ISSUES PAPER
AND
CALL FOR PUBLIC SUBMISSIONS

Proposal P239

Listeria Risk Assessment
and
Risk Management Strategy

A partnership between the Australia New Zealand Food Authority (ANZFA), New Zealand Ministry of Health, Food Science Australia and the New Zealand Institute of Environmental Science and Research Limited (ESR)

Note:
This Issues Paper is the “Proposal” referred to in Section 21 of the Australia New Zealand Food Authority Act (1991).

Public comments are now sought to enable a comprehensive assessment by ANZFA. Details about food standards setting in Australia and New Zealand are contained in Attachment 1.
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EXECUTIVE SUMMARY

Listeria monocytogenes is a foodborne pathogen, which has been responsible for a wide variety of outbreaks of listeriosis in the last twenty years. Foodborne disease has always been a concern for regulators, the food industry and the community, however with rapid advances in food technology and changes in consumer preferences, there is an emergence of new microbiological hazards. This has led to an increased focus on some foodborne pathogens, such as L. monocytogenes. A number of strategies are available to industry and regulators to reduce the risk posed by this hazard but to be effective and appropriate a comprehensive risk management strategy is needed.

On 24 November 2000, Health Ministers in the Australia New Zealand Food Standards Council (ANZFSC) agreed to adopt the new Australian New Zealand Food Standards Code (the joint Code). The joint Code was gazetted on 20 December 2000 in both Australia and New Zealand as an alternate to existing food regulations until December 2002 when it will become the sole food code for both countries. The acceptance of the joint Code was conditional on the review of a number of outstanding matters, including the microbiological limits for Listeria monocytogenes in fish and crustacea.

The recommendation that low levels of L. monocytogenes should be permitted in processed finfish (smoked salmon being the key food in this category) was the outcome of a risk assessment, which identified that this type of product does not always receive a listericidal treatment during processing. However, since it may be possible under some packaging regimes that growth of L. monocytogenes could occur during storage prior to consumption, there have been some concerns expressed about the ability of the standard to provide the required level of protection for public health.

Proposal P239 seeks to further review the scientific information to develop a risk management strategy, taking into account relevant L. monocytogenes risk analysis activities and materials available in Australia, New Zealand, and internationally. The strategy will be developed building on existing programs and standards in both countries. The project will seek input and participation from all stakeholders, including industry, regulators and the scientific community. The outcome is intended to reflect the use of a strong evidence base, a collaborative approach to manage the health risks and the common objective of all stakeholders of a safe food supply.

This project is a collaboration between ANZFA, the New Zealand Ministry of Health, Food Science Australia and the New Zealand Institute of Environmental Science and Research Limited (ESR). A major component of the strategy development to be undertaken by Food Science Australia and ESR will be a quantitative risk assessment rather than qualitative, if possible, on the risk posed by L. monocytogenes for selected foods. The risk assessment outcome will be used in the first instance to evaluate the appropriateness of the microbiological criteria in Standard 1.6.1 of the joint Code.

A Reference Group with expertise in L. monocytogenes will be assisting ANZFA and its partners, providing advice and peer reviewing the risk assessment.
ANZFA is calling for data from Australia and New Zealand detailed below to contribute to the risk assessment and risk management stages:

- information on current risk management strategies for *L. monocytogenes* in dairy and seafoods, used by the food industry, regulators and public health authorities;
- information on levels of *L. monocytogenes* found in select seafoods;
- information on occurrence of cases and outbreaks of listeriosis and the distribution of *L. monocytogenes* in food linked to outbreaks;
- identification of all interested parties in all aspects of *Listeria* risk assessment and risk management in Australia and New Zealand;
- the costs and/or benefits for industry in relation to compliance; and
- information on effects on international trade; and
- what are the most effective risk management tools for the control of *L. monocytogenes* in foods? Some examples of risk management tools include standards (mandatory requirements), guidelines (not mandatory), food safety plans, communication / education.

In addition, ANZFA seeks to initiate discussion on the topic of zero tolerance for *L. monocytogenes* in foods. Zero tolerance means that *L. monocytogenes* cannot be detected in a stipulated amount of food (eg. *L. monocytogenes* cannot be detected in 25g of the sample food).

This Issues Paper is the first of two opportunities to comment on Proposal P239. A second paper, which will include the risk assessment and risk management options, will be circulated for comment in 2002.

