoxin-producing *E. coli*, verocytotoxin-producing *E. coli* (VTEC), as well as *E. coli* O157 and *E. coli* O157:H7. There is some confusion with the use of the above terms to describe EHEC. One of the reasons is that not all STEC or VTEC strains associated with human illnesses possess LEE, which is characteristic to EHEC organisms. Additionally, EHEC contains a range of other serotypes in addition to *E. coli* O157 or *E. coli* O157:H7 (Whittam, 1998). For the purpose of this report, the term EHEC is used to describe a group of *E. coli* that causes symptomatic illnesses such as haemorrhagic colitis and haemolytic uraemic syndrome (HUS).

Among different EHEC serotypes, *E. coli* O157:H7 is the single most important EHEC serotype that dominates the number of reported foodborne illnesses caused by EHEC. Mead et al. (1999) reported that *E. coli* O157:H7 caused approximately 73,000 cases of illness each year, and non-O157:H7 EHEC caused approximately 37,000 cases of illness in the USA. Because of the scarcity of microbiological and epidemiological data of non-O157:H7 EHEC serotypes, this risk assessment relies heavily on research data on *E. coli* O157:H7. For this
reason, the terms of EHEC and *E. coli* O157:H7 are sometimes used interchangeably in this report.

Since 1982 when *E. coli* O157:H7 was identified as a human pathogen (Riley et al., 1983), more than 100 EHEC serotypes have been identified (Rowe et al., 1993 and Griffin, 1995). The major EHEC serotypes commonly associated with intestinal diseases are listed in Table 1.

Table 1. Major serotypes of EHEC organisms causing intestinal diseases in humans

<table>
<thead>
<tr>
<th>Serotype</th>
<th>Source</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2: Anon (1995B)</td>
</tr>
<tr>
<td></td>
<td>3: Anon (1995C)</td>
</tr>
<tr>
<td></td>
<td>4: Desmarchelier, P. (2001)</td>
</tr>
</tbody>
</table>

Pathology of EHEC caused illnesses

Normally, EHEC infection results in diarrhoea like symptoms. Haemorrhagic colitis, an acute illness caused by EHEC organisms, is characterized by severe abdominal pain and diarrhoea.

This diarrhoea is initially watery but becomes grossly bloody. Symptoms such as vomiting and low-grade fever may be experienced. The illness is usually self-limiting and lasts for an average of 8 days. The duration of the excretion of EHEC is about one week or less in adults, but it can be longer in children (ICMSF, 1996).

Complications resulting from EHEC infections vary. About 5% of haemorrhagic colitis victims may develop HUS (European Community, 2000). This involves the rupture of red blood cells (haemolysis), subsequent anaemia, low platelet count and kidney failure. The case-fatality rate of HUS is 3% to 5% (WHO, 1996). Shigella toxins produced by EHEC organisms attack the lining of the blood vessels throughout the body, predominantly affecting the kidney. However other organs such as the brain, pancreas, gut, liver and heart are also affected and may result in further complications such as thrombotic thrombocytopenic purpura (TTP).

HUS became a notifiable disease in Australia from 1998, although it was notifiable earlier in some of the States. During 1995 to 2001, Australia recorded 94 cases of HUS (Communicable Diseases - Australia, 2002). There is no data for the number of notified cases of TTP in Australia.

Pathogenicity of EHEC

The mechanism of EHEC pathogenicity is not fully understood, but the important virulence factors have been identified.

The onset of the illness is due to the attachment of the EHEC organisms to the mucosal surface of the intestine. This results in an attachment/effacement lesion and may be sufficient to cause the initial non-bloody diarrhoea (Todd & Dundas, 2001). The adhesion molecule,
intimin (coded by the *eae* gene), is an outer membrane protein required for *E. coli* O157:H7 to adhere to mammalian cells.

All clinical EHEC isolates produce at least one or two Shiga toxins (Bopp et al., 1987). The two toxins are designated Shiga toxin 1 (Stx 1) and Shiga toxin 2 (Stx 2). Stx 1 and Stx 2 expressed by EHEC, are similar in structure, and both are cytotoxins that can block eukaryotic translation. Once established on the mucosal surface, the organism produces Shiga toxins, which bind to the globotriaosylceramide receptor (Gb3 receptor) in the membranes of the eukaryotic cells. The subsequent internalisation of the toxins acts to block cellular protein synthesis, which can lead to apoptosis in endothelial cells, i.e. the development of bloody diarrhoea (Todd & Dundas, 2001). HUS is the result of microvascular damage when the Shiga toxins enter the bloodstream and bind to Gb3 receptors on endothelial cells. Further development of HUS affects the kidney and the brain because Gb3 receptors are abundant in these two organs (Nataro and Kaper, 1998).

EHEC strains that produce Stx 2 or both toxins are more commonly associated with human illness than strains that produce only Stx1 (Strockbine et al., 1998 and Gansheroff & O’Brien, 2000).

*Age and susceptibility to EHEC infection*

Age is the most consistent risk factor for susceptibility to complications resulting from EHEC infection. Children less than 5 years (Drummond, 1985 and Duncan et al., 1986) and adults older than 65 years (Carter et al., 1987 and Ryan et al., 1986) are at a greater risk of developing HUS/TTP. In an analysis of 347 confirmed cases from a Central Scotland outbreak of EHEC infection in 1996, 34 cases developed HUS/TTP. This analysis identified a statistically significant association between the age and the development of HUS/TTP. Cases of people younger than 15 or older than 65 years of age were four times more likely to develop HUS/TTP, than people aged between 15 and 65 years (Todd & Dundas, 2001). Gender has not been identified to be associated with the development of HUS/TTP (Todd & Dundas, 2001).

*EHEC transmission*

EHEC have also been isolated from animals such as pigs, sheep, dogs, cats, horses, and birds including seagulls and geese (European Commission, 2000). The main reservoir of EHEC is ruminants, particularly cattle.

The four major routes of EHEC transmission to humans are:

- person to person;
- foodborne including drinking water;
- acquired from the environment, such as swimming in a lake or pool; and
- direct contact with farm animals.

A model identifying potential pathways of *E. coli* O157:H7 transmission to humans is shown in Figure 1.
Prevalence of EHEC serotypes in Australia

In Australia, *E. coli* O157:H7 is not commonly isolated (Goldwater & Bettelheim, 1995 and Robins-Brown et al., 1998), but *E. coli* O111 is common. During 1987 to 1994, seven of the 14 non-O157 EHEC strains from Australians with HUS were identified as *E. coli* O111 (Goldwater & Bettelheim, 1995). *E. coli* O111 was the second most common non-O157 EHEC serotypes isolated from disease specimens submitted to the Centre for Disease Control and Prevention (USA) for stereotyping between 1983-1998 (Anon. 2000A). Table 2 lists a number of reported cases of EHEC outbreaks due to serotype O111 in the developed countries.
**Table 2. Reported outbreaks referred to E. coli serotype O111**

<table>
<thead>
<tr>
<th>Outbreak</th>
<th>Serotype</th>
<th>No. Affected</th>
<th>No. with HUS/TTP</th>
<th>No. of Death</th>
<th>Likely vehicle</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1986 Japan</td>
<td>O111:H</td>
<td>22</td>
<td>1</td>
<td>1 (&lt; 3 year-old)</td>
<td>Unknown</td>
<td>Tanaka et al., 1989</td>
</tr>
<tr>
<td>1987 Finland</td>
<td>O111:B4</td>
<td>650</td>
<td>0</td>
<td>0</td>
<td>Unknown</td>
<td>Viljanen et al., 1990</td>
</tr>
<tr>
<td>1988 Australia</td>
<td>O111:H2</td>
<td>2</td>
<td>2</td>
<td>0</td>
<td>Unknown</td>
<td>Gunzburg et al., 1988</td>
</tr>
<tr>
<td>1990 USA</td>
<td>O111:NM</td>
<td>5</td>
<td>1</td>
<td>0</td>
<td>Unknown</td>
<td>Banatvala et al., 1996</td>
</tr>
<tr>
<td>1991 Japan</td>
<td>O111:H</td>
<td>234</td>
<td>Not reported</td>
<td>0</td>
<td>Unknown</td>
<td>Kodoh &amp; Kai, 1995</td>
</tr>
<tr>
<td>1992 Italy</td>
<td>O111:H</td>
<td>9</td>
<td>9</td>
<td>1</td>
<td>Unknown</td>
<td>Caprioli et al., (1994)</td>
</tr>
<tr>
<td>1992 France</td>
<td>O111:B4</td>
<td>26</td>
<td>10</td>
<td>0</td>
<td>Unknown</td>
<td>Capek &amp; Ilef, 1993</td>
</tr>
<tr>
<td>1995 France</td>
<td>O111</td>
<td>37</td>
<td>0</td>
<td>0</td>
<td>Unknown</td>
<td>Wright et al., 1997</td>
</tr>
<tr>
<td>1999 USA</td>
<td>O111:H8</td>
<td>58</td>
<td>2</td>
<td>0</td>
<td>Unknown</td>
<td>Anon. (2000A)</td>
</tr>
</tbody>
</table>

*Outbreak of infection due to EHEC contamination in UCFM products*

A large outbreak in South Australia in 1995 resulted in approximately 200 cases of foodborne illness (Anon. 1995B and Robins-Browne et al., 1998). Twenty-two patients aged between 4 months and 12 years developed HUS and were hospitalised. A 4-year-old child died. Investigations of the outbreak identified EHEC strain O111:NM (or strain O111:H-, NM for nonmotile) as the principal cause of the outbreak. A locally produced mettwurst (a type of UCFM) was identified as the vehicle for the pathogen. The product was found to contain a variety of EHEC strains in addition to O111 (Paton et al., 1996). A recent investigation of a foodborne illness indicated that consumption of cacciatore, a UCFM product contaminated by E. coli O157:H7, was the cause of the illness (Table 3).

Elsewhere, an E. coli O157:H7 caused outbreak of human illness associated with the consumption of dry-cured salami (a type of UCFM), was reported in the United States in 1994 (Anon. 1995A). During 1997, 1998 and 1999, large-scale product recalls were issued for possible contamination of E. coli O157:H7 in UCFM by several Canadian UCFM producers, and health hazard alerts were issued by the Canadian Food Inspection Agency. In the spring of 1998, an E. coli O157:H7 outbreak was traced to a naturally fermented Genoa salami product manufactured in Ontario, Canada; and in November 1999, another E. coli O157:H7 outbreak in Western Canada was traced to a Hungarian-style UCFM. With the latter outbreak, over 150 people became sick and at least five developed HUS30. A summary of the incidences of EHEC caused illness resulting from consumption of EHEC contaminated UCFM products in Australia and the USA is shown in Table 3.

---

30 Health Canada, Interim guidelines for the control of verotoxinogenic *Escherichia coli* including *E. coli* O157:H7 in ready to eat fermented sausages containing beef or beef product as an ingredient, Guideline no. 12, issued by Food Directorate, Health Protection Branch, Health Canada, 24 February 2000.
Examination of the data of UCFM product recalls in Australia (Table 4) shows that EHEC are detected from time to time in UCFM products. Notably, the three reported EHEC recalls were the result of systematic investigations into the cause of the human illnesses or in a wake of a significant outbreak.

**Table 3. Reported incidents of EHEC contamination in UCFM products**

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>EHEC serotype</td>
<td>O157:H7</td>
<td>O111:H -</td>
<td>O157:H7</td>
</tr>
<tr>
<td>No. Affected</td>
<td>24</td>
<td>~200</td>
<td>2</td>
</tr>
<tr>
<td>No. Hospitalisation</td>
<td>7</td>
<td>&gt;35</td>
<td>1</td>
</tr>
<tr>
<td>No. with HUS</td>
<td>3 (20 months, 2 and 4 year-old)</td>
<td>22 children (median age 4 years) and a number of others</td>
<td>0 (a 67 year-old developed bloody diarrhoea but did not progress to HUS)</td>
</tr>
<tr>
<td>No. of Death</td>
<td>0</td>
<td>1 (4 year-old)</td>
<td>0</td>
</tr>
<tr>
<td>No. with TTP</td>
<td>Not available</td>
<td>4</td>
<td>Not available</td>
</tr>
</tbody>
</table>

* Growth characteristics of EHEC organisms*

Under optimal growth conditions, *E. coli* grows well in the temperature range of 35 to 40°C, although some pathogenic *E. coli* strains can grow at temperatures as low as 7°C and as high as 46°C (ICMSF, 1996).

Minimum temperature requirement for the growth of *E. coli* O157:H7 under otherwise ideal conditions is 8°C and a maximum is about 44 to 45°C. *E. coli* O157:H7 may survive freezing conditions. For example, little or no changes were observed in *E. coli* O157:H7 populations in ground beef stored over 9 months at –20°C (ICMSF, 1996).

EHEC is destroyed by thorough cooking of foods provided all parts reach a temperature of 70°C or higher (WHO, 1996), or a temperature of 65°C for at least 10 minutes or an equivalent combination of time and higher temperature according to the Code.

Some EHEC may survive or grow in acidic foods, such as at pH of 4.4 but not with lactic acid as the buffering agent (Glass et al, 1992).

EHEC grow poorly in a low water activity (a_w) environment although some EHEC may survive in foods with a minimum a_w of 0.95 (ICMSF, 1996).

EHEC do not grow in typically finished UCFM products and the population declines with time (Grau, 1996). This is because of a low pH due to the production of lactic acid from fermentation, and a low water activity due to maturation/drying in the production process.

*Factors affecting survival and growth of EHEC in UCFM products*

Figure 2 shows the general steps involved in UCFM productions.
Meat is the principal ingredient in UCFM products and can be contaminated by EHEC organisms because faecal contamination on the meat surface is internalised through the manufacturing process. Meat stored either frozen or chilled to less than 5°C, will prevent EHEC growth. The process of chopping is usually carried out below the freezing temperature. This process however distributes the microorganisms throughout the meat mass.

Table 4. Reported UCFM product recalls due to presence of microbial pathogens in Australia (FSANZ data, 2002)

<table>
<thead>
<tr>
<th>Year</th>
<th>Product</th>
<th>Reason for Recall</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>1995 (South Australia)</td>
<td>Garlic Mettwurst</td>
<td>EHEC (O111:NM)</td>
<td>A number of precautionary recalls were made nationwide with products sourced from the manufacturer involved in the 1995 EHEC outbreak in South Australia</td>
</tr>
<tr>
<td>1995 (Western Australia)</td>
<td>Spreadable Mettwurst</td>
<td>E. coli O157:H7</td>
<td></td>
</tr>
<tr>
<td>1999 (Western Australia)</td>
<td>Teewurst fermented smoked soft meat spread</td>
<td>E. coli</td>
<td></td>
</tr>
<tr>
<td>1999 (Western Australia)</td>
<td>Cacciatore</td>
<td>E. coli</td>
<td></td>
</tr>
<tr>
<td>2002 (New South Wales)</td>
<td>Nam Thai fermented meat</td>
<td>E. coli</td>
<td></td>
</tr>
<tr>
<td>2002 (Western Australia)</td>
<td>Cacciatore</td>
<td>E. coli O157:H7</td>
<td>Manufacturer recall (Goodchild, Department of Health in Western Australia, Per. Communication, 2002)</td>
</tr>
<tr>
<td>1994 (South Australia)</td>
<td>Mettwurst</td>
<td>Salmonella</td>
<td></td>
</tr>
<tr>
<td>1995 (Victoria)</td>
<td>Felino Salami</td>
<td>Salmonella</td>
<td></td>
</tr>
<tr>
<td>2001 (Western Australia)</td>
<td>Cacciatore (Hot &amp; Mild)</td>
<td>Salmonella</td>
<td></td>
</tr>
<tr>
<td>1997 (Victoria)</td>
<td>Salami cheese</td>
<td>Listeria monocytogenes</td>
<td></td>
</tr>
<tr>
<td>2002 (Queensland)</td>
<td>Pepperoni in vacuum pack</td>
<td>Listeria monocytogenes</td>
<td></td>
</tr>
</tbody>
</table>

Salt is usually added to UCFM at about 2.5%. Taking into consideration the amount of water in fat (approximately 15%) and lean meat (approximately 72%), the final salt concentration is approximately 4.5% in the aqueous phase, assuming the product has 70% lean meat and 30% fat. This amount of salt cannot prevent EHEC growth completely as *E. coli* O157:H7 has been demonstrated to grow slowly in a broth containing 6.5% NaCl but not 8.5% NaCl (Ross & Shadbolt, 2001). A small amount of sugar is usually added to the raw ingredients to facilitate acid production through fermentation. Nitrite and various kinds of spices are added to impart desirable flavour and other features for the final product. Since 1995, most UCFM products made in Australia are fermented with the use of starter cultures. These cultures contain mainly *Staphylococcus xylosus* and/or *Pediococcus pentosaceus*. These ingredients are unlikely to be a source of EHEC.