1. **INVITATION FOR PUBLIC SUBMISSIONS**

On 24 November 2000, Health Ministers in the Australia New Zealand Food Standards Council (ANZFSC) agreed to adopt Volume 2 of the *Food Standards Code* (the joint Code). The joint Code was gazetted on 20 December 2000 in both Australia and New Zealand as an alternate to existing food regulations until December 2002 when it will become the sole food code for both countries (see Attachment 1). The acceptance of the joint Code was conditional on the review of a number of outstanding matters, including the microbiological limits for *Listeria monocytogenes* in fish and crustacea. Concerns were raised both about the range of foods for which microbiological limits were set and the actual levels set.

Proposal P239 is the mechanism by which ANZFA will address these issues. Proposal P239 commences with this Issues Paper, which provides further detail and seeks public input and comment on Proposal P239. There will be two opportunities for the public to comment on Proposal P239, of which this Issues Paper is the first.

The second opportunity to comment will occur in 2002. At that time a draft assessment report will be circulated for public comment. The draft assessment report will assess the scientific evidence, the public comment on the Proposal, suggest risk management options, and the proposed course of action.
ANZFA invites public submissions on any issues raised in this Issues Paper, or any other relevant issue, for the purposes of assessing the Proposal. In particular, ANZFA invites comment on:

- current *L. monocytogenes* management programs used by the dairy and seafood industries;
- information on levels of *L. monocytogenes* found in select seafoods;
- occurrence of cases and outbreaks of listeriosis and the distribution of *L. monocytogenes* in food linked to outbreaks;
- identification all interested parties in all aspects of *Listeria* risk assessment and risk management in Australia and New Zealand;
- zero tolerance for *L. monocytogenes* in food;
- the costs and/or benefits for industry in relation to compliance; and
- information on effects on international trade and
- what are the most effective risk management tools for the control of *L. monocytogenes* in foods? Some examples of risk management tools include standards (mandatory requirements), guidelines (not mandatory), food safety plans, communication / education.

Please refer to Section 4 for more details. Ideally, technical information presented should be in sufficient detail to allow independent scientific assessment.

After the second public consultation process, ANZFA will finalise recommendations to the Australia New Zealand Food Standards Council (consisting of Health Ministers from Australia and New Zealand), which will make the final decision as to whether or not to adopt the recommended approach.

The processes of ANZFA are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of ANZFA and made available for public inspection. If you wish any confidential information contained in a submission to remain confidential to ANZFA, you should clearly identify the sensitive information and provide justification for treating it in confidence. The *Australia New Zealand Food Authority Act 1991* requires ANZFA to treat in confidence trade secrets relating to food and any other information relating to food, the commercial value of which would be or could reasonably be expected to be, destroyed or diminished by disclosure.

All correspondence and submissions on this matter should be addressed to the Project Manager, Proposal P239 at one of the following addresses:

Australia New Zealand Food Authority
PO Box 7186
Canberra Mail Centre ACT 2610
AUSTRALIA
Tel (02) 6271 2222
Fax (02) 6271 2278

Australia New Zealand Food Authority
PO Box 10559
The Terrace WELLMINGON 6036
NEW ZEALAND
Tel (04) 473 9942
Fax (04) 473 9855
ANZFA should receive submissions by no later than **12 October 2001**. Submissions may be sent by email to slo@anzfa.gov.au. However, ANZFA cannot guarantee accurate transmission and it is suggested that you also forward a hard copy by mail.

General queries on this matter and other ANZFA business can be directed to the Standards Liaison Office at the above address or by email on slo@anzfa.gov.au. Requests for more general information on ANZFA can be directed to the Information Office at the above address or by email on info@anzfa.gov.au.

2. **OVERVIEW OF PROPOSAL**

2.1 **Background**

The Health Ministers of the Australia New Zealand Food Standards Council (ANZFSC) agreed to adopt Volume 2 of the *Food Standards Code* (the joint Code) on November 24, 2000. The acceptance of the joint Code was conditional on a further review of several issues, including the microbiological limits for *Listeria monocytogenes* in fish and crustacea.

The Review of Microbiological Standards in the development of the joint Australia New Zealand Food Standards Code was based on the *Framework for the Assessment and Management of Health Risks in Relation to Food*, released by ANZFA in September 1996, the Step 8 Codex (1998) document, *Draft Principles and Guidelines for the Conduct of Microbiological Risk Assessment* and on *The Regulation of Microbiological Hazards in Food – Discussion Paper* released by ANZFA in January 1999. Due to data constraints, the risk analyses were largely qualitative in nature.

In addition to microbiological limits set in standards, enforcement agencies and the food industry have strategies in place for sampling foods, for responding to positive samples, and for recalling foods. The need for these strategies relates to the unique characteristics of *L. monocytogenes*, in particular the ability to grow at refrigeration temperatures, the widespread occurrence of the bacteria in the environment and the susceptibility of specific consumer groups to infection, in contrast to the apparent tolerance by the majority of the population.

In Australia, the *Food Standards Code* requires a zero tolerance (not detected in 25 g) for meat paste and pâté, smoked fish products, marinated smoked mussels and cheeses with a moisture content equal to or greater than 40% and a pH greater than or equal to 5.0. These regulations apply only at the end of the production process or at the wholesale retail stage (see Attachment 2).

In New Zealand, the “General microbiological reference criteria for *L. monocytogenes*” require that all ready-to-eat foods and those that undergo a listericidal step meet a zero tolerance (absence in five samples of 25g). Some foods are exempt from this requirement. These criteria apply until the end of the stated shelf-life of the food. These criteria are not part of New Zealand law, but are to be used where no standard exists in law for monitoring purposes, or as supplements to existing standards where public health concerns dictate (see Attachment 2).
The joint *Australia New Zealand Food Standards Code* microbiological standards for *L. monocytogenes* apply to foods sampled at any point during their stated shelf life. Zero tolerance applies to butter made from unpasteurised milk, soft and semi-soft cheeses, all raw milk cheeses, unpasteurised milk, packaged cooked cured/salted meat and heat treated paste and pâté, cooked crustacea and processed molluscs. For processed ready-to-eat finfish a level of up to 100 in one of 5 samples applies.

The microbiological risk assessment for processed finfish completed during the review of food standards recommended that low levels of *L. monocytogenes* should be permitted in processed finfish (smoked salmon being the key food in this category), as this type of product does not always receive a listericidal treatment during processing. However, some concerns have been expressed about the ability of the standard to provide the required level of protection for public health, since it may be possible under some packaging regimes that growth of *L. monocytogenes* could occur during storage prior to consumption.

Regulatory approaches adopted for managing *L. monocytogenes* in foods in Australia, New Zealand, the United States of America, Canada, the European Union, and Codex are detailed in Attachment 2.

### 2.2 Objectives

The purpose of Proposal P239 is to review the *L. monocytogenes* requirements of Standard 1.6.1, and if necessary, to reflect a risk management strategy that is evidence and risk-based and takes into account relevant *L. monocytogenes* risk analysis activities and materials available in Australia, New Zealand, and internationally. The strategy will be developed building on existing programs and standards in both countries. The project will seek input and participation from all stakeholders, including industry, regulators and the scientific community. The outcome is intended to reflect the use of a strong evidence base, a collaborative approach to manage the health risks and the common objective of all stakeholders of a safe food supply. The proposal will extend and improve on previous analyses by introducing a quantitative element and a focus on local data.

Development of the risk management strategy will require that a quantitative risk assessment model be developed, rather than qualitative, if possible. The outcome of this modelling will be used in the first instance to evaluate the appropriateness of the microbiological criteria in Standard 1.6.1 of the joint Code. It will also contribute to the overall risk management strategy for *L. monocytogenes* being developed by ANZFA.

### 2.3 Project partners

The project is being undertaken in partnership with the New Zealand Ministry of Health, Food Science Australia and the New Zealand Institute of Environmental Science and Research Limited (ESR). Food Science Australia and ESR will develop the risk assessment model and undertake assessments on *L. monocytogenes* in selected ready-to-eat foods. Food Science Australia and ESR have agreed to work in a collaborative effort with ANZFA, as they have experience in quantitative risk assessment, as well as with *L. monocytogenes*.
A Reference Group\textsuperscript{1} with expertise in \textit{L. monocytogenes} is assisting ANZFA and its partners, providing advice and peer reviewing the risk assessment.

2.4 Methodology

In assessing the relevant public health and safety issues, the principles of microbiological risk analysis will be employed. Microbiological Risk Analysis aims to reduce the risk of infection of consumers with foodborne microorganisms and has three components:

\begin{itemize}
  \item Risk Assessment;
  \item Risk Management; and
  \item Risk Communication.
\end{itemize}

2.4.1 Risk Assessment

The general principles of risk assessment defined by the Codex Alimentarius Commission will be applied (see Attachment 3). Existing risk assessments for \textit{L. monocytogenes} available from international sources (eg WHO 2000 and US FDA 2001) and any available from New Zealand, Australian state or territory governments and industry will be reviewed and used as a basis for this project. Elements of these existing risk assessments will be used as considered appropriate for application in the Australian and New Zealand context to achieve the objectives of the risk assessment process.