In the production process, fermentation temperatures are usually controlled at 15 to 33°C for a period of 24 to 72 hours (FSANZ data31). The ability of the starter culture to dominate the microbial population and to produce a sufficient amount of acid (lactic acid) results in

31 Extracted from 96 production protocols used in manufacturing UCFM in Australia (2002).
significant pH reductions during the fermentation process. This reduces the initial number of EHEC organisms present in the raw ingredients.

Figure 2. A flow diagram showing the processing steps in making UCFM (modified from Ross & Shadbolt, 2001)
A maturation/drying period of 3 to 20 days at temperature of 15 to 25°C follows the fermentation step (FSANZ data). A smoking process is usually placed between the steps of fermentation and maturation/drying, although in some cases, the smoking process takes place at the end of maturation. The maturation/drying process in UCFM production reduces the product $a_w$, and is the most significant step in EHEC inactivation (Grau, 1996).

Data collected by the then ANZFA between 1997 and 2000 indicate a final average pH of 4.91 and a final average $a_w$ of 0.90 in Australian UCFM products (Ross & Shadbolt, 2001). According to Grau (1996), a pH of 4.6 on its own is not sufficient to result in significant EHEC cell deaths. However, in combination with $a_w$ of about 0.90, death of EHEC cells could be around $2 \log_{10}$. The inactivation of EHEC as a result of pH reduction and water activity reduction in UCFM production is time and temperature dependent.

Limitation in hazard identification

Most *E. coli* O157 strains ferment sorbitol slowly. This trait together with their ability to grow in the presence of cefixime and potassium tellurite has been used to distinguish *E. coli* O157:H7 from other EHEC strains through the growth characteristics on sorbitol MacConkey medium (Desmarchelier & Grau, 1997). The method is not applicable to screening for EHEC serotypes other than *E. coli* O157.

Immunomagnetic separation using O157 antigen coated beads is used in routine isolations of *E. coli* O157:H7. Polymerase chain reactions are used to detect *stx* genes, *eae* gene in the LEE locus, and *ehx* gene (hemolysin gene) located in the large plasmid that is frequently found in EHEC.

Techniques used for isolating *E. coli* O157:H7 from foods and clinical specimens are not capable of identifying all the EHEC responsible of causing human illnesses (Desmarchelier & Grau, 1997). As a result, research data on non-O157:H7 EHEC is limited, and the reported incidences of illnesses resulting from EHEC contamination of foods may be underestimated.

Summary

EHEC are one of the four emerging microbial pathogens in food impacting on human health. Published data indicates in Australia, human illnesses due to serotype O157:H7 infection are not found as frequently as those in the United States. However, serotype O111 was identified in a significant outbreak due to consumption of a contaminated UCFM product.

EHEC growth in UCFM products is restricted by a combination of environmental factors including a low pH (4.4), and a low water activity (0.95).

Hazard Characterisation

The hazard characterisation establishes a relationship between the magnitude of exposure to EHEC in UCFM products and the severity of the associated adverse health effects, i.e. a dose-response relationship. More specifically this section examines the dose-response relationship for subgroups of the Australian population who may be more susceptible to the complications of EHEC infection.
**Dose-response relationship**

Only limited information is available for determining a typical dose-response relationship between the consumption of EHEC contaminated food and the likelihood of illnesses. The dose-response estimate is further complicated by a large number of serotypes of EHEC and the association of EHEC with a variety of food. Because of the scarcity of dose-response data on non-O157:H7 EHEC strains, information referred here are drawn mainly from those on *E. coli* O157:H7.

There have been many attempts to use data from investigations of known outbreaks or through systematic studies to quantify the dose-response relationship. Estimates of dose leading to adverse health effects vary from as little as 1 up to 700 EHEC organisms (Table 5 and Figure 3). The general consensus is that EHEC infectious dose is low (Griffin 1998).

**Table 5. Reported estimates of EHEC dose in foods resulting in illnesses**

<table>
<thead>
<tr>
<th>Estimated dose</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1  Less than 2 <em>E. coli</em> O157:H7 organisms</td>
<td>USDA, 1993; Willshaw et al., (1994)</td>
</tr>
<tr>
<td>2  As little as one <em>E. coli</em> O111:H1</td>
<td>Paton et al., 1996</td>
</tr>
<tr>
<td>3  Fewer than 50 organisms of <em>E. coli</em> O157:H7</td>
<td>Tilden et al., (1996)</td>
</tr>
<tr>
<td>4  Less than 700 <em>E. coli</em> O157:H7 (in hamburger patties prior to heat treatment)</td>
<td>Armstrong et al. 1996</td>
</tr>
<tr>
<td>5  Less than 100 <em>E. coli</em> O157:H7 cells</td>
<td>Doyle et al., (1997)</td>
</tr>
<tr>
<td>6  Ingestion of 100 cells can cause disease</td>
<td>Cray et al., 1998</td>
</tr>
<tr>
<td>7  The number of EHEC required to cause illness is very low</td>
<td>Anon. (1999)</td>
</tr>
<tr>
<td>8  Infection dose can be low</td>
<td>European Commission, (2000)</td>
</tr>
<tr>
<td>9  As few as 50 to 100 <em>E. coli</em> O157:H7 bacteria</td>
<td>Chinen et al., (2001)</td>
</tr>
</tbody>
</table>

**Figure 3. Reported estimates of EHEC threshold leading to illnesses**

<table>
<thead>
<tr>
<th>Threshold (number of EHEC cells)</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td><em>E. coli</em> O111:H1</td>
</tr>
<tr>
<td>109 UCFM per serve of foodstuff</td>
<td>less than 2 <em>E. coli</em> O157:H7</td>
</tr>
<tr>
<td>25g foodstuff</td>
<td>(Unspecified quantities)</td>
</tr>
<tr>
<td>Hamburger patties</td>
<td></td>
</tr>
</tbody>
</table>
Investigations in 1995 and 1996 following the Garibaldi outbreak in South Australia suggest that the outbreak strain, serotype O111:H−, had a low infectious dose that was comparable with some of the O157:H7 outbreak strains (Cameron et al., 1995 and Anon. 1998). Studies have shown that the level of O111:H− contamination in the affected mettwurst may have been as little as one organism per 10 gram of mettwurst (Paton et al., 1996). The investigations during the period of 1995 and 1996 did not come to a conclusion on the relationship of the dose of EHEC ingested and the response of the illnesses. Evidence from the above investigation suggests that intake of as low as one EHEC organism could result in adverse health effects to those consumers who are susceptible to EHEC infection.

On the other hand, estimates listed in Table 5 indicate that EHEC infectious dose tends to vary from one incident to another. The following investigation data suggest that EHEC infectious dose is associated with individual’s susceptibility.

Investigation of the USA outbreak of EHEC infection in 1994 due to consumption of E. coli O157:H7 contaminated dry cured salami reported fewer than 50 organisms as the estimated infectious dose (Tilden et al., 1996). The estimated number of E. coli O157:H7 organisms ingested by individual patients varied from 2 to 45 (Table 6). In this case, the infectious dose for case patient C, is 7 E. coli O157:H7 organisms or lower. The infectious dose for the case patient D is 45 E. coli O157:H7 organisms or lower. In the absence of quantified severity of the illnesses, the infectious dose apparently varies from one patient to another. With the available data (Table 6), the infectious dose in this outbreak can be defined as ‘ingestion of fewer than 50 organisms may cause illnesses’, or ‘ingestion of as few as 2 organisms may cause illnesses’.

**Table 6. Estimated infectious dose of E. coli O157:H7 due to consumption of dry fermented salami in the 1994 USA outbreak**

<table>
<thead>
<tr>
<th>Case patient</th>
<th>Age</th>
<th>Sex</th>
<th>Estimated number of E. coli O157:H7 organisms ingested</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>5</td>
<td>Female</td>
<td>19-24</td>
</tr>
<tr>
<td>B</td>
<td>4</td>
<td>Female</td>
<td>2-5</td>
</tr>
<tr>
<td>C</td>
<td>24</td>
<td>Male</td>
<td>7</td>
</tr>
<tr>
<td>D</td>
<td>4</td>
<td>Female</td>
<td>23-45</td>
</tr>
</tbody>
</table>

(From Tilden et al., 1996)

Data in the above table suggests that an effective infectious dose for an individual is determined by the individual’s susceptibility to EHEC infection. On the other hand, the severity of EHEC infection to an individual is determined by the degree of complications resulting from the infection. These arguments are supported by the 1995’s outbreak data in South Australia (Coroner’s Report, 1995) in which a pair of twins was infected with EHEC due to consumption of EHEC contaminated mettwurst. One twin died from the complications of the EHEC infection. The other twin showed no signs of illness although this child also consumed the same product.

**Susceptibility of the population to the complications of EHEC infection**

Data from the 1996 Central Scotland outbreak of E. coli O157:H7 infection due to food consumption indicates that individuals younger than 15 years of age or older than 65 years of age were four times more likely to develop HUS/TTP than those between 15 and 65 years (Todd & Dundas, 2001). The Pennington report which investigated the outbreaks (Anon.
1997) showed that 12 out of 18 deaths in the outbreaks were aged 69 to 93 years, and most of the deaths were among people in two nursing homes and people attending a lunch held in a church hall.

It is possible that the high rate of death of the elderly and those with physical disabilities was associated with the inadequacy of this group of people in maintaining adequate personal hygiene. This may include people in residential facilities, day-care centres, institutions or patients in hospitals or nursing homes. The Food Safety Authority of Ireland identified infants, the frail elderly, and those people suffering from chronic diseases, or with depressed immune systems as more susceptible to EHEC infections than the rest of the population (Anon. 1999).

Other outbreaks caused by consumption of EHEC contaminated foods in the past suggest that severe adverse health effects, such as HUS, kidney failure, and death are often associated with young children (López et al., 1998 and Robin-Browne et al., 1998). Clinical data from the 1995 South Australia outbreak, due to consumption of EHEC contaminated mettwurst (Cameron et al., 1995) identified more than two thirds of the 22 children who developed HUS were under the age of 6 (Figure 4). Similar evidence is found in the 1994 USA outbreak due to consumption of EHEC contaminated semi-dry sausages (Anon. 1995A) where the median age of people affected was 6 years.

![Figure 4. Age distribution of HUS cases reported in the Garibaldi outbreak (from Coroner’s Report, 1995)](image)

A survey of HUS cases between 1984 and 1994 in Western Australia (Cameron et al., 1996) demonstrated that the occurrence of HUS in the population under the age of 5 (1.4 per 100,000) was 7 times more than that of the general population (0.19 per 100,000).

The data outlined above suggests that young children under the age of six are most susceptible to complications resulting from EHEC infection among the vulnerable groups, i.e. the young, the frail elderly and those people suffering from chronic diseases, or with depressed immune systems. Clinical reason for this high susceptibility is inconclusive. A
mechanistic reason has been suggested, which postulates the disappearance of receptor to Shiga toxins produced by EHEC, as children grow older. Another hypothesis suggests that Shiga toxins produced by EHEC organisms spread more quickly in the bloodstream of young children than in adults (Monnens et al., 1998).

Summary

EHEC in food may cause severe illnesses in susceptible consumers.

- The available information indicates that EHEC infectious dose is low, and ingestion of as little as 1 EHEC organism could lead to adverse health effects to those consumers who are susceptible to EHEC infection. The infectious dose tends to vary according to individual’s susceptibility to EHEC infection.

- The available evidence suggests that young children, the frail elderly, and those people suffering from chronic diseases, or with depressed immune systems are more susceptible to the development of complications as a result of EHEC infection than the rest of the population. Among them, children under the age of six are most susceptible.

Exposure Assessment

The exposure assessment establishes the level of EHEC contamination in UCFM products through an analysis of the critical steps affecting EHEC population in UCFM production processes. Consumption data of specific Australian population groups are used to estimate the exposure to EHEC through intake of UCFM. The combined measure of these two parameters leads to a qualitative measure of the hazard exposure.

Restricted by the available data, this exposure assessment relies heavily on the relevant parameters published on or available for E. coli O157:H7.

Pathway of EHEC contamination in UCFM products

Production of UCFM products involves:

- comminution of meat;
- filling the sausage casing; and
- fermentation and maturation/drying (Figure 2).

Ingredients for making UCFM include meat, salt, sugar, spices, nitrite/nitrate, glucono delta lactone, vinegar, starter culture and/or manufactured curing mix. Spices may contain EHEC, but meat is considered the primary source of EHEC (Table 7).

Assuming good manufacturing practice and good hygiene practice are followed, i.e. chance of cross contamination and handling caused contamination are reduced, the most likely source of EHEC in UCFM products is the raw meat ingredients.
Table 7.  Hazard (EHEC) introduction in UCFM production

<table>
<thead>
<tr>
<th>Steps in UCFM processing</th>
<th>Potential for introducing EHEC</th>
<th>Possible reason of introducing EHEC</th>
</tr>
</thead>
<tbody>
<tr>
<td>Meat</td>
<td>+</td>
<td>Faecal contamination</td>
</tr>
<tr>
<td>Other ingredients</td>
<td>+/-</td>
<td>EHEC contamination of fresh spices</td>
</tr>
<tr>
<td>Bowl chopping/mincing</td>
<td>+/-</td>
<td>Cross contamination</td>
</tr>
<tr>
<td>Fermentation</td>
<td>-</td>
<td>Unlikely</td>
</tr>
<tr>
<td>Maturation</td>
<td>-</td>
<td>Unlikely</td>
</tr>
</tbody>
</table>

+: likely
+/-: occasionally
-: unlikely

EHEC contamination in UCFM begins at the farm. Contamination of meat is exacerbated by the abattoir processes and transportation of meat (Hoornstra & Notermans, 2001). A number of studies reported EHEC prevalence in faecal samples of bovine animals at the farm and abattoirs (Chapman et al., 1997; Hancock et al., 1998; Heuelink et al., 1998; Strokbine et al., 1998; Van Donkersgoed et al., 1999 and Elder et al., 2000).

Due to the scope of this assessment, EHEC prevalence in faecal samples of bovine animals at the farm and in the abattoirs is not considered. The key Australian studies in this area can be found elsewhere (Desmarchelier et al., 1997; Fegan et al., 1997; Sidjabat-Tambundan et al., 1997; Robins-Browne et al., 1998 and Cobbold & Desmarchelier 2000).

Hazard introduction

Meat used for making UCFM products and point of EHEC contamination

According to Ross and Shadbolt (2001), beef and pork are the principal meats for making UCFM products.