The initial focus of the risk assessments will be on ready-to-eat food product categories with selected seafoods considered a priority.

2.4.2 Risk Management

ANZFA will assess the current regulatory framework and risk management programs applied by governments and industry for the control of foodborne listeriosis. A watching brief will be maintained on international developments and Codex activities in this area.

Risk management options will be formulated from the outcomes of the risk assessments, based on ANZFA’s objectives (see Attachment 1 for a list of ANZFA’s objectives). These options will be detailed in the draft assessment report, which will be circulated for public comment.

All comments received will be considered. ANZFA will then finalise the risk management options, and make a recommendation to the Health Ministers. Existing risk management measures will be amended as appropriate, to ensure consistency with the proposed risk management strategy.

\textsuperscript{1} Members of the Reference Group:
Mr John Bassett \hspace{1cm} Professor Tom McMeekin
Dr Phil Bremer \hspace{1cm} Ms Joanne Patterson
Mr Chris Chan \hspace{1cm} Dr Tom Ross
Dr Rob Chandler \hspace{1cm} Dr John Sumner
Dr Craig Dalton \hspace{1cm} Mr Peter Sutherland
Dr Martyn Kirk \hspace{1cm} Mr Philip Walsh
2.4.3 Risk Communication

Risk communication involves the interactive exchange of information and opinions concerning risk and risk management among risk assessors, risk managers, consumers and other interested parties.

The communication strategy developed for this Proposal identifies ANZFA’s partners and the Reference Group, the scientific community in Australia and New Zealand, enforcement agencies, and consumers, especially pregnant women, as its target audience.

The message to these audiences is that ANZFA and its partners are reviewing the latest scientific data on *Listeria*, and if necessary, will recommend risk management options aimed at lowering the incidence of listeriosis.

ANZFA will be holding stakeholder forums in Australia and New Zealand as the project progresses. ANZFA notes that many other organisations and individuals currently engage in risk communication for *Listeria*, and hopes that this work continues.

3. *LISTERIA AND FOODBORNE DISEASE*

3.1 What is *Listeria*?

*Listeria* are gram-positive, facultatively anaerobic, short, regular non-sporing rod-shaped bacterium, with seven species: *L. monocytogenes*, *L. innocua*, *L. welshimeri*, *L. seeligeri*, *L. ivanovii* subsp. *londoniensis*, *L. ivanovii* subsp *ivanovii*, and *L. grayi* (Sutherland and Porritt 1997) (ICMSF 1996). *L. grayi* and *L. innocua* are considered non-pathogenic. *L. ivanovii*, *L. seeligeri* and *L. welshimeri* rarely cause human infection (Gellin and Broome 1989). Thus, *L. monocytogenes* is considered the most important species with respect to foodborne illness (ICMSF 1996).

*L. monocytogenes* can be subdivided into four serogroups (1/2, 2, 4 and 7) (Bannerman 1995). Serovars 4b, 1/2a and 1/2b account for most cases of human listeriosis (ICMSF 1996).

*L. monocytogenes* is a foodborne pathogen, which has been responsible for a wide variety of outbreaks of foodborne disease in the last twenty years. Foodborne disease has always been a concern for regulators, the food industry and the community, however with rapid advances in food technology and changes in consumer preferences, we are now seeing the emergence of new microbiological hazards. This has led to an increased focus on some foodborne pathogens, such as *L. monocytogenes* (Hasell 2000) (US FDA 2001).

3.2 History of *Listeria*

Gram-positive rods were observed in tissue sections from patients who died of what retrospectively appears to have been a listeric infection, in 1891 by Hayem in France and in 1893 by Henle in Germany (Gray and Killinger 1966).
The first recorded isolation of *L. monocytogenes* was by Murray in 1926, in rabbits and guinea pigs (Hird and Genigeorgis 1990; McCarthy 1990). The organism was named *Bacterium monocytogenes*. Pirie isolated and described the same organism in 1927 from gerbil in South Africa. Pirie named the organism *Listerella hepatolytica*, however in 1940 he suggested the name be changed to *L. monocytogenes* (McCarthy 1990).

Nyfeldt first reported human listeriosis in 1929 (Kampelmacher 1989). In 1953 Potel linked foodborne listeriosis with animals, isolating *L. monocytogenes* from a cow with *Listeria* mastitis and stillborn twins from a women who had ingested untreated milk from the infected animal (McCarthy 1990). For more information on outbreaks linked to *L. monocytogenes*, see Attachment 4.

### 3.3 Listeriosis

There are generally two types of listeriosis – listerial gastroenteritis, where usually only mild, flu-like symptoms are reported, and invasive listeriosis, which can be very severe, and in some cases, life-threatening. Invasive listeriosis is a relatively rare disease (US FDA 2001), and can have a wide range of symptoms. For more information on the symptoms and conditions caused by listeriosis, see Attachment 5.

Many people carry *L. monocytogenes* in their intestinal tract, which suggests that people are frequently exposed to *L. monocytogenes* (Gellin and Broome 1989; Farber and Peterkin 1991; Schlech 1995). This may also suggest that most people have tolerance to infection by *L. monocytogenes*, and given the relatively low number of reported cases, exposure rarely leads to serious illness (US FDA 2001; Marth 1988).

However, a number of risk groups for listeriosis have been identified, including pregnant women and their foetuses, neonates, elderly, and the immuno-compromised (e.g. HIV/AIDS patients and renal transplant patents). Healthy individuals may become infected, but only very rarely (Sutherland and Porritt 1997).

The majority of foodborne disease caused by *L. monocytogenes* occurs sporadically (Farber and Peterkin 1991; Schuchat et al. 1992; Pinner et al. 1992; Gellin and Broome 1989).

Infection usually occurs via the intestine. *L. monocytogenes* binds internalin to a protein called E-cadherin (Lecuit et al. 2001). The incubation period varies from between 1 to 90 days (European Commission 1999).

The minimum infective dose\(^{ii}\) for listeriosis is not defined and may never be, as it will probably vary significantly between individuals (Farber and Peterkin 1991; McLauchlin 1995; US FDA 2001; Marth 1988). Factors affecting the infectious dose include the immune status of the infected individual, the type of food consumed, the virulence and infectivity of the pathogen, the concentration of the pathogen in the food, and the number of repetitive challenges (NACMF 1991). However, it is generally believed that the minimum effective dose is >100 viable cells (ICMSF 1996).

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\(^{ii}\) Minimum infective dose is defined as the level of a microorganism required to cause infection in hosts
3.3.1 Incidence of Listeriosis

The number of reported cases of invasive listeriosis in Australia is approximately 56 cases per year (Communicable Diseases Network Australia 2001), which equates to an estimated incidence of invasive listeriosis in Australia of 3 cases per million of the general population per year (Sutherland and Porritt 1997). The annual average number of reported cases of invasive listeriosis in New Zealand since 1994 is 18. The estimated incidence of invasive listeriosis in New Zealand is 5 cases per million of the general population per year (Anon 1996-2001). The fatality rate in New Zealand since 1995 is approximately 17% (Kieft et al 2000). The fatality rate in Australia is not known. The costs to the community for listeriosis in Australia and New Zealand are not known.

The estimated incidence of invasive listeriosis in European countries is 4 – 8 cases per million of the general population per year. In France, the estimated incidence of invasive listeriosis is 16 cases per million general population per year (Bille 1990). The United States estimates that approximately 8.8 people per million general population become seriously ill with invasive listeriosis each year, with a fatality rate of 20%. Of all the foodborne pathogens, \textit{L. monocytogenes} resulted in the highest hospitalisation rate in the United States (US FDA 2001).

While the incidence rate is low compared to other foodborne illnesses, such as \textit{Salmonella}, the mortality rate is much higher, ranging between 5 and 33%, and averaging 22% (Rocourt and Brosch 1992).

3.4 \textit{Listeria} in the environment

\textit{L. monocytogenes} is widely present in the environment, including soil, sewage, plant matter, animal feed, dust and water (Sutherland and Porritt 1997; Fenlon 1999). \textit{L. monocytogenes} is able to survive in plant vegetation for up to 12 years (Beuchat \textit{et al}. 1990).

Silage is often the source of listeriosis infection in farm animals, which can in turn be passed through the food chain (Fenlon 1999). \textit{L. monocytogenes} is able to survive for long periods in processing plants, household refrigerators and freezers (US FDA 1999; Salamina 1996).

Humans and other animals can serve as hosts to \textit{Listeria} without the organism causing illness (Sutherland and Porritt 1997). \textit{L. monocytogenes} can be isolated from a cow suffering from mastitis, an asymptomatic carrier, or by environmental contamination of the udder, such as by soil or animal waste (Farber 1992).