Research on EHEC as a human pathogen in the past 20 years identified cattle as the principal reservoir of EHEC organisms (Gansheroff & O’Brien, 2000). EHEC contamination on bovine meat is the result of the slaughtering process that transmits faecal contaminants onto the meat surface. The reason for ground beef being a major source of EHEC contamination and EHEC infection is because the grinding process distributes the surface faecal contamination into the meat mass. Such contamination is difficult to remove by conventional methods such as washing and cooking because the microorganisms are no longer on the meat surface but internalised. The same reason applies to UCFM, where chopping or mincing transfers surface faecal contamination into the meat mass.

In an examination of 11 human and 18 porcine Shiga toxin-positive isolates from 1,352 human and 620 porcine faecal samples, Desrosiers et al., (2001) found the porcine and human isolates were not genetically related. More specifically most porcine Shiga toxin isolates do not appear to possess known virulence factors associated with infections in humans.

However, a recent investigation of hospitalisation due to consumption of cacciatore contaminated with *E. coli* O157:H7 in Western Australia, found that the product was made entirely of porcine meat (Goodchild, Department of Health in Western Australia, Per. Communication, 2002). This suggests that the porcine meat may be a source of EHEC or the porcine meat may have been cross contaminated. However, from published data, we are not
aware of any established causative relationship between EHEC carried by porcine animals and EHEC isolated from the infected patients.

Sheep meat and game meat can be, and have been used in Australia as ingredients in UCFM products. Little is known about EHEC prevalence in game meat. However, sheep do carry EHEC organisms (Sidjabat-Tambunan & Bensink, 1997) and *E. coli* O157:H7 has been recovered from sheep meat in Australia (Vanderlinder et al., 1999, Phillips et al., 2001B).

- Based on the above comparison and for the purpose of this assessment, it is assumed that bovine meat is the principal source where EHEC organisms are introduced into UCFM products. This assumption enables a simplified approach in the following exposure assessment.

**Impact of meat transportation on EHEC prevalence**

From a microbiological viewpoint, variation of and contact with contaminated surfaces during meat transportation, combined with the time period of such exposures, will influence EHEC prevalence in meat. The Australian Standard of HYGIENIC PRODUCTION AND TRANSPORTATION OF MEAT AND MEAT PRODUCTS FOR HUMAN CONSUMPTION (Standards Australia, AS 4696-2002) requires that carcass, side, quarter and bone-in major separated cut be transported at a temperature of 7°C or less. For any other meat, the transportation temperature must not be greater than 5°C. *E. coli* organisms require a temperature higher than 7°C for growth. If these recommended temperatures for meat transportation are followed and contact with potentially contaminated surfaces are avoided, the probability of growth of EHEC on meat during meat transportation will be reduced.

The 1998 Australian survey on ‘Hazards and Exposure in the Meat Distribution, Foodservice and Home Sectors’ (Meat Research Corporation, 1998) indicated that there was a significant non-compliance with the temperature requirements of the Australian Standard for Transportation of Meat for Human Consumption (Standards Australia, AS 4463-1997) in the meat distribution sector. The survey report predicted an increase of bacterial population of 0.22 log (mean) from abattoir to wholesale and an increase of 0.06 log (mean) from wholesale to retail site.

Taking into consideration that UCFM production premises are part of the retail site in meat distribution, it is assumed that a total increase of the bacterial population is the sum of the above two, i.e. 0.28, being (0.22 + 0.06). For the purpose of this assessment, it is assumed that this total increase is applicable to EHEC population found in boxed beef at the abattoir to that on arrival at the UCFM production site.

**Prevalence of EHEC in UCFM products**

**EHEC prevalence in raw meat**

Vanderlinde et al., (1998) reported an *E. coli* O157:H7 prevalence of 0.45% on Australian beef carcasses but none in boneless boxed beef in the export meat production plants. The survey was conducted over a period of 12 months between 1993 and 1994. It examined 893 beef carcasses and 685 boxes of frozen beef trimmings. A second nationwide survey conducted in 1998 reported a 0.1% recovery of *E. coli* O157:H7 on Australian beef carcasses.
and none in boneless boxed beef in the export meat production plants (Phillips et al., 2001A). The survey collected samples from 1,275 beef carcasses and 990 cartons of frozen boneless boxed beef in the period of June to November 1998 (winter period mainly). The above variations of *E. coli* O157:H7 prevalence could be explained by the different methodologies used in the two surveys (such as the sampling method) and the influence of seasonal factors. For the latter, a higher EHEC prevalence associated with a higher level of cattle shedding has been observed for the summer season in the USA (Elder et al., 2000 and Gansheroff & O’Brien, 2000).

A comprehensive survey carried out by United States Department of Agriculture in the summer 1999, reported a contamination rate of 1.8% *E. coli* O157:H7 in postprocessing samples, i.e. bovine carcasses in the cooler room (Elders et al., 2000). The European Commission’s Opinion paper estimated that prevalence of *E. coli* O157:H7 in beef is at 0 – 1% (European Commission, 2000). *E. coli* O157:H7 prevalence of 0.45% in Australian beef carcasses is thus comparable with the level reported by the European Commission, and is approximately 1/5 of the level found in the USA in the summer season (1.8%).

The above prevalence data however cannot be translated into the numbers of *E. coli* O157:H7 organisms per volume of beef because *E. coli* O157:H7 was not counted in the original report (Vanderlinde et al., 1998), but the number of the *E. coli* organisms in boneless boxed beef was enumerated.

For this reason, the level of generic *E. coli* organisms in boneless boxed beef and a ratio of 1% to represent the highest level\(^{32}\) of EHEC contamination in a generic *E. coli* population are used to estimate the level of EHEC contamination in meat ingredients of UCFM products.

Other assumptions used for the estimation of EHEC contamination in meats for making UCFM are:

- EHEC contamination occurs in beef carcasses from abattoirs producing beef for the domestic market.

Each year, approximately 76% of beef produced in Australia is exported (Haslam, Australia Quarantine and Inspection Services - AQIS, Per. Communication, 2002). Because of this, the presence of *E. coli* O157:H7 in export beef carcasses (Vanderlinde et al., 1998, Phillips et al., 2001A) is indicative for the overall Australian beef.

Abattoirs processing meat for export market must comply with the Meat Safety Quality Assurance scheme (MSQA) issued by AQIS in addition to comply with The Australian Standard of HYGIENIC PRODUCTION AND TRANSPORTATION OF MEAT AND MEAT PRODUCTS FOR HUMAN CONSUMPTION. The MSQA scheme is a HACCP based approach and sets a high level of requirement on meat safety. For this reason, it is reasonable to assume that prevalence of

---

\(^{32}\) The assumption of this ratio is based on a discussion with Food Science Australia and refers to *E. coli* O157:H7 in a generic *E. coli* population in cattle faeces. *E. coli* O157:H7 numbers in cattle faeces were evaluated by Zhao et al. (1995), however no data were presented for generic *E. coli* numbers. Generic *E. coli* levels in cattle faeces were estimated in the publication of ‘Quantitative risk assessment of *Escherichia coli* O157:H7 in ground beef hamburgers’ (Cassin et al., 1998). The ratio given above was based on data presented in these two publications. An additional evidence that supports this assumption can be found in an investigation study of the 1995 Garibaldi outbreak (Paton et al., 1996) where *E. coli* O111:H\(^{7}\) isolation accounted for approximately 0.04% - 0.14% of the generic *E. coli* counts found in EHEC contaminated mettwurst.
*E. coli* O157:H7 in beef carcasses from abattoirs producing meat for domestic market is the same as the level found in the export abattoirs if not higher. No detection of *E. coli* O157:H7 in abattoirs producing meat for domestic market but in those producing meat for export market in the two national surveys (Vanderlinde et al., 1998, Phillips et al., 2001A) can be attributed to sampling differences in the surveys, where the number of samples taken from export abattoirs was 3 to 5 times of that taken from domestic abattoirs.

- **EHEC contamination occurs in boneless boxed beef**

This assumption is based on the positive detection of *E. coli* O157:H7 on beef carcasses. As stated earlier, *E. coli* O157:H7 prevalence was 0.1% to 0.45% in Australian beef carcasses. The boning process converts the carcasses into boneless boxed beef and removes bones. Bones do not carry faecal contamination and faecal contamination that harbours EHEC on the carcass surface is transferred into boneless boxed beef as a result of the boning process.

Based on the above assumptions, the number of EHEC in 100 grams of boneless boxed beef can be estimated as the following.

- **The geometric mean of the most probable number of *E. coli* per gram of boneless boxed beef is 8** (Vanderlinde et al., 1998). Assuming the ratio of EHEC in a generic *E. coli* population is 1% and taking into account of the population increase during transportation, the number of EHEC per 100 grams of boneless boxed beef would be 15 (see Table X1).

The following section examines the effect of production, storage, and handling on EHEC population in UCFM products.

**Changes of EHEC population through UCFM production**

Figure 5 shows the key steps in UCFM production processes that are likely to influence the level of EHEC contamination in the final product.

**EHEC population in UCFM products prior to fermentation**

UCFM products comprise almost entirely meat and fat with a small amount of spices and salt (Ross & Shadbolt, 2001). Lean meat comprises approximately 75% (w/w) of the raw ingredients in making UCFM. Assuming all the lean meat is boneless boxed beef, the number of EHEC per 100 grams of UCFM prior to fermentation (i.e. UCFM batter) would be 11.25, being 15 EHEC organisms per 100 grams x 75%, i.e. ‘11.25 EHEC organisms per 100 grams of batter’ (see Table X1).

A recent survey conducted by Food Standards Australia New Zealand (FSANZ) on UCFM manufacturing practices in Australia examined 96 production protocols. These protocols indicate that most producers use a mixture of frozen and chilled meat as the starting material. Bowl chopping or mincing is carried out at temperatures no higher than 7°C, which prevents the growth of the EHEC. Under these conditions, the initial contamination level of 11.25 EHEC organisms per 100 grams of batter would remain the same if no additional EHEC were introduced into the products at this stage of the processing.
Figure 5. A flow diagram of EHEC exposure estimation in UCFM products

MEAT COMMUTION

Meat chopping or mincing could introduce EHEC into the product if there are failures in GMP/GHP. Otherwise, contaminated meat is the only source of EHEC introduction.

FERMENTATION

EHEC introduction is unlikely during fermentation. pH reduction in fermentation results in EHEC inactivation.

MATURATION/DRYING

EHEC introduction is unlikely. Reduction of water activity as a result of maturation/drying leads to EHEC inactivation.

STORAGE AND HANDLING

If GHP is followed in slicing UCFM products, EHEC introduction is unlikely. Further reduction of water activity in storage if allowed leads to further EHEC inactivation.

CONSUMPTION

If there were an EHEC contamination in a UCFM product, the amount of exposure to EHEC would be proportional to the amount of consumption.
**EHEC population in UCFM products at the end of production process**

In the same FSANZ survey, it was identified that UCFM production processes in Australia deliver a maximum of $9.08 \log_{10}$ reduction of *E. coli* organisms and a minimum of $0.13 \log_{10}$ reduction, based on a predictive model of *E. coli* inactivation (Ross & Shodblatt, 2001). These reductions are the result of fermentation and maturation/drying in UCFM production. The median reduction was $2.00 \log_{10}$, which is comparable with the level of *E. coli* O157:H7 inactivation reported in a number of independent studies (Grau, 1996; Hinkens et al., 1996; Nickelson et al., 1996; Calicoglu et al., 1997; Ellajosyula et al., 1998; Riordan et al., 1998; Pond et al., 2001 and Hoornstra & Notermans, 2001).

Applying a $2.00 \log_{10}$ reduction of *E. coli* organisms as a result of fermentation and maturation/drying, the number of EHEC organisms is reduced from the initial level of 11.25 per 100 grams to 0.11 per 100 grams (see Table X1).

The amount of weight loss as a result of maturation/drying in UCFM production was determined from the production protocols collected in the FSANZ survey. The maximum amount of weight loss was 50% and the minimum was 10%. The median was 28%.

Applying a weight loss of 28% and assuming a zero impact of weight loss on EHEC survival\(^{33}\), the number of EHEC organisms in the final UCFM products would be 0.15 per 100 grams (see Table X1).

**Limitation of the above estimation:**

While *E. coli* was detected in 20.9% of frozen boneless boxed beef in the Australia wide survey (Vanderlinde et al., 1998), 13.7% of the beef had *E. coli* between 2 to 10 per gram, 5.8% of the beef had *E. coli* between 11 to 100 per gram, and 1.4% of the beef had *E. coli* exceeding 100 per gram. Because 1% is assumed as the highest level of EHEC contamination in a generic *E. coli* population (see section - EHEC prevalence in raw meat), only those beef containing 100 or more *E. coli* organisms per gram would likely to contain one or more EHEC organisms per gram.

Assuming the above *E. coli* populations in beef is transferred into UCFM production without change and without cross over from highly contaminated beef to beef with low or no *E. coli* contamination, 79.1% of UCFM products would be unlikely to contain *E. coli*, therefore contain no EHEC. Under these assumptions, ‘0.15 EHEC per 100 grams of final UCFM product’ would be applicable only to a small proportion of the remaining UCFM products, i.e. approximately 7.2% of the UCFM products made in Australia using Australian beef. 7.2% is the sum of 5.8% of beef containing *E. coli* between 11 to 100 per gram and 1.4% of beef containing *E. coli* above 100 per gram. A statistical treatment to estimate the probability of the occurrence of ‘0.15 EHEC per 100 grams of final UCFM products’ was not possible due to a lack of appropriate data in the referred publication.

**Impact of processing conditions on level of EHEC contamination in UCFM products**

The above estimation is based on the median $\log_{10}$ reduction of *E. coli* organisms and the median weight loss as a result of the UCFM production processes. If minimum values of

\(^{33}\) For the purpose of this calculation only - the reduction of *E. coli* organisms as a result of weight loss (water loss) has been captured in the overall $2-\log_{10}$ reduction stated in the previous section.
these two parameters were used (a 0.13 log_{10} reduction and a 10% weight loss), the number of EHEC in the final products would be 9.27 per 100 grams in approximately 7.2% of the UCFM products made in Australia (see Table X1).

This higher number may be applicable in certain circumstances where minimum periods of fermentation and maturation/drying are used. Products manufactured under these conditions would have a high final pH and/or a high final water activity, and may not be shelf stable.

**UCFM product storage and handling**

Shelf stable UCFM products at the end of the production cycle can be stored at room temperatures though large manufacturers would store them in an environment with controlled temperature and humidity. Sliced UCFM products are usually stored in a refrigerated environment, the same way as other sliced deli meats. Because of their low water activity and low pH, pathogenic microorganisms like EHEC will not grow and will gradually die off in UCFM products.

Prolonged storage of UCFM products would further reduce the product water activity although slowly, making the environment increasingly unfavourable to the survival of pathogenic microorganisms (Grau, 1996; Faith et al., 1998). As a result of such storage, further inactivation of EHEC occurs. The longer the product is stored at room temperature, the greater the inactivation of the EHEC is anticipated.

The handling of UCFM products may introduce fresh EHEC onto the products through contact with EHEC contaminated raw meat, knives, or through transmission by food handlers who carry these pathogens.

In the absence of adequate surveillance data, the impact of storage and handling on EHEC in finished UCFM products cannot be determined.

Survey data on the presence or absence, but not the number of EHEC organisms present per unit of the products, provides an indication on the probability of consumer exposure to EHEC contaminated UCFM products (Table 8). The data, however, are less useful for determining how many EHEC organisms are likely to be ingested through the consumption of UCFM. The number of EHEC organisms present in UCFM products at the retail stage provides a better indication to the estimation of the number of EHEC organisms potentially ingested by a consumer.