3.5 \textit{Listeria} in food

According to published data, \textit{L. monocytogenes} has been isolated from a wide range of foods, including:

- Dairy foods (such as raw and pasteurised milk, butter, cheese, ice cream, yoghurt, cultured buttermilk, dairy desserts and custard)
- Raw vegetables (such as radishes, cucumbers, cabbage, potatoes, lettuce, asparagus, broccoli, cauliflower, endive, watercress, tomatoes, celery and parsley)
- Ready-to-eat salads
• Raw and minimally processed meat (such as minced pork, frozen beef patties, vacuum packaged meat, sausages, beef, pork, lamb)
• Uncooked, fermented sausages (such as salami, mettwurst)
• Processed meat products (such as ham, pâté, turkey frankfurters, and jerky)
• Raw, frozen and cooked poultry
• Liquid egg products
• Fresh, frozen and processed seafood (such as raw and smoked fish)

(Sutherland and Porritt 1997; Ryserb 1999; Farber and Peterkin 1999; Cox et al 1999; Jinneman et al 1999; Brackett 1999; Porto and Eiroa 2001; Farber et al 1989).

Given the ubiquitous nature of \textit{L. monocytogenes}, its presence in raw foods is unavoidable. It is interesting to note that a number of outbreaks of listeriosis in the last decade have occurred in processed foods, where the processes used should have been capable of providing a listericidal treatment (i.e. a treatment sufficient to kill \textit{L. monocytogenes}). This infers contamination has occurred after the listericidal treatment has been applied, or there has been an inadequate application of the listericidal process.

Table 1 lists foods that have been implicated in sporadic and epidemic cases of listeriosis. Please note not all of these foods have been proven to be the cause of listeriosis.

\begin{table}
\begin{tabular}{|l|l|}
\hline
\textbf{Sporadic cases} & \textbf{Outbreaks} \\
\hline
Alfalfa tablets & Blue-mould or hard cheese \\
Cajun meat and rice sausage & Butter \\
Cooked chicken & Chocolate milk \\
Fish & Cold-smoked Rainbow trout \\
Fresh and ice cream & Coleslaw \\
Human breast milk & Cooked chicken \\
Medwurst & Corn and tuna salad \\
Pickled olives & Hot dogs and deli meat \\
Raw milk & Ice cream \\
Rennet & Jellied pork tongue \\
Salted mushrooms & Pasteurised milk \\
Sausages & Pork \\
Smoked cod roe & Pork tongue in aspic \\
Soft cheese & Prawns \\
Turkey frankfurters & Processed meats or pâté \\
Whey cheese & Raw milk, sour milk, cream, cottage cheese \\
& Raw salad \\
& Raw vegetables \\
& Rice salad \\
& Rillettes (processed pork product) \\
& Salami \\
& Shellfish, raw fish \\
& Sliced corned beef \\
\hline
\end{tabular}
\end{table}
Smoked mussels
Soft cheese


3.5.1 Growth Conditions

Many factors influence the growth of *L. monocytogenes* in foods, including the nature and concentration of nutrients in foods, pH, temperature, water activity and food additives (Lovett et al. 1990; Doyle 1988). Growth conditions are summarised in the following table:

<table>
<thead>
<tr>
<th></th>
<th>Minimum</th>
<th>Optimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Temperature (°C)</td>
<td>-1.5</td>
<td>37</td>
<td>45</td>
</tr>
<tr>
<td>pH</td>
<td>4.39</td>
<td>7.0</td>
<td>9.4</td>
</tr>
<tr>
<td>Water activity (a_w)</td>
<td>0.90</td>
<td>-</td>
<td>-</td>
</tr>
</tbody>
</table>

(ANZFA, unpublished)

*L. monocytogenes* can grow at salt concentrations as high as 10%, and survive in concentrations of 30% (Fuchs and Reilly 1992).

*L. monocytogenes* grows well under both aerobic and anaerobic conditions, and in the presence of carbon dioxide (Sutherland and Porritt 1997).

4. PRELIMINARY ISSUES AND QUESTIONS

This section of the Issues Paper is concerned with identifying some of the issues of importance to stakeholders in relation to the Proposal and seeks further information and views from stakeholders about these or any other issues.

The information gathered in response to this Issues Paper will be used in undertaking risk assessments on *L. monocytogenes* in foods, and developing a risk management strategy.

The initial focus of the risk assessment will be selected seafoods. The risk assessment is intended to be quantitative, although this will depend, in sort, on the amount and quality of data received.

4.1 Current Status of *Listeria monocytogenes* management

Industry, regulators and public health authorities in Australia and New Zealand currently implement *Listeria* management programs. ANZFA would like to identify all programs currently being used by the seafood industry, so that an analysis can be made of the types of programs being applied, and the uniformity of coverage that is provided.
ANZFA will undertake a targeted consultation in order to start gathering this information, by identifying some regulatory bodies and sectors of the food industry and asking them to provide such information, if available.

**ANZFA seeks information on current L. monocytogenes management programs used by the seafood industry.**

### 4.2 Data on *Listeria monocytogenes* in food

Industry, enforcement agencies and researchers currently test for the presence of *Listeria* in foods. Knowledge of the amount of *L. monocytogenes* in select seafoods would assist in undertaking a quantitative risk assessment.

ANZFA will undertake a targeted consultation in order to start gathering this information, by identifying some regulatory bodies and sectors of the food industry and asking them to provide such information, if available.

**ANZFA seeks information on levels of *L. monocytogenes* found in select seafoods.**

### 4.3 Surveillance and Epidemiology

ANZFA would like to collate and analyse reports and data on the occurrence of cases and outbreaks of listeriosis and the distribution of *L. monocytogenes* in food linked to outbreaks. ANZFA notes that only invasive listeriosis is a notifiable disease in Australia and New Zealand, although outbreaks of listerial gastroenteritis may be notified in some jurisdictions if they are thought to be associated with a common source.

This information will provide a benchmark against which the effectiveness of the management strategy can be measured over a period of time. It will assist in the identification of areas of food processing or food handling that need to be addressed, and the potential areas for further risk assessment work.

ANZFA has undertaken a targeted consultation in order to start gathering this information by identifying regulatory bodies and asking them to provide such information, if available.

**ANZFA seeks information on occurrence of cases and outbreaks of listeriosis and the distribution of *L. monocytogenes* in food linked to outbreaks.**

### 4.4 Resource Identification

ANZFA seeks to identify all interested parties in all aspects of *Listeria* risk assessment and risk management in Australia and New Zealand. Aspects could include regulatory, enforcement, research, the food industry etc. This will provide for timely and comprehensive dissemination of requests for additional information and of the project outcomes.

### 4.5 Zero Tolerance

Some experts believe that the ingesting low levels of *L. monocytogenes* may not result in illness (Anon® 1999). If this is the case, low levels of *L. monocytogenes* in foods may not be considered a public health and safety issue.
A zero tolerance has traditionally been set as a cautionary approach due to the lack of information regarding listeriosis and *Listeria* in foods. In this context, zero tolerance means that *L. monocytogenes* cannot be detected in a stipulated amount of food (e.g., *L. monocytogenes* cannot be detected in 25g of the sample food). Some experts have argued against the establishment of a zero tolerance for *L. monocytogenes* in foods, for the following reasons:

- Gilbert (1995) argues that sampling plans involving tests for *L. monocytogenes* and other pathogens are best used as a verification tool for HACCP programmes, not for microbiological standards based on public health and safety.

- Teufel (1994) suggests that some foods would vanish from the market if a zero tolerance for *L. monocytogenes* in foods was enforced, particularly for foods that may support the growth of *L. monocytogenes*.

- The Codex committee on Food Hygiene is currently developing a document entitled “Guidelines for the control of *Listeria monocytogenes* in foods”. This draft document recommends that a general zero tolerance for *L. monocytogenes* in foods be reviewed in light of current knowledge (Codex Committee on Food Hygiene 2000).

**ANZFA seeks comment on zero tolerance for *L. monocytogenes* in foods.** Ideally, technical information presented should be in sufficient detail to allow independent scientific assessment.

ANZFA seeks this information for the risk management stage, and this discussion should not be construed as an intention on ANZFA’s behalf to impose a zero tolerance or other limits on *L. monocytogenes* in foods. A risk assessment must first be undertaken in order to determine appropriate risk management tools.

### 4.6 Regulatory Impact Statement

ANZFA is required to assess the costs and benefits associated with adopting or changing food regulations. This is known as the Regulatory Impact Statement, or RIS. The RIS identifies the affected parties, any alternative regulatory options, and the potential impacts of any regulatory or non-regulatory provisions. The information needed to make an assessment of this proposal will include information from public submissions.