Data in Table 8 refers to *E. coli* O157:H7 only. It is possible to extrapolate the observations to all EHEC organisms by assuming that approximately 2/3 of EHEC caused illnesses are caused by *E. coli* O157:H7, based on a USA study (Mead et al., 1999). This extrapolation however is less relevant to this report because *E. coli* O157:H7 is not commonly isolated in Australia (Robins-Brown et al., 1998).

Assuming a zero impact of storage and handling on the number of EHEC organisms, EHEC organisms in UCFM products at the retail stage would remain at the same level as that at the end of UCFM production, i.e. 0.15 EHEC per 100 grams in approximately 7.2% of UCFM products made in Australia under the conditions of a 2 log_{10} reduction of *E. coli* organisms and a 28% weight loss; or 9.27 EHEC per 100 grams in approximately 7.2% of UCFM.
products made in Australia under the conditions of a 0.13 \( \log_{10} \) reduction of \( E. \text{coli} \) organisms and a 10% weight loss.

**Table 8. \( E. \text{coli} \) O157:H7 prevalence in UCFM products reported from literature**

<table>
<thead>
<tr>
<th>Year</th>
<th>( E. \text{coli} ) O157:H7 in UCFM products</th>
<th>Number of samples in the survey</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>1996</td>
<td>The Netherlands 0.3% (cooked or fermented ready-to-eat meats)</td>
<td>328</td>
<td>Heuvelink A.E. et al., 1999</td>
</tr>
<tr>
<td>1996</td>
<td>European Economic Community 0.07% (dry and semi-dry sausages)</td>
<td>4491</td>
<td>Anon. 1996</td>
</tr>
<tr>
<td>1996-1997</td>
<td>Western Australia None &gt;400</td>
<td></td>
<td>Surveillance data of the Department of Health in Western Australia (Goodchild, Per. Communication, 2002)</td>
</tr>
<tr>
<td>2000</td>
<td>Argentina 3.3% (dry sausages – corresponding to dry-cured salami)</td>
<td>30</td>
<td>Chinen I. et al., 2001</td>
</tr>
</tbody>
</table>

**Exposure estimation according to population groups**

The potential level of exposure to EHEC organisms though consumption of UCFM products has been determined for different age groups.

**Level of intake of UCFM products**

The level of intake of UCFM products was estimated through dietary modelling for the whole population using FSANZ dietary modelling program, DIAMOND. This program accesses food consumption data in the 1995 Australian National Nutrition Survey (NNS).

**Table 9. Estimated consumption of salami all types (Code 18611301) by Australians (1995 NNS)**

<table>
<thead>
<tr>
<th>Age group</th>
<th>Respondents</th>
<th>Consumers</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Number</td>
<td>Number (percentage)</td>
</tr>
<tr>
<td>2-5 years</td>
<td>793</td>
<td>7 (0.9%)</td>
</tr>
<tr>
<td>6-15 years</td>
<td>1781</td>
<td>18 (1.0%)</td>
</tr>
<tr>
<td>55-100 years</td>
<td>3397</td>
<td>40 (1.2%)</td>
</tr>
<tr>
<td>All (2+) years</td>
<td>13858</td>
<td>214 (1.5%)</td>
</tr>
</tbody>
</table>

* This is the mean consumption of only those respondents who reported consuming salami on the day of survey.
Some of the data in Table 9 have been incorporated into the risk assessment subject to the following assumptions and limitations:

- The NNS estimates of food consumption are based on one day of measurement, which tends to overestimate food consumption.
- All salami included in the food code ‘salami all types’ was consumed without further cooking.
- ‘Salami all types’ represents all UCFM products.
- The food consumption patterns observed in 1995 are still current in 2002.

Consumption data for high consumers (95th percentile) has been used for the risk assessment. This would overestimate the quantity of salami consumed by the 2-5 and 6-15 year age groups because of the small number of individuals who consumed salami on the day of survey.

**Time and frequency of consumption**

Australia’s cultural diversity impacts on UCFM consumption. Migrants from traditional UCFM producing countries such as Germany, Spain, Italy, Hungary and Netherlands are likely to consume more UCFM.

For school age children (6-15 years), UCFM products are usually consumed as part of the lunch meal and snack meals. While lunch meals taken to school are exposed to temperature fluctuations, it is highly unlikely that the number of EHEC, if present in the UCFM products, would increase because of the combined effect of the low pH and the low water activity of UCFM products.

Hazard Identification and Hazard Characterisation concluded that the population group under the age of 6 are more susceptible to the adverse health outcomes of EHEC infection. It is assumed that 50.3 grams per day (Table 9) is the maximum intake of UCFM products of this population group. The maximum number of EHEC organisms potentially ingested per day through consumption of UCFM products would be 0.08 per UCFM meal for this population group if all the UCFM products contained 0.15 EHEC per 100 grams, being 0.15 per 100 grams x 50.3 grams. A UCFM meal is defined as consuming 50.3 grams of UCFM products in a day. Taking into consideration of approximately 7.2% of the UCFM products made in Australia are likely to be contaminated by EHEC, a UCFM consumer in the age group of less than 6 years is likely to encounter 1 EHEC organism in approximately 174 UCFM meals (see Table X2).

For the elderly population group (55-100 years), the maximum number of EHEC organisms potentially ingested through consumption of UCFM products per day would be 0.23 per UCFM meal, if all the UCFM products contained 0.15 EHEC per 100 grams, being 0.15 per 100 grams x 150.7 grams. A UCFM meal for this sub-population is defined as consumption of 150.7 grams of UCFM products in a day (Table 9). Taking into consideration of approximately 7.2% of the UCFM products made in Australia are likely to be contaminated by EHEC, a consumer of UCFM products in the age group of 55 to 100 is likely to encounter 1 EHEC organism in approximately 60 UCFM meals (see Table X2).
Summary

The fermentation and maturation/drying steps in the production of UCFM play a critical role in reducing the number of EHEC organisms potentially present in the raw meat ingredients used for making UCFM. The assessment has estimated the number of EHEC organisms potentially present in UCFM products at the retail level at:

- 0.15 per 100 grams in approximately 7.2% of UCFM products produced in Australia, based on the median figures of UCFM processing conditions, i.e. a 2 log₁₀ reduction of *E. coli* and a 28% weight loss. The probability of encountering 1 EHEC through consumption of UCFM products by an individual in the age group of less than 6-years who normally consumes UCFM products is estimated to be 1 in approximately 174 UCFM meals.

- With the minimums of *E. coli* reduction (0.13 log₁₀) and weight loss (10%) in a UCFM production process, the number of EHEC organisms potentially present in UCFM products at the retail stage is likely to be 9.27 per 100 grams. Under such circumstances, the probability of ingesting 1 EHEC through the consumption of UCFM products by an individual in the age group of less than 6-years would be 1 in approximately 3 UCFM meals (see Table X2).

The above estimates highlight the critical role of UCFM production processes in reducing the level of the hazard (EHEC), and that under-processed UCFM products may present a significantly high risk to consumers.
Table X1  Summary of calculations used to derive EHEC contamination levels in UCFM products

<table>
<thead>
<tr>
<th>Steps in UCFM production</th>
<th>Estimation of EHEC population</th>
<th>Assumptions and criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td>Raw beef</td>
<td>8 <em>E. coli</em> per gram is converted into 0.90 log unit per gram. i.e. 8 = 10^{0.90} The above plus transportation resulted increase, together with 1% of EHEC in an <em>E. coli</em> population give 15 EHEC per 100 gram of boneless box beef: i.e. 15 = 10^{(0.90+0.28)} x 100 x 1%</td>
<td>A mean value of 8 <em>E. coli</em> per gram in boneless box beef; a transportation resulted increase of 0.28 log <em>E. coli</em>; and assuming 1% represents the highest EHEC contamination in a generic <em>E. coli</em> population.</td>
</tr>
<tr>
<td>All the ingredients just prior to fermentation, i.e. UCFM batter</td>
<td>Convert 15 EHEC per 100 grams of boneless box beef into EHEC number per 100 grams of UCFM batter i.e. 11.25 = 15 x 75%</td>
<td>Assuming Australian boneless boxed beef is all the lean meat used for making UCFM, which is about 75% (w/w) of all the ingoing ingredients.</td>
</tr>
<tr>
<td>Final UCFM products after a typical UCFM process</td>
<td>Convert EHEC number in UCFM batter to EHEC number in final products After a 2-log_{10} reduction: i.e. 0.11 = 11.25 / 10^2 At the end of 28% weight loss: i.e. 0.15 = 0.11 x 1/(1-28%)</td>
<td>A mean <em>E. coli</em> reduction of 2-log_{10}; a mean weight loss of 28%; assuming zero impact of the weight loss on EHEC survival; and EHEC in UCFM batter is 11.25 per 100 grams.</td>
</tr>
<tr>
<td>Final UCFM product under minimum processing conditions</td>
<td>Convert EHEC number in UCFM batter to EHEC in final products After a 0.13-log_{10} reduction: i.e. 8.34 = 11.25 / 10^{0.13} At the end of 10% weight loss: i.e. 9.27 = 8.34 x 1/(1-10%)</td>
<td>A minimum <em>E. coli</em> reduction of 0.13-log_{10}; a minimum weight loss of 10%; and EHEC in UCFM batter is 11.25 per 100 grams.</td>
</tr>
</tbody>
</table>
Table X2  Summary of calculations used to derive probabilities of encountering 1 EHEC through the consumption of UCFM products

<table>
<thead>
<tr>
<th>Specific estimation</th>
<th>Calculation</th>
<th>Assumptions and criteria</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Probability of encountering 1 EHEC by UCFM consumers under the age of 6 years</strong></td>
<td>If all UCFM products were contaminated at the same level, EHEC number in one UCFM meal (50.3 grams) would be approximately 0.08. i.e. 0.08 = 0.15/100 x 50.3 Under the above conditions, 1 EHEC corresponds to approximately 12.50 UCFM meals. i.e. 12.50 = 1/0.08 Taking into consideration of “7.2% UCFM are contaminated by EHEC”, 1 EHEC then corresponds to approximately 174 meals. i.e. 174 = 12.50/7.2%</td>
<td>A UCFM meal for the sub-population under the 6-years is defined as 50.3 grams per day; and approximately 7.2% of UCFM products are likely contaminated by EHEC at 0.15 per 100 grams.</td>
</tr>
<tr>
<td><strong>Probability of encountering 1 EHEC by elderly UCFM consumers</strong></td>
<td>If all UCFM products were contaminated at the same level, EHEC number in one UCFM meal (150.7 grams) would be approximately 0.23. i.e. 0.23 = 0.15/100 x 150.7 Under the above conditions, 1 EHEC corresponds to approximately 4.35 UCFM meals. i.e. 4.35 = 1/0.23 Taking into consideration of “7.2% UCFM are contaminated by EHEC”, 1 EHEC then corresponds to approximately 60 meals. i.e. 60 = 4.35/7.2%</td>
<td>A UCFM meal for the elderly sub-population (55 – 100 years) is defined as 150.7 grams per day; and approximately 7.2% of UCFM products are contaminated by EHEC at 0.15 per 100 grams.</td>
</tr>
<tr>
<td><strong>Probability of encountering 1 EHEC by UCFM consumers under the age of 6 years if UCFM products were produced under minimum processing conditions</strong></td>
<td>If all UCFM products were contaminated at the same level, EHEC number in one UCFM meal (50.3 grams) would be approximately 4.66. i.e. 4.66 = 9.27/100 x 50.3 Under the above conditions, 1 EHEC corresponds to approximately 0.21 UCFM meals. i.e. 0.21 = 1/4.66 Taking into consideration of “7.2% UCFM are contaminated by EHEC”, 1 EHEC then corresponds to approximately 3 meals. i.e. 3 = 0.21/7.2%</td>
<td>A UCFM meal for the sub-population under the age of 6-years is defined as 50.3 grams per day; and approximately 7.2% of UCFM products are contaminated by EHEC at 9.27 per 100 grams under minimum processing conditions.</td>
</tr>
</tbody>
</table>
Risk Characterisation

Risk Characterisation identifies the likelihood of adverse health outcomes, i.e. a risk estimate that the Australian population is likely to experience from exposure to UCFM products that may be contaminated by EHEC. The risk characterisation also describes the variability and uncertainty of the risk estimate, and identifies data gaps in this risk assessment.

EHEC in UCFM products as a hazard to public health

Outbreaks of illnesses (Table 3) caused by consumption of EHEC contaminated UCFM indicate UCFM products, if contaminated by EHEC, present a public health risk. This risk is the result of three combined factors:

1. UCFM products are ready-to-eat food, which are made of comminuted raw bovine and/or porcine meat principally that may carry EHEC organisms; neither the manufacturing process nor the preparation before consumption involves a thermal killing step that eliminates EHEC organisms potentially present in the products;

2. EHEC infectious dose is very low; and

3. the consequences of EHEC infection in young children and other vulnerable population groups can be very severe.

While this assessment could not establish a definitive dose-response relationship, data presented in the section of Hazard Characterisation indicates that ingestion of as little as 1 EHEC organism could lead to adverse health effects in susceptible population groups.

The number of EHEC organisms likely to remain in contaminated UCFM products at the retail stage, according to the Exposure Assessment, is approximately 0.15 per 100 grams. This estimate is based on a 2-log_{10} E. coli reduction and a 28% weight loss (28%) of the UCFM manufacturing practices in Australia. The estimate applies to approximately 7.2% UCFM products made in Australia.

The probability of ingesting 1 EHEC organism by a child less than 6-years who is a consumer of UCFM products is estimated to be 1 in approximately 174 UCFM meals. An elderly individual who is a consumer of UCFM products has a probability of ingesting 1 EHEC organism in approximately 60 UCFM meals.

These estimates of exposure to EHEC organisms are derived from consumption of UCFM products only. Exposure to EHEC through consumption of other foods has not been examined in this assessment. Therefore a total exposure to EHEC through food consumption was not determined.

Susceptibility of the Australian population to EHEC infection from UCFM consumption

Hazard Identification and Hazard Characterisation in this assessment demonstrate young children, the frail elderly, and those people suffering from chronic diseases, or with depressed immune systems are more susceptible to the development of complications as a result of EHEC infection than the rest of the population. Young children under the age of 6-years are
most susceptible. Gender and pregnancy have not been identified as risk factors to EHEC infection.

Uncertainty and variability in this assessment

Uncertainty

Uncertainties in the risk estimation come primarily from the following three aspects.

A: Uncertainty of the risk estimate due to absence of key data sets

This risk assessment used the following key parameters to estimate the likely number of EHEC organisms in UCFM produced in Australia. They are: an *E. coli* prevalence of 20.9% in boneless boxed beef; a ratio of 1% to represent the highest level of EHEC contamination in a generic *E. coli* population; and a mean value of 8 *E. coli* per gram of boneless boxed beef. Preferably only those beef, with a sufficiently high number of *E. coli* able to result in one or more EHEC in UCFM products of a nominal serving size (approximately 100 grams according to Table 9) subject to a typical UCFM processing, is considered in the exposure assessment. This approach could not proceed fully because the necessary data sets were unavailable. As a result, the risk estimate can only be narrowed to approximately 7.2% of the UCFM products.

There is a degree of uncertainty in applying 1% as the highest level of EHEC contamination in a generic *E. coli* population because of the lack of such specific estimates published elsewhere to allow for comparison. In addition, this 1% represents *E. coli* O157:H7 in a generic *E. coli* population but not all the EHECs, despite a reference to *E. coli* O111:H- in an investigation of the 1995 Garibaldi outbreak. This together with the less frequent isolation of serotype O157:H7 in Australia (Goldwater & Bettelheim, 1995 and Robins-Brown et al., 1998) may have resulted in an underestimation for the level of EHEC contamination in UCFM products in this assessment.

B: Uncertainty of the risk estimate due to lack of data

This assessment evaluates the risk of EHEC from bovine meat only. With the available Australian data, reasonable estimates of the risk of EHEC infection to humans from the consumption of UCFM products cannot be established for other animal meat that may be incorporated into UCFM products. For example, there is an uncertainty about whether EHEC organisms carried by pig animal would be pathogenic to humans.

The available surveillance and epidemiological data are limited. Particularly there is a lack of data to allow a relationship to be established between the amount of UCFM consumed, the level of EHEC contamination in consumed UCFM products, the number of patients resulting from EHEC infection as a result of the consumption, and the severity of the illnesses.

C: Robustness of the risk estimate is impacted by the availability of appropriate survey data

The risk estimates reported in this assessment are derived from a collection of data including EHEC prevalence in beef and survey results of Australian UCFM production processes. The limited surveillance data sourced from the Department of Health in Western Australia is
inadequate for the purpose of validation of the risk estimates. The robustness of the risk estimates reported in this assessment may only be assessed when appropriate survey data become available.

Variability

The risk estimates are dependent on a range of factors, primarily the following ones.

- The level of EHEC contamination in the raw meat ingredients

  The risk estimates are based on the mean *E. coli* counts of 8 per gram in boneless boxed beef with an assumption of 1% EHEC in a generic *E. coli* population. Changes to these two parameters, will change the risk estimates accordingly. For example, if the *E. coli* counts were 20 per gram in the ingoing meat ingredients, the probability of ingesting 1 EHEC by an individual in the age group of less than 6-years, who normally consumes UCFM, would be 1 in approximately 70 UCFM meals.

- The production process in making UCFM products

  The risk estimates are based on a 2-log\(_{10}\) reduction of *E. coli* organisms initially present in the meat ingredients as a result of Australian UCFM production processes. If the number of log reduction is changed, the risk estimates will change in a reversed order. In other words, a lower reduction of *E. coli* organisms leads to higher risk estimates, and vice versa.

- Weight loss of UCFM products

  The risk estimates are based on the weight loss of 28% as a result of the UCFM production processes. Variation of the weight loss will change the risk estimates.

Data gaps

Gaps in the available data:

- Surveillance data of EHEC levels in raw ingredients and in the final UCFM products, if available, will improve the risk estimation.

- Consumption data of different UCFM products by different population groups, if available, would improve the risk estimation.

- Significant data gap exists between the severity of the adverse health effects and the number of EHEC organisms ingested.

- There is a lack of Australian data to describe the proportion of *E. coli* O157:H7 in all the EHEC organisms. Although the USA data reported by Mead et al., (1999) shins
some light to this data gap, the data may not be applicable to Australia because incidents of O157:H7 caused illnesses in Australia are less frequent reported than those in the USA.

The risk estimates reported in this risk assessment, will need to be re-evaluated as new and relevant information become available, particularly when new EHEC strains are identified. The predicted risk estimates will need to be compared with the data of human illnesses as a result of EHEC infection, when they become available, to verify the reliability of the risk estimates.

**Summary**

This risk report assessed the likelihood of contamination of UCFM by EHEC and the implication of such a contamination on public health and safety in food consumption. The report identified:

- a very low level of EHEC (approximately 0.15 per 100 grams) is likely to be present in a small proportion (approximately 7.2%) of UCFM products produced in Australia;

- with this level of EHEC, the probability of being affected by EHEC through consumption of UCFM produced in Australia is anticipated to be small;

- however, EHEC infectious dose can be very low to susceptible subpopulations; and

- the consequence of an EHEC infection can be very severe for susceptible subpopulations including young children, the frail elderly and people suffering from chronic diseases or with depressed immune systems, and particularly children under the age of 6 years.

**References**


European Commission (2000) Opinion of the scientific committee on veterinary measures relating to public health on Food-borne zoonoses, 12 April 2000, Health & Consumer Protection Directorate-general, European Commission


75


Meat Research Corporation (1998) Hazards and Exposure in the meat distribution, foodservice and home sector, Project MSHE.007, Meat Research corporation, Australia


Tanaka H., M. Ohseto, Y. Yamashita, N. Shinoara, H. Inoue, Y. Sasaki, Y. Kakihara, T. Tsukamoto, T.
Yutsudo, Y. Oka & Y. Takeda (1989) Bacteriological investigation on an outbreak of acute enteritis associated
with verotoxin-producing Escherichia coli O111:H-. Kansenshogaku Zasshi 63:1187-1194

Tilden, J., W. Young, A. McNamara, C. Custer, B. Boesel, M.A. Lambent-Fair, J. Majkowski, D. Vugia, B.


United States Department of Agriculture, Food safety and Inspection Services, May 21, (1993) Reports on the
E. coli O157:H7 outbreak in the Western State.

Vanderlinde, P.B., B. Shay, and J. Murray (1998) Microbiological quality of Australian beef carcass meat and
frozen bulk packed beef. J. Food Prot. 61: 437-443

62:380-385

Van Donkersgoed, J. Graham, T., & V. Canon (1999). The prevalence of verotoxin, Escherichia coli O157:H7,

Outbreak of diarrhoea due to Escherichia coli O111:B4 in schoolchildren and adults: association of Vi antigen-
like reactivity, The Lancet 336:831-834

In: Escherichia coli O157:H7 and other Shiga toxin-producing E. coli strains. Eds Kaper J. B. & O’Brien A. O.,
American society for Microbiology, Washington, p195-209

to Escherichia coli O111 and Campylobacter associated with coach trips to northern France, Epidemiol. Infect.
119:9-14

Escherichia coli O157 in beefburgers linked to an outbreak of diarrhoea, haemorrhagic colitis and haemolytic

WHO (1996) Information Fact Sheet N125, 1996

Food Technology Report

P251 Uncooked Comminuted Fermented Meat

Introduction

The purpose of this report is to provide information on the types of uncooked fermented meats (UCFM) available in Australia and overseas and their processes for production and process variables that require controlling to produce safe, stable products under the expected storage conditions. The effectiveness of regulations to cover the control of pathogens during preparation of UCFM are considered in the Microbiology report (Attachment 2).

Following the 1995 outbreak in South Australia (the ‘Garibaldi outbreak’) the Australia New Zealand Food Authority (ANZFA) instituted regulations to cover the preparation of uncooked fermented meats. The regulations included a requirement that a 1000 fold reduction in \(E. coli\) (often expressed as ‘3-log kill’) be achieved for UCFM. Options to demonstrate that a process satisfies this criterion include microbial pathogen challenge tests or evaluation of the process by reference to an Expert Advisory Panel convened by ANZFA. Many manufacturers chose to evaluate their processes by reference to the ANZFA panel rather than using expensive and technically difficult challenge tests.

In order for UCFM processes to be evaluated by the panel for performance against the ‘3-log kill’ criterion, data on the process variables for the production of UCFM are necessary. This report provides information on the kinds of process variables involved in the production of UCFM.

Types of UCFM

Fermented meat products can be classified in a number of different ways depending on the particular premise adopted for the classification system. Classification can be derived from the processing techniques, product type, or raw materials used.

European UCFM are generally considered to fall in to two categories – semi-dry and dry. In the USA these products are generally termed as cervelat and salami, respectively. Migrants to Australia brought their methods for producing UCFM with them, so there are a large variety of products in Australia including Thai fermented Nham and Chinese style pork sausages in addition to European and American varieties.

Fermented meat products can be divided into three groups, based upon the form of the meat.

1. Products made by using large, whole pieces of meat, with the country ham products forming a large part of this group. With some processes, the meat is cut into small pieces or strips, but still fermented as whole pieces. Examples include biltong and jerky.
2. The second, and major, group of fermented meats is made from meat, which has been chopped into small pieces. These are the fermented sausages, with the various types of salami being well known.

3. The third, minor group of fermented products is made from parts of animals, such as bones or intestines. These products are usually locally produced and are not as well known in commercial trade.

The fermented meat products can be classified by water content into:

- Moist 50—60%
- Semi-dried 35-50%
- Dried 20-35%

**Australian UCFM**

In Australia there are many varieties of fermented sausages available. Table 1 compares the characteristics of Australian UCFM products marketed as ‘salami’ or ‘mettwurst’, and reveals there is little difference and so product names are not reliable descriptions of processing methods or product characteristics.

| Table 1. Average characteristics of Australian UCFM processes and products. |
|---------------------------------|---------------------------------|
| Characteristic                 | ‘Salami’ (range of variation)   | ‘Mettwurst’ (range of variation) |
| Composition (lean : fat %)     | 80.4:19.6 (70:30 – 90:10)       | 83.25:16.75 (70:30 – 96:4)      |
| Salt (%)                       | 2.45 (2.0-3.30)                 | 2.02 (1.3-2.8)                  |
| Nitrite (ppm)                  | 284 (145-490)                   | 211 (35-490)                    |
| Final pH                       | 4.72 (5.0-4.4)                  | 4.66 (4.8-4.4)                  |
| Fermentation time (hrs)        | 49 (24-72)                      | 42 (18-72)                      |
| Fermentation temperature (°C)  | 23.3 (18-28)                    | 28.6 (17-40)                    |
| Ripening time (days)           | 14.8 (1-30)                     | 5.3 (0-28)                      |
| Ripening temperature (°C)      | 14.1 (4-32)                     | 18 (0-40)                       |

**Processes**

There are a large number of fermented meat products made from chopped, comminuted meat, with or without additives. The term ‘sausage’ does not mean that the products are necessarily fermented. There are a number of fresh, non-fermented sausages, which must always be cooked before eating.

Raw meat, most often pork or beef, is chopped into small pieces in a silent bowl cutter at low speed to produce a course emulsion. Water is added for lubrication.
A starter culture of certain bacteria is added to the mixture. The mixture may have added various other ingredients before being filled into casings and placed in a warm room with high humidity. Other non-meat ingredients usually include sodium chloride, sometimes nitrate or nitrates and occasionally a small amount of sugar, plus various spices or seasonings. The bacteria in the meat using the carbohydrates in the meat as food, ferment the product and produce lactic acid. This may take from 2-7 days at temperatures varying from 10-30 °C. The sausages are placed in a drying room where the moisture evaporates over a period of about 2 weeks. The length of process involved and the shelf stability of the products depend on the final water content achieved reducing from the initial water content of the meat of approximately 75%.

To direct sausage fermentations ‘back-slopping’ was used originally used, in which some meat from a previous successful fermentation was added to encourage establishment of the desired microflora. Manufacturers now use starter cultures. These consist of a single culture or mixture of lactic acid bacteria of *Pediococcus* spp., *Lactobacillus plantarum* or *Lactobacillus brevis*, *Micrococcus* or non-pathogenic *Staphylococcus* spp. The microorganisms are helpful in reducing nitrate to nitrite. Nitrate-reducing micrococci and coagulase-negative staphylococci also produce catalase, which removes the hydrogen peroxide produced by the lactic acid bacteria.

Preservation is achieved by a combination of fermentation through microbial action, and lowering water activity through addition of salt and dehydration. Smoking can be used to aid drying, and to deposit residues on the surface of the meat, which can inhibit surface mould growth. Alternatively, other anti-mould preservatives such as potassium sorbate can be used.

**Process variables in making UCFM**

The selection of favourable conditions to encourage the growth and development of a desirable safe microflora is particularly important for fermented meat products, as the meat may not be cooked, before or after the fermentation. In the past relatively few processes, especially among the traditional craft practices, used starter cultures, and meat can be a good substrate for the growth of spoilage bacteria such as *Pseudomonas*, or food poisoning bacteria including *Salmonella*, *Escherichia coli* and *Listeria*.

Variables in the production of fermented meats include:

- type of meat;
- amount of fat added;
- starter culture used;
- curing mix composition and concentration;
- fermentation time and temperature;
- maturation time and temperature;
- sausage diameter;
• final pH, final water activity; and
• recommended storage temperatures.

Ingredients

Meat and Fat type used is important for product quality but is less important for the microbiological safety of the product unless some of the meat types are more highly contaminated with pathogens than others. Beef and pork are the meats predominantly used in UCFM production. Both are known to be contaminated occasionally with pathogenic *Escherichia coli*. The percentage of meat to fat, and type of fat, is also an important quality consideration, and among the defining characteristics of the final product. The proportion of the fat affects the amount of free water in the product and this can be important for microbial control.

Binders and extenders such as milk powder, cereal flours, and soy protein are added as a lower cost ingredient to increase the overall yield of the formulation, to improve binding qualities and slicing characteristics and to add specific flavour characteristics. There are labelling requirements for adverse reactions for some of these ingredients.

Water is added to improve the consistency of the mixture and to substitute for fats.

Salt is used to preserve the product, enhance flavour and to solubilise the meat proteins in order to improve the binding properties of the formulation. The most important use of salt in a sausage product is its ability to solubilise proteins. This enhances the product texture and improves water and fat binding. Typically 2.5-3.0% salt is added to UCFMs.

Glucono-delta-lactone is sometimes added to UCFM to reduce the pH, and so inhibit the growth of pathogens during the initial stages of fermentation. It also adds to the texture and colour of the product. Typically 0.25 – 0.50% may be added to UCFMs.

Curing agents such as nitrite and nitrate are used for bacterial control. Nitrites provide bacteriostatic and antioxidant properties, and improve the taste and colour of the sausage. Nitrites also inhibit the oxidation of fats in meats, reducing the development of oxidative rancidity. Nitrites and/or nitrates are usually added to the mix, either separately or as part of a commercial curing mix, in levels of at least 40-50 ppm. In Australia, there is a general requirement that processed meats do not contain more than 125 ppm nitrite. No maximum nitrite levels are specified for UCFM, but the combined nitrate and nitrite must not exceed 500 ppm.

Cure accelerators such as ascorbates and erythorbates are used to speed the curing process. They also stabilize the colour of the final product.

Sugars such as sucrose and glucose are used in formulations to reduce the flavour intensity of the salt and flavourings, and to provide a food source to enable microbial fermentation. Typically 0.4-0.8% sugars are added to UCFMs.

Antioxidants such as butylated hydroxytoluene (BHT), butylated hydroxyanisole (BHA), proply gallate, tertiary butylhydroquinone (TBHQ) and tocopherols may be used to retard
oxidative rancidity and protect flavour. These additives are not permitted in the Code, but could be found in trace amount in oil-based ingredients.

**Phosphates** are used to improve the water-binding capacity of the meat, solubilise proteins, act as antioxidants and stabilise the flavour and colour of the products. Their main advantage is that they can reduce water loss during cooking.

**Mould inhibitors** such as potassium sorbate are commonly used for dry sausages where mould may be a problem.

**Spices, Seasonings and Flavourings** are used to add flavour to the product and affect the consistency of the ground mixture. Spices may include pepper, paprika, garlic, mace, pimento and cardamom.

**Starter cultures** are required by regulation in Australia. The cultures usually comprise *Lactobacillus sakei, Lactobacillus curvatus, Lactobacillus planatarum, Pediococcus acidilactici* or *Pediococcus pentosaceus* either singly or in combination. Starter cultures are added at high levels (10⁶ - 10⁷ CFU/g of mix) so that they rapidly dominate the microbiota of the mix and begin to reduce the pH, thereby minimising the potential for growth of pathogenic bacteria that may be present.

**Equipment**

Smallgoods manufacture requires the use of specialised equipment, not normally found in an abattoir.

**Guillotine or Chipper** is used to chop up frozen blocks of meat into chips and slices. A number of different systems are used. The most popular is a machine with revolving blades, which cuts off pieces of meat from a block pressed against it.

**Mincer** is like the kitchen mincer, is used to cut up fresh meat. An auger drives the meat against a plat, where it is cut by revolving blades and passed through.

**Silent Cutter** is a large, revolving, doughnut-shaped, metal bowl. It is fitted with a set of knives that revolve at high speed to cut the meat up into a fine emulsion.

**Fillers** function to fill the meat into casings. The casings are threaded over the filling nozzle and pressure is applied to force the emulsion into casing.

**Slicers** are machines that automatically slice the product into controlled slices.

**Smokehouses** are heated drying rooms into which the manufacturer injects smoke. The smoke adds specific flavours to the product and helps dry and cure the product.

**Pathogen Control**

As with any food product, proper worker hygiene, raw ingredient handling and storage procedures and the final product handling and storage procedures are essential to control product contamination by organisms that are harmful to humans.
Manufacturers must control the fermentation, smoking and drying processes to reduce pathogens present in meat formulations. Pathogen control requires the establishment of a food safety plan that documents a systematic approach to process control that will be followed at the facility.

Production of safe UCFM relies largely on the prevention of growth of pathogens during the fermentation step and maximising death of surviving pathogens during maturation and storage.

As indicated in Table 2, the lower water activity limit for growth of *E. coli* is 0.95. The water activity of UCFM is controlled by the combination of salt content, the fat content and the amount of water in the mix. In most mixes the water activity is in the range of 0.955 –0.965, insufficient on its own to prevent growth of the pathogen. As fermentation progresses the water activity is reduced to a point where it does prevent the growth of *E. coli*.

The principal organic acid produced during fermentation is lactic acid. The potential for growth of *E. coli* will be limited also by undissociated lactic acid (Table 2.) in the UCFM batter, initially present in the meat at levels in the millimolar range, but this is insufficient on its own to prevent *E. coli* growth.

Generally fermentation temperatures are well below 50 °C which means that the inactivation of *E. coli* during UCFM production is not due to temperature. In contrast to thermal inactivation, data concerning the kinetics of non-thermal death are scarce and the mechanisms for death are not well understood.

**Table 2.**  Growth limits of *Escherichia coli* in response to factors relevant to UCFM.

<table>
<thead>
<tr>
<th>Factor</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Water Activity</td>
<td>0.95</td>
<td>0.999</td>
</tr>
<tr>
<td>Temperature (°C)</td>
<td>7.5</td>
<td>49</td>
</tr>
<tr>
<td>PH</td>
<td>3.9</td>
<td>10</td>
</tr>
<tr>
<td>Undissociated Lactic acid</td>
<td>8-10 mM</td>
<td></td>
</tr>
</tbody>
</table>

**Conclusion**

Uncooked fermented meat products (UCFM) have long shelf lives due to a combination of acidification (through fermentation or addition of acidulant), removal of oxygen, addition of compounds that favour the growth of some microorganisms while retarding the growth of others, and ultimately the removal of water. The significance in terms of the stability of the UCFM depends on the extent to which additives or processes are involved, the conditions, and the length of the process. To determine the effectiveness of a UCFM process in controlling pathogens, data such as the product’s final water activity, temperature, pH and undissociated lactic acid content are necessary.

The large number of process variables makes evaluation of UCFM processes for performance against the ‘3-log kill’ criterion difficult to determine.
References

Andriessen E.H. Meat inspection and Veterinary and Public Health in Australia.


An Overview of the Australian UCFM Industry and the Impact of Garibaldi Outbreak on the Australian Economy

The UCFM industry is a part of the smallgoods industry. Typical UCFM products include various types of salami, summer sausage, mettwurst and others. Although there are approximately 150 UCFM producers domestically, twenty large producers (producing up to 40 tonnes per week) dominate the industry. Smaller producers routinely produce less than 100 kilograms a few times per year. There are no UCFM producers located in the Australia Capital Territory, Tasmania and Northern Territory.

The Australian industry produces approximately 10,681 tonnes of salami per year (Figure 1), however this figure does not include all the sales from butcher shops. The industry is worth approximately $160 million to $214 million per year in sales.

Figure 1. Distribution of the Australian UCFM Industry (2002)

The consequence of the Garibaldi outbreak was highly significant to the Australian society. As a result, regulatory measures to ensure the safety of UCFM products were put in place. It is impossible to place an acceptable value to count for the human cost of the Garibaldi outbreak, for those people both the young and elderly who suffered serious complications from EHEC infections in the outbreak. The following assessment estimates the economic cost of the Garibaldi outbreak to the Australian economy.

Consumer confidence in UCFM products was severely affected by the Garibaldi outbreak. After the 1995 outbreak, 17 out of 42 smallgoods manufacturers who had business operating in South Australia in 1995 either closed their business or were placed under administration. This does not include the Garibaldi Company, which produced the contaminated UCFM product and went out of business after 24 years in operation with a loss of 120 jobs.

34 2002 estimation from Don Smallgoods, Per. Communication.
35 Assuming a retail value of $15 to $20 per kilogram of salami and based on the production of 10,681 tonnes of salami per year.
36 Correspondence from Mr. John Wintulich, 2002
37 Minter Ellison Consulting paper of “Case Study on Enterohaemorrhagic Escherichia coli (E. coli O111) in
The Wintulichs Pty. Ltd., producing good quality UCFM products according to the Coroner’s report\(^38\) was placed under administration soon after the outbreak. John Wintulich, the owner of the Wintulichs Pty. Ltd. at that time, estimated that his personal loss as a result of the Garibaldi outbreak was close to $4 million.

Data obtained from an independent source\(^39\) suggests the Australian UCFM industry as a whole, suffered a severe downturn (Figure 2). Seven and a half years after the Garibaldi outbreak, sales of UCFM products are still 25% below what was achieved in 1994. Using the current figure of the industry turnover of $160 million – $214 million, and assuming the industry did not grow but maintained at the same level of value as that in late 1994, the accumulated loss of sales in the past 7.5 years is approximately $400 million - $535 million\(^40\). Part of this economic loss could be attributed to the impact of the 1997 *Salmonella* poisoning in Victoria where a smallgoods producer was implicated.

The Garibaldi outbreak not only affected the UCFM industry, but the smallgoods sector and the meat industry as a whole. The cost estimation made here refers to the UCFM industry only.

Additional economic cost as a result of the Garibaldi outbreak included:

- $0.75 million – FSANZ cost\(^41\) in developing the processing requirements and maintaining an Expert Panel to deal with enforcement issues;

- More than $1 million – State enforcement authorities’ cost\(^42\) in monitoring and enforcing the processing requirements;

- $199 million – Industry costs\(^43\) in capital injection to comply with the processing requirements;

- $70 million – Industry cost\(^44\) in implementation of the processing requirements; and

- $89 million – Industry cost\(^45\) in increased operating costs due to compliance with the standards.

The above estimated cost to the economy is conservative for a number of reasons.

\(^{38}\) Inquest into death of Nikki Dearne Robinson, The Coroner’s Report, South Australia 1995

\(^{39}\) Hans Smallgoods, 2002

\(^{40}\) Being $160 million / 75% x 25% x 7.5 years = $400 million, and $214 million / 75% x 25% x 7.5 years = $535 million.

\(^{41}\) FSANZ estimation

\(^{42}\) FSANZ estimation according to data supplied by Safe Food Production Queensland and Department of Health, Western Australia.

\(^{43}\) Minter Ellison Consulting paper of ‘Case Study on Enterohaemorrhagic *Escherichia coli* (E. coli O111) in contaminated mettwurst in South Australia, 1995’, 2002

\(^{44}\) As above

\(^{45}\) As above
• The enforcement cost at the State level was based on figures provided by Safe Food Production Queensland and Department of Health in Western Australia. The actual cost incurred in South Australia would be significantly higher because of the Garibaldi incident occurred in that State.

• The cost estimates did not take into consideration Coroner’s Inquiry and technical investigation cost in South Australia in 1995;

• The cost estimates did not take into consideration a number of forums and research expenses occurred nationwide in 1995 and 1996 involving scientific organisations, regulators and industry to address the issue of UCFM product safety;

• The cost estimates did not take into consideration many small sized producers who simply stopped production of UCFM products due to low consumer demand for the products;

• The cost estimates did not take into consideration opportunity cost incurred by a number of UCFM producers who switched away from making UCFM products.

Figure 2. Impact of the 1995 outbreak and the introduction of regulatory measures on salami sales in Australia
## Summary of Issues Raised through Public Consultation at Initial Assessment

<table>
<thead>
<tr>
<th>Submitter</th>
<th>Comments</th>
</tr>
</thead>
</table>
| **David Gill**<br>Food Technology Association of Victoria | • The Option of ‘developing food safety objective based requirements’ is considered the only viable proposition;  
• Questioned the validity of ‘due to the relevant absence of ongoing disease outbreak’ in justifying the appropriateness of the processing requirement. |
| **Marisa Princi**<br>Princi Smallgoods | • HACCP program is a preferred option instead of the processing requirements;  
• Compliance burden to the industry due to disclosure of trade secrets, costly challenge test, and costly micro testing;  
• Ensure the real risk is separated from the perceived risk;  
• Performance and outcome based approach in standard setting is preferred;  
• Ensure the standards take into consideration of the ‘farm to plate’ approach, i.e. considering the risk management of the whole food processing chain. |
| **ED Reed**<br>Pro-Micro Pty Ltd | • Concern about the high cost of challenge test, which is prohibitive for manufacturers;  
• Question the logic of 3-log_{10} reduction where the level of E. coli in most cases, is 20 per gram;  
• Microbiological quality of meat needs to be tightened at abattoirs;  
• Raise the hygiene level in UCFM factories (cleaning/external sampling and testing) will improve product safety;  
• Regards 3 MPN/gram is zero tolerance, which should be accepted for all fermented meats;  
• Batch test before release to market is acceptable;  
• HACCP for all smallgoods manufacturers together with appropriate approval and auditing system in place is the preferred option. |
| **Barry Shay**<br>SafeFood NSW | • The current requirements are highly prescriptive;  
• The requirements are ineffective due to poor compliance by UCFM manufacturers;  
• Deficiencies in the current requirements are reflected by the following difficulties: 3-log_{10} reduction is a difficult concept which results in auditing / enforcement difficulty and compliance difficulty;  
• There is a need for outcome based approach in standard setting;  
• Prefer Food Safety Program together with monitoring of pH and fermentation temperature, and retaining compulsory use of starter culture as alternative requirements for making UCFM products;  
• There is an incompatibility of processing requirements with the microbiological limits;  
• Microbiological testing of raw material and end product is unnecessary;  
• Need to rectify the two microbiological limits in the Food Standards Code, and a fully justified microbiological limit should be used to replace the existing limits (0 per gram, or undetectable per 0.1 g).  
• Believe zero-tolerance is beyond the ability that the industry can reach, and |
### Horst Schurger
**Continental butchery supply import-export Pty. Ltd.**
- Question the term of ‘uncooked fermented meat’ against some of the products in the marketplace which are eaten raw, but no need for fermentation;
- Question Clause 9 (3), and suggested that cooked product cannot be put into a raw product and be fermented because there is no mention of how much cooked product can be put into the new product.

### Ian Jenson
**Meat & Livestock Australia**
- Consider that MLA has not made any statement about the safety or otherwise of UCFM products, other than the note in Ross and Shadbolt’s report that there has been a relative absence of ongoing disease outbreaks;
- Support on outcome-based approaches to food safety of UCFM products
- Question if current processing requirements on UCFM products and the associated Guidelines are sufficient to ensure an acceptable level of protection to the public health;
- Consider that the current processing requirements are prescriptive;
- If the current processing requirements on UCFM products are not sufficient to ensure an acceptable level of protection to the public health, MLA questioned whether further prescriptive requirements will achieve a public health benefit;
- Support the retention of a microbiological criterion (microbiological limit) as a basis for regulatory action.
- Consider that *E. coli* not detected in 0.1 g of finished product is qualitative, and the raw meat containing no more than 100 *E. coli* per gram is quantitative. These definitions are reflected by the use of different microbiological methods. Consequently, there is a need for means to correlate quantitative results to qualitative results if 3-log reduction is considered;
- Consider that the limit of detection by the qualitative microbiological method is 10 *E. coli* cells per gram. This translates to a detection limit of 1 *E. coli* cell per 0.1 g. Provided that 100 *E. coli* cells per gram in the raw meat is set correctly, the above method limitation restricts the log reduction to 1 over the UCFM process, but not 3-log reduction.

### Brian Devine
**Environmental Health Department of Health Western Australia**
- Support the retention of the current processing requirement and prefer in the meantime, a maximum limit of *E. coli* levels in the incoming raw meat to be specified;
- Sampling needs to be performance based, which is controlled by the manufacturers and verified by the controlling authority;
- Notifiable Pathogen Program and WA Health’s sampling program identified low number of *E. coli* and *Listeria monocytogenes* pathogens in UCFM products;
- Concern about the spread of *E. coli* O157:H7 in the meat chain as it has been detected in sheep, beef, and pork carcasses;
- Removal of the 3-log reduction requirement would necessitate the implementation of standards of pH and water activity or end product testing.
<table>
<thead>
<tr>
<th>Name</th>
<th>Statement</th>
</tr>
</thead>
<tbody>
<tr>
<td>Elaine Attwood</td>
<td>• Consider that any lessening of the process requirements would result in ill health and possible death;</td>
</tr>
<tr>
<td>National Council of Women of Australia Inc. Ltd.</td>
<td>• Contend that any lessening of the process requirements would result in ill health and possible death;</td>
</tr>
<tr>
<td></td>
<td>• Contend that it is because of the processing requirements there is a ‘relative absence of disease outbreak’;</td>
</tr>
<tr>
<td></td>
<td>• Contend that there is absolutely no evidence to suggest that consumers are unhappy with the diversity of the range of UCFM products available;</td>
</tr>
<tr>
<td></td>
<td>• Require that no positive <em>E. coli</em> and any other pathogens are present in UCFM products;</td>
</tr>
<tr>
<td></td>
<td>• Contend the statement of incapable of auditor verification. Consider that Food Safety Plan and microbiological testing are complementary to the above verification in the auditing process;</td>
</tr>
<tr>
<td></td>
<td>• Require that any changes to the current requirements should not be at the consumers’ risk;</td>
</tr>
<tr>
<td></td>
<td>• Consider that adoption of any international standards should not lower the current Australian standards, and should not act as a barrier to Trade and Fair Trading;</td>
</tr>
<tr>
<td></td>
<td>• Removal of current processing requirements and rely solely on Food Safety Programs is not in the interest of consumers or public health and safety as currently such programs are not mandatory.</td>
</tr>
</tbody>
</table>

| Jill Bailey                                      | • Support the submission made by the National Council of Women of Australia on this Proposal. |

| Agnes Tan                                       | • Require a single microbiological limit for *E. coli*; |
| Microbiological diagnostic Unit, Public Health Laboratory Department of Microbiology & Immunology The University of Melbourne | • Regard that performance standard, i.e. 3-log reduction, if removed, should be based on inability for regulators to verify rather than inability of compliance by the industry; |
|                                                  | • Regard that relative absence of disease outbreak is due to the safety margin in the microbiological limit and the relatively good quality of the incoming raw material; |
|                                                  | • Recommend the removal of 3-log reduction requirement; |
|                                                  | • Recommend retaining monitoring of pH and fermentation temperature; |
|                                                  | • Consider the combination of end-product specification together with GMP would achieve the same outcome; |
| Michael Redlich  
National Meat Association of Australia | • Consider Food Safety Objective is premature at this stage due to lack of sufficient data to determine Food Safety Objective;  
• Consider that any adoption of International standards, the underlying assumptions used by other countries should be carefully compared with those in Australia, particularly the prevalence of EHEC in meat supply.  
• Consider Food Safety Programs only will not be able to ensure UCFM product safety due to their relatively short history in Australia and lack of sufficient specialist auditors on FSP.  
• Recommend retention of E. coli limit (not detected in 0.1 g); removal of performance standard of 3 log reduction; maintaining existing process requirements with possible relocation of pH, temperature and E. coli monitoring as well as record keeping into the advisory Guidelines.  

| Request for the removal of monitoring E. coli in raw meat ingredients, but retain the monitoring of E. coli in the finished product. Alternatively a safe product can be achieved through a combination of E. coli monitoring in the raw meat ingredients and the validation knowledge of E. coli reduction by the process.  
• Consider the requirement of 99.9% reduction of E. coli organisms does not relate to a food safety outcome as 99.9% reduction relates to the E. coli load in the incoming raw meat ingredients;  
• Consider compliance with the 99.9% reduction of E. coli organisms is difficult to demonstrate. This is due to (1) high cost of challenge test and introduction of E. coli into the process environment is problematic; (2) assessment of production process is subjective, and the predictive model of E. coli inactivation is has a substantial margin of error and is yet to be validated;  
• Consider that the industry has difficulty to achieve 99.9% reduction of E. coli organisms;  
• Consider that 99.9% reduction of E. coli organisms is difficult to verify by enforcement authorities;  
• Consider that there is an inconsistency between the two E. coli specifications for UCFM products;  
• Against the retention of 3-log reduction and regard that end product microbiological specification alone would be adequate;  
• Against the proposal of 2-log reduction requirement and regard that end product microbiological specification alone would be sufficient to ensure product safety;  
• Support Food Safety Objectives based approach, but have doubt on its practicality. Emphasized that Food Safety Objectives should derived an evidence-based microbiological specification for the end product;  
• Accept the approach of adaptation of an international standard but ask for relevance to Australia;  
• Accept the approach of implementation of Food Safety Programs, but require appropriate guidelines and criteria to be set for the industry and enforcement authorities. Regards that Food Safety Programs may be seen as a deregulation of the UCFM industry, and perceive unacceptable to the public;  
• Recommend the removal of E. coli limit from Standard 1.6.2. In the absence of a Food Safety Objective based microbiological specification, the E. coli limit should be set at ‘not detectable in 0.1 g’ and list in Standard 1.6.1;  
• Recommend to replace Clause 9 of Standard 1.6.2 with a requirement for development and implementation of a HACCP Program and mandate the |
following: initiation of fermentation through the use of a starter culture; prohibition of backslopping and the use of uncooked salami as rework in a UCFM product; monitoring and recording of pH and fermentation room temperature during fermentation; monitoring and recording of maturation conditions; and microbiological monitoring and recording to verify program efficacy (where the point in the process at which microbiological monitoring is applied is not regulated) to achieve the following (1) combining raw ingredient testing with process knowledge to ensure compliance with microbiological specification in the finished product; or (2) statistically valid sampling plans for finished product microbiological testing;

- Request for consideration to restrict the term ‘salami’ to fermented meat products (using a starter culture) only.

| **Tony Downer**  
Australian Food and Grocery Council | • Due to variation in the initial microbial load in the incoming ingredients, the requirement for 3-log reduction is not a valid;  
• Against the retention of 3-log reduction 1 for the reason of not in line with the government policy for ‘minimum effective regulation’. Regards that the combination of maximum *E. coli* count in the raw material, a 3-log reduction over the process, and a maximum *E. coli* in the finished product contributes to the overkill for this option. AFGC supports the retention of the remaining requirements, but not pre and post-processing microbiological testing and the 3-log reduction;  
• The predictive model of *E. coli* inactivation is limited in its accuracy;  
• Against 2-log reduction for the same reason stated above;  
• Against Food Safety Objective based approach due to no indication is given for what the ‘Food Safety Objective based requirements’ might be.  
• Against the adaptation of an international standard, and indicating the only international standard is USA’s 5-log reduction on *E. coli* O157:H7, or less than 1 *E. coli* O157:H7 per 100 g. Citing this international standard suffers the same problem of auditor verification as the current Australian requirement of 3-log reduction. AFGC cautions the serotype difference between O157:H7 in USA and O111:NM detected in South Australia, as well as any equivalency between the limit of 1 *E. coli* O157:H7 per 100 g and ‘*E. coli* not detected in 0.1 g’.  
• Against the implementation of Food Safety Program as part of the Standard 3.2.1, which is not mandatory nationally.  
• Consider the following option is adequate to provide an appropriate level of protection to the public health for UCFM products: mandatory refrigerated storage of meat - clause 9 (7); a prohibition on the use of mechanically separated meat and rendered trimmings - Clause 8 (4); prohibition on the use of uncooked ferment or fermenting products as ingredients – clause 9 (3); mandatory use of starter culture – clause 9 (1b) and 9 (2); monitoring of pH and fermentation room temperature – clause 9 (5); a limit of zero *E. coli* in 0.1 g – clause 2 (1) and 5 in Standard 1.6.1.  
• Recommend the term ‘salami’ be restricted to fermented meat products.  

| **Karen Krist**  
National Meat Association of Australia | • Provided Australian UCFM industry segmentation data  

| **Des Underwood** | • 3-log reduction is very difficult to verify;  
• HACCP based food safety plan is the current requirement in Queensland;  

92
<table>
<thead>
<tr>
<th>Name</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>SafeFood Queensland</td>
<td>• Question the need for manufacturers to test raw and finished product unless for the purpose of verification;</td>
</tr>
<tr>
<td></td>
<td>• Concur views submitted from Safe Food NSW.</td>
</tr>
<tr>
<td></td>
<td>• Provided estimated cost of enforcement cost on the processing requirements for UCFM production.</td>
</tr>
<tr>
<td>Graham Keillor</td>
<td>• Consider that there is a consistent demand for UCFM products in the market place;</td>
</tr>
<tr>
<td>Franz Continental</td>
<td>• Consider that the impact of past adverse incidents is small to the UCFM industry, and preferably FSANZ can provide some data on the probabilities of the incidents;</td>
</tr>
<tr>
<td>Smallgoods</td>
<td>• Consider that there is no importation of smallgoods.</td>
</tr>
<tr>
<td>Peter Bergman</td>
<td>• Consider that in the past 5 years, the demand for good UCFM products has gone up 300%;</td>
</tr>
<tr>
<td>Chrberg Fine Food</td>
<td>• Consider that the impact of the past adverse incidents is on low quality or inconsistent UCFM products;</td>
</tr>
<tr>
<td>International</td>
<td>• Consider that there is no importation of smallgoods;</td>
</tr>
<tr>
<td></td>
<td>• Concern about the lack of knowledge for making safe and quality UCFM products with some of the UCFM manufacturers. Recommend that only qualified people can make quality products.</td>
</tr>
<tr>
<td>Odino Borgo</td>
<td>• Provided estimated production volume of UCFM products, and cost of compliance with the processing requirements in the Food Standards Code.</td>
</tr>
<tr>
<td>Borgo Smallgoods</td>
<td></td>
</tr>
<tr>
<td>Stan Goodchild</td>
<td>• Provided estimated cost of enforcement and monitoring costs on processing requirements for UCFM production</td>
</tr>
<tr>
<td>Environmental Health</td>
<td></td>
</tr>
<tr>
<td>Department of Health</td>
<td></td>
</tr>
<tr>
<td>Western Australia</td>
<td></td>
</tr>
<tr>
<td>Jennifer McDonald</td>
<td>• The Proposal merely addresses the difficulty of monitoring compliance with clause 9(8) of Standard 1.6.2, and doe not propose to deliver any public safety benefits.</td>
</tr>
<tr>
<td>Food and Health</td>
<td>• Concern about how to determine with confidence that the UCFM products produced are safe once the 3-log kill step is removed.</td>
</tr>
<tr>
<td>Development,</td>
<td>• End product testing is the only way to demonstrate that the product is safe.</td>
</tr>
<tr>
<td>Department of Human</td>
<td>• Setting an upper limit of 1.0 (E. coli) per gram for finished UCFM products as a precondition for removing the 3-log kill requirement.</td>
</tr>
<tr>
<td>Services, Victoria</td>
<td>• Initiating a study to determine the prevalence of EHEC in UCFM products, and to determine the ratio of EHEC to generic (E. coli).</td>
</tr>
<tr>
<td></td>
<td>• Recommend to set maximum levels of (E. coli) permitted in raw meat for producing UCFM products.</td>
</tr>
</tbody>
</table>
## Summary of Issues Raised through Public Consultation at Draft Assessment

<table>
<thead>
<tr>
<th>Submitter</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kevin Cottrill</td>
<td>• Concerned about the inclusion of raw meat ingredient testing (for \textit{E. coli}) and the raw meat ingredient microbiological limit (of \textit{E. coli}) in the options proposed.</td>
</tr>
<tr>
<td>National Meat Association of Australia</td>
<td></td>
</tr>
<tr>
<td>Steve Bonny</td>
<td>• There are significant numbers of small “backyard” operators who are usually unregistered and largely unregulated making UCFM products.</td>
</tr>
<tr>
<td>Lago Smallgoods Pty. Ltd.</td>
<td>• These manufacturers are a far greater risk to the public and industry.</td>
</tr>
<tr>
<td></td>
<td>• Risks do not come from those manufacturers who are currently manufacturing under HACCP systems and the like.</td>
</tr>
<tr>
<td>Marisa Princi</td>
<td>• Verifiable and auditable HACCP programs should be compulsory for UCFM manufacturers and be extended to all those in the food industry.</td>
</tr>
<tr>
<td>Princi Smallgoods</td>
<td>• Safety of UCFM products relies on not only UCFM manufacturers who are at the end of the food production chain, but also those at the early stages of food production, namely animal growers and abattoirs.</td>
</tr>
<tr>
<td>Tony Downer</td>
<td>• Rejects option 1.</td>
</tr>
<tr>
<td>Australian Food and Grocery Council</td>
<td></td>
</tr>
<tr>
<td></td>
<td>• Option 2 is supported with following amendments:</td>
</tr>
<tr>
<td></td>
<td>− UCFM products should be produced using a validated and independently audited HACCP based food safety program;</td>
</tr>
<tr>
<td></td>
<td>− It should be made clear that for routine monitoring purpose, any appropriate method that gives comparable results as that of the MPN method for \textit{E. coli} testing, is allowed;</td>
</tr>
<tr>
<td></td>
<td>− In relation to the subclause concerning the use of a previously fermented or fermenting meat product, AFGC recommends a modification of the wording, i.e. such meat “must not contain, or must be treated to eliminate, all microbial pathogens and toxins prior to use as an ingredient in a UCFM product”, which would permit the rework of perfectly safe product;</td>
</tr>
<tr>
<td></td>
<td>− AFGC recommends the removal of the prescribed maximum \textit{E. coli} limit for raw meat ingredients;</td>
</tr>
<tr>
<td></td>
<td>− In relation to record keeping, AFGC recommends that, if retained records should be kept for 12 months after the end of the products’ durable life only, not 24 months.</td>
</tr>
<tr>
<td></td>
<td>− AFGC recommends the “lot” definition be further defined for the purposes of this Standard.</td>
</tr>
<tr>
<td></td>
<td>− AFGC is generally opposed to “test and hold”, but recommends that for the purpose of “test and hold” in the absence of a food safety program, a more comprehensive sampling plan needs to be prescribed.</td>
</tr>
<tr>
<td></td>
<td>− AFGC considers that monitoring \textit{E. coli}, pH, temperature and time of fermentation and maturation be omitted for the reason that it does not impact directly the safety of a UCFM product (it is the actions taken if these parameters are not correct that affects safety) and is an essential</td>
</tr>
</tbody>
</table>
part of any HACCP based food safety program;

- AFGC recommends the omission of the clause of “A UCFM product may be sold where it is produced using an alternative production process or system specified elsewhere in this Code, provided that the equivalent food safety outcome in subclause (3) is achieved.” because application for approval of any alternative process not involving a HACCP plan and use of starter culture, etc will need to be made to FSANZ to enable it to be listed in the Food Standards Code.

<table>
<thead>
<tr>
<th>Michael Redlich</th>
</tr>
</thead>
<tbody>
<tr>
<td>National Smallgoods Council, National Meat Association of Australia</td>
</tr>
<tr>
<td>• Reject Option 1</td>
</tr>
<tr>
<td>• Supports Option 2 with the following amendments:</td>
</tr>
<tr>
<td>- unlike finished products, monitoring and recording <em>E. coli</em> in raw meat ingredients should be used by UCFM manufacturers to verify process control and verify food safety program efficacy, but should not be a regulatory instrument; the need for advice/guidance on a sampling plan design was also noted, and</td>
</tr>
<tr>
<td>- NMAA reject the setting of a maximum limit for <em>E. coli</em> in raw meat ingredients; and</td>
</tr>
<tr>
<td>- NMAA does not support the clause of “A UCFM product may be sold where it is produced using an alternative production process or system specified elsewhere in this Code, provided that the equivalent food safety outcome in subclause (3) is achieved.” because this level of flexibility already applies to any part/clause of the Food Standards Code; and</td>
</tr>
<tr>
<td>- NMAA rejects the proposed clause of “A UCFM product may be sold where microbiological end product testing has been conducted for each lot and each lot complies with the relevant <em>Escherichia coli</em> limits in Standard 1.6.1 of this Code” unless the manufacturer complies also with those in the part a of Option 2.</td>
</tr>
<tr>
<td>• Supports Option 3 but a maximum limit of <em>E. coli</em> in incoming raw meat ingredients should be removed; and recommends that “microbiological testing for <em>E. coli</em>, is used to monitor process control” instead of as a regulatory instrument; and recommends an advice/guidance on sampling plan design to be developed in a separate document.</td>
</tr>
<tr>
<td>• NMAA is opposed to prescribing the 3-tube MPN method as the only method by which compliance with the <em>E. coli</em> limit can be demonstrated, and recommends any method of equivalent sensitivity should be permitted.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Odino Borgo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Borgo Smallgoods</td>
</tr>
<tr>
<td>• Rejects <em>E. coli</em> testing for raw material.</td>
</tr>
<tr>
<td>• Appropriate sampling plan/schedule is required for <em>E. coli</em> monitoring in the end products to minimise testing cost on every batch.</td>
</tr>
<tr>
<td>• A verified HACCP system and good GMP as well as a sampling plan/schedule should be adequate to ensure product safety.</td>
</tr>
<tr>
<td>• Diseases such as foot and mouth disease and BSE need to be addressed if UCFM products are to be imported into the country.</td>
</tr>
<tr>
<td>• What is the possibility of irradiation in eliminating EHEC in UCFM products?</td>
</tr>
<tr>
<td>• The requirement of 3-log reduction of <em>E. coli</em> in UCFM production imposes restriction on the range of UCFM products being produced in Australia.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>David Gill</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Supports Option 2, which implements a HACCP based food safety program.</td>
</tr>
</tbody>
</table>
| Food Technology Association of Victoria | • It is recommended that the risk assessment be used to determine and justify the microbiological limit.  
• It is recommended that the assessment indicate the incidence of adverse public health outcomes attributable to UCFM since the implementation of the UCFM processing standard.  
• It is recommended that the assessment report compile available microbiological data to demonstrate that the microbiological limits can be met for a wide range of UCFM products.  
• Manufacturers were able to improve the ability of their processes to inactivate *E. coli* by reference to the MLA model of *E. coli* inactivation.  
• MLA remains willing to work with FSANZ and other members of MLA’s expert panel on smallgoods to revise the chapter of “Uncooked fermented comminuted meats” in MLA’s ‘Guidelines for the safe manufacture of smallgoods’ to incorporate the changes as a result of proposal P251.  
• It is unclear how the value of 20 *E. coli* per gram in the raw meat ingredients was derived and why any value should be specified.  
• Define what activities may constitute monitoring and the frequency with which those activities should be conducted.  
• It is recommended that the Standard require monitoring of the production process without prescribing the parameters (such as pH, temperature, time etc) to be monitored.  
• The triplicate tube method provides an almost equivalent probability of rejecting a batch of product as the MPN method proposed.  
• It is recommended that microbiological limits (in Standard 1.6.1) be written without a decimal.  
• MLA critically reviewed the microbiological risk assessment attached to the Draft Assessment Report, and expressed different opinion on the way the risk assessment conducted despite that these may have no impact on the Proposal. The area concerned includes the use of available data, basis of assumptions, data treatment and expression and others.  
• It is not clear how the content of the microbiological assessment report is used to formulate the proposed Standard. |

| Ian Jenson Meat & Livestock Australia |  |

| Agnes Tan  
Microbiological diagnostic Unit,  
Public Health Laboratory  
Department of Microbiology & Immunology  
The University of Melbourne | • Support Option 2 with following amendments:  
  − define “safe” in the proposed subclause of “the number of *Escherichia coli* organisms in raw meat ingredients must be no more than 20 per gram unless the production of a safe UCFM product be demonstrated with existing processing protocols; and”  
  − change “throughout production…” to “at the different stages in production…” in the proposed subclause of “the following must be monitored and recorded - (i) the pH of UCFM products, throughout production…”  
  − The subclause “A UCFM product may be sold where is produced using an alternative production process or system specified elsewhere in this Code, provided that the equivalent food safety outcome in subclause (3) is achieved” does not appear to deliver the intention of allowing “industry to apply new technologies or measures in manufacturing safe UCFM products” |
| Kevin Cottrill  
National Meat Association of Australia | • There should be no prescribed *E. coli* limit or a requirement for operators to set maximum *E. coli* levels for incoming raw meat ingredients;  
• There should be no “test and hold” as an alternative to the food safety plans;  
• Ban on mechanically separated meat in UCFM manufacture should be maintained;  
• The prescribed method for microbiological testing (MPN) is for health investigation purposes only that industry is free to use alternative equivalent methods for process verification purposes. |
| Fiona Fleming  
Weston Technologies (George Weston Foods Limited) | • Supports the recommendations made by AFGC.  
• Fully supports the requirement for UCFM products to be manufactured under a food safety program based on HACCP principles.  
• The options put forward by FSANZ are excessive when compared with other products with a similar level of risk.  
• Rejects Option 1.  
• The most appropriate course of action would be a revision to Option 2 based on input set out in the AFGC submission and additional comments below:  
  − supports:  
    the prescription of microbiological limits in one standard; and  
    the removal of the 99.9% reduction requirement for *E. coli*; and  
    that previously fermented or fermenting meat products must be treated to eliminate all microbiological pathogens and toxins prior to use.  
  − does not support, but is prepared to accept:  
    the initiation of fermentation through the use of a starter culture; and  
    that the records to be kept for 12 months after the end of the minimum durable life or 24 months from the date of production; and  
    that meat for UCFM products to be stored at or below 5 degree C prior to fermentation.  
  − does not support:  
    the prescription of a maximum *E. coli* level for raw meat ingredients: and  
    the requirement for monitoring of meat ingredients and finished product for *E. coli*; and  
    the requirement for monitoring of pH, temperature and time of fermentation and maturation/drying; and  
    “test and hold” as a viable alternative to the implementation of a food safety program; and  
    the permission for an alternative production process or system.  
  − recommends  
    the addition of a definition of “heat treated” as that in Clause 8 to Clause 9 of Standard 1.6.2 of the *Food Standards Code*; and  
    amending Schedule 1 of Standard 1.6.2 to include permission to use direct pH probe as well as the current dilution method for pH measurement. |
| Kevin Cottrill  
National Meat Association of Australia | • The Smallgoods Expert Panel on UCFM products should be retained considering the significance of the Panel in achieving the following objectives:  
  − flexibility to allow smallgoods makers to continue to product UCFM products which have been proven safe to consume; and  
  − innovation in manufacturing technologies; and  
  − national consistency in implementation; and |
a significant level of regulation so as to ensure that all products produced are safe for consumption.

| Regulatory agencies of Meat Standards Committee (MSC) | • A determination needs to be made of the appropriate regulatory approach for UCFM products – ‘risk based’ (prescriptive 3-log reduction or non-prescriptive HACCP) versus ‘risk free’ (eg. cooking).  
• Enforceability of proposed regulatory options needs to be considered.  
• Where does the ultimate responsibility lay for UCFM process ‘approval’ (current assessment process for UCFM production protocols)?  
• Questioned the scientific validity of the requirement for a 3-log reduction and the appropriateness for it to be included in the standard.  
• Questioned the feasibility of a specification of \( E. \ coli \) limit for ingoing raw meat ingredient; and the determination of equivalence.  
• Oppose to ‘test and hold’ measure proposed. |
| --- | --- |
| David Miles  
Safe Food NSW | • “Retaining the current standard” is not supported as the current regulation has proved to be difficult for both industry to meet, and regulatory authorities to properly enforce.  
• The assistance of the ANZFA/FSANZ Expert Panel on UCFM Products is acknowledged during the difficult implementation of the current standard.  
• Supports the retention of an Expert Panel under a more appropriate forum, to provide technical advice to States when requested and aid in the future assessment of UCFM Food Safety Programs.  
• Support the following in Option 2 and 3 that UCFM manufacturers are required to:  
  - have a HACCP based Food Safety Program in place;  
  - follow the current processing requirements for the use of starter cultures, the prohibition of backslopping, the monitoring of fermentation/maturation pH, time and temperature and proper storage temperature for meat to be used as an ingredient in making UCFM; and microbiological testing as a verification tool.  
• The Use of a “test and hold” program would only be appropriate in conjunction with a suitable HACCP based Food Safety Program.  
• Does not support the inclusion of a specified \( E. \ coli \) limit for raw ingredient in the standard, but supports the inclusion of a maximum level of \( E. \ coli \) in the raw meat ingredients as part of the HACCP based Food Safety Program.  
• Recommends a specified frequency for the monitoring of pH, time and temperature during fermentation and maturation for each production.  
• Supports the retention of microbiological testing of both raw and finished product.  
• Does not object the proposed microbiological standard for \( E. \ coli \) in UCFM to an MPN based number.  
• Supports the removal of clause (c) (i.e. test and hold) from Option 3. |
| Regulatory agencies of Meat Standards Committee (MSC)  
Safe Food Queensland  
Safe Food NSW  
Victoria Meat | • Key dates of MSC enforcement action on the compliance with the 3-log reduction in the current standard:  
  - by 30 September 2001 UCFM producers undertake product testing in accordance with the Food Standards Code;  
  - UCFM producers submit a completed protocol to the respective controlling authorities by 31 December 2001;  
  - UCFM producers have the protocol assessed by the ANZFA Expert Panel by 30 June 2002; and  
  - MSC wrote to ANZFA expressed its concerns with current risks in the |
<table>
<thead>
<tr>
<th>Authority</th>
<th>production of UCFM products, the problems with 3-log reduction and associated auditor verification issues and requesting ANZFA to proceed urgently to review the current requirements.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department of Primary Industries, Water and Environment, Tasmania</td>
<td>• In addition to those defined in the <em>Food Standards Code</em>, MSC and its member regulatory authorities initiated additional measures such as HACCP implementation and mandatory accreditation/licensing of UCFM manufacturers, which aided some of the positive aspects of the current regulatory outcome for UCFM products.</td>
</tr>
<tr>
<td>Meat Hygiene Unit, Primary Industries and Resources, South Australia</td>
<td>• Regulators of the production of UCFM products under the MSC met in a number of occasions and developed a common position on the preferred future regulatory management of UCFM production.</td>
</tr>
<tr>
<td>Department of Health, Western Australia</td>
<td>• “Test and hold” as a sole compliance measure is not acceptable.</td>
</tr>
<tr>
<td>Department of Primary Industries, Northern Territory</td>
<td>• There is a requirement for a defined food safety objective.</td>
</tr>
<tr>
<td>Australian Quarantine and Inspection Service</td>
<td>• Food safety plans incorporating the application of HACCP need to be mandated.</td>
</tr>
<tr>
<td>Murray Patterson Environmental</td>
<td>• There is a need for flexibility through the recognition of alternative processes.</td>
</tr>
<tr>
<td></td>
<td>• Important process parameters need to be defined – use of starter culture, no backslopping, measurement/monitoring/recording of pH, water activity, temperature, humidity, raw and finished product monitoring.</td>
</tr>
<tr>
<td></td>
<td>• The standard needs to be able to be consistently applied and enforced nationally. To achieve this, it needs to be easily understood by users.</td>
</tr>
<tr>
<td></td>
<td>• The opportunity for centralised assessment of food safety plans needs to be maintained, such as the FSANZ Expert Panel model which has been used successfully to date and continues to be supported.</td>
</tr>
<tr>
<td></td>
<td>• Published guidelines need to be referenced to the <em>Food Standards Code</em> and relevant State/Territory legislation.</td>
</tr>
<tr>
<td></td>
<td>• There is a requirement for mandatory training for UCFM businesses and food safety auditors in HACCP, food safety principles and UCFM production processes.</td>
</tr>
<tr>
<td></td>
<td>• There is a need to mandate process/product testing, i.e. the minimum requirement necessary to verify HACCP based food safety program.</td>
</tr>
<tr>
<td></td>
<td>• There is a need for a protocol for the assessment of food safety plans. Prerequisites in the establishment of a protocol include:</td>
</tr>
<tr>
<td></td>
<td>- use of starter culture and starter culture specifications</td>
</tr>
<tr>
<td></td>
<td>- pH monitoring and nature of monitoring</td>
</tr>
<tr>
<td></td>
<td>- fermentation time, temperature and humidity</td>
</tr>
<tr>
<td></td>
<td>- maturation time, temperature and humidity</td>
</tr>
<tr>
<td></td>
<td>- water activity or weight loss</td>
</tr>
<tr>
<td></td>
<td>- temperature of meat storage</td>
</tr>
<tr>
<td></td>
<td>- monitoring of <em>E. coli</em> in raw materials</td>
</tr>
<tr>
<td></td>
<td>- monitoring of <em>E. coli</em> in final products</td>
</tr>
<tr>
<td></td>
<td>- review of previous history/records.</td>
</tr>
<tr>
<td></td>
<td>• Option 3 is supported with the following changes:</td>
</tr>
<tr>
<td></td>
<td>- subclause (c) is only supported when applied in conjunction with a suitable HACCP plan; and</td>
</tr>
<tr>
<td></td>
<td>- an Expert Panel needs to be formed and retained to provide a centralised assessment of UCFM applications (i.e. assessment of HACCP based Food Safety Program); and</td>
</tr>
<tr>
<td></td>
<td>- mandatory training for UCFM businesses and food safety auditors (in HACCP, food safety principles and UCFM production processes) should be specified.</td>
</tr>
<tr>
<td>Murray Patterson Environmental</td>
<td>• DoH (Department of Health) introduced the following regulations in Western Australia after the Garibaldi food poisoning outbreak.</td>
</tr>
<tr>
<td></td>
<td>1. Registration of all UCFM premises by local government;</td>
</tr>
</tbody>
</table>
2. Licensing key personnel involved in the manufacturing of UCFM products by local government (a UCFM license is issued after successful completion of a recognised UCFM processing course conducted by the Curtin University or by assessment of food technology or science qualifications).

3. Key quality assurance personnel to be rained by a recognised training provider in the application of HACCP systems.

4. All UCFM producers to implement auditable HACCP based quality assurance programs addressing the quality management system elements of ISO 9002, the UCFM standards in the Food Standards Code and the good manufacturing practices of the “ANZFA Advisory Guidelines for Making Uncooked Fermented Comminuted Meat Products”.

- DoH recommends FSANZ to provide further justification for testing of Coagulase-positive staphylococci and Salmonella species in the end product.
- DoH recommends FSANZ to consider the inclusion of Listeria monocytogenes into microbiological limits in the end products with pH > 5.3 and aw > 0.90.
- DoH recommends that the equivalent combination of time and higher temperature for “cook” be reviewed, as it is contradictory to the requirement of “heat treatment” combination of temperature and time. DoH recommends Clause 8 (2) of Standard 1.6.2 be moved to Clause 9 of Standard 1.6.2
- Application of HACCP plans (HACCP based food safety program) must ensure national consistency including desk audit approval and compliance auditing by the controlling authority or an accredited agency.
- DoH recommend FSANZ to reconsider the definition of UCFM products, particularly if UCFM products are ready-to-eat products and if UCFM products do not require a cooking step during the manufacturing process or by the consumers before consumption.
- DoH recommends the removal of the prescribed 20 E. coli per gram for raw meat ingredients.
- DoH considers that sampling plan and test frequency for E. coli organisms in the raw meat ingredients and subsequent processes should be left to the manufacturers as a validation/verification responsibility.
- DoH considers that “Lot testing” does not reward manufacturers whom have demonstrated safe UCFM production processes, but “lot testing” is useful as a controlling authority sanction or for the manufacturer who needs to re-establish food safety control measures.
- DoH recommends that the schedule of Standard 1.6.2 for determination of pH permit the use of calibrated, direct-contact pH probes or meters.
- DoH recommends changes to be made for the temperature requirement for meat used for UCFM product to include batter mixes and UCFM products which are going to be stored for further processing (filling and fermentation) other than on the day of production.
- DoH recommends that the “test and hold” measure include coagulase-positive staphylococci and salmonella microbiological testing.
- DoH supports additional labelling requirement to inform consumers of the risk associated with UCFM products.
- DoH supports the addition of the word “salami” in the prescribed product name.
- DoH supports Option 3 proposed by FSANZ with considerations being given to recommendations listed above.
- DoH recommends FSANZ in consultation with the UCFM industry and the
State/Territory controlling authorities to amend the *Advisory Guidelines for Making Uncooked Fermented Comminuted Meat Products* to ensure uniform application of revised UCFM standards and good manufacturing practices in the production of UCFM.

- DoH recommends that FSANZ support the continued development of the *E. coli* predictive model.

<table>
<thead>
<tr>
<th>Brian Devine</th>
</tr>
</thead>
<tbody>
<tr>
<td>Environmental Health Directorate</td>
</tr>
<tr>
<td>Department of Health</td>
</tr>
<tr>
<td>Western Australia</td>
</tr>
<tr>
<td>- Competency of skill and knowledge should be defined and referenced as a reflection of the food safety severity associated with producing UCFM and to assist the uniform application of this provision.</td>
</tr>
<tr>
<td>- The required competencies should be included in the “Guidelines for safe manufacture of smallgoods” and be a component for registration of manufacturer of UCFM products. The method of assessing competencies should be left to the controlling authorities.</td>
</tr>
</tbody>
</table>
| - Recommend amending the subclauses relating to starter culture and no backslopping to “Fermentation of a UCFM must be initiated through the use of a starter culture; and previously fermented meat or fermenting meat must not be used as a starter culture or an ingredient of UCFM”.

<table>
<thead>
<tr>
<th>Brian Delroy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Department of Human Services</td>
</tr>
<tr>
<td>South Australia</td>
</tr>
<tr>
<td>- Given that Standard 3.2.1 is to be called up there may be a need for a number of jurisdictions to enact a regulation to call up the “voluntary” standard. The call up of this standard may require jurisdictions to have mechanisms in place to allow for Approved Food Safety Auditors.</td>
</tr>
<tr>
<td>- It would be very useful if supporting documentation describes the key requirements and what training or courses would provide for compliance for skill and knowledge in Standard 3.2.2.</td>
</tr>
<tr>
<td>- Requirements described under the HACCP based food safety program are strictly unnecessary, and arguably these requirements should be in a guideline.</td>
</tr>
</tbody>
</table>