**ANZFA seeks information on:**

- what are the costs and/or benefits for industry in relation to compliance?
- are there any effects on international trade?
- what are the most effective risk management tools for the control of *L. monocytogenes* in foods? *Some examples of risk management tools include standards (mandatory requirements), guidelines (not mandatory), food safety plans, communication / education.*
5. CONCLUSION

Proposal P239 seeks to further review the scientific information to develop a risk management strategy, taking into account relevant *L. monocytogenes* risk analysis activities and materials available in Australia, New Zealand, and internationally. The strategy will be developed building on existing programs and standards in both countries. The project will seek input and participation from all stakeholders, including industry, regulators and the scientific community. The outcome is intended to reflect the use of a strong evidence base, a collaborative approach to manage the health risks and the common objective of all stakeholders of a safe food supply.

ANZFA is calling for data from Australia and New Zealand to contribute to the risk assessment and risk management of *L. monocytogenes* in foods.
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ATTACHMENT 1 - Food Standards Setting in Australia and New Zealand

The Governments of Australia and New Zealand entered an Agreement in December 1995 establishing a system for the development of joint food standards. On 24 November 2000, Health Ministers in the Australia New Zealand Food Standards Council (ANZFSC) agreed to adopt the new Australian New Zealand Food Standards Code. The new Code was gazetted on 20 December 2000 in both Australia and New Zealand as an alternate to existing food regulations until December 2002 when it will become the sole food code for both countries. It aims to reduce the prescription of existing food regulations in both countries and lead to greater industry innovation, competition and trade.

Until the joint Australia New Zealand Food Standards Code is finalised the following arrangements for the two countries apply:

- **Food imported into New Zealand other than from Australia** must comply with either Volume 1 (known as Australian Food Standards Code) or Volume 2 (known as the joint Australia New Zealand Food Standards Code) of the Australian Food Standards Code, as gazetted in New Zealand, or the New Zealand Food Regulations 1984, but not a combination thereof. However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the New Zealand (Maximum Residue Limits of Agricultural Compounds) Mandatory Food Standard 1999.

- **Food imported into Australia other than from New Zealand** must comply solely with Volume 1 (known as Australian Food Standards Code) or Volume 2 (known as the joint Australia New Zealand Food Standards Code) of the Australian Food Standards Code, but not a combination of the two.

- **Food imported into New Zealand from Australia** must comply with either Volume 1 (known as Australian Food Standards Code) or Volume 2 (known as Australia New Zealand Food Standards Code) of the Australian Food Standards Code as gazetted in New Zealand, but not a combination thereof. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the New Zealand Food Regulations 1984.

- **Food imported into Australia from New Zealand** must comply with Volume 1 (known as Australian Food Standards Code) or Volume 2 (known as Australia New Zealand Food Standards Code) of the Australian Food Standards Code, but not a combination of the two. However, under the provisions of the Trans-Tasman Mutual Recognition Arrangement, food may **also** be imported into Australia from New Zealand provided it complies with the New Zealand Food Regulations 1984.

- **Food manufactured in Australia and sold in Australia** must comply with Volume 1 (known as Australian Food Standards Code) or Volume 2 (known as Australia New Zealand Food Standards Code) of the Australian Food Standards Code but not a combination of the two. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the New Zealand Food Regulations 1984.
In addition to the above, all food sold in New Zealand must comply with the New Zealand *Fair Trading Act 1986* and all food sold in Australia must comply with the Australian *Trade Practices Act 1974*, and the respective Australian State and Territory *Fair Trading Acts*.

Any person or organisation may apply to ANZFA to have the *Food Standards Code* amended. In addition, ANZFA may develop proposals to amend the Australian *Food Standards Code* or to develop joint Australia New Zealand food standards. ANZFA can provide advice on the requirements for applications to amend the *Food Standards Code*.

ANZFA has the following objectives (in descending order of priority) in developing food regulatory measures:

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

ANZFA must have regard to the following factors when developing food regulatory measures:

- 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; and
- the promotion of fair trading in food.
ATTACHMENT 2 - Regulations for Listeria monocytogenes

New Zealand

New Zealand criteria for L. monocytogenes in food are contained in the Microbiological Reference Criteria for Food (Ministry of Health, October 1995). These criteria apply until the end of the stated shelf-life of the food. These criteria are not part of New Zealand law, but are to be used where no standard exists in law for monitoring purposes, or as supplements to existing standards where public health concerns dictate.

The “General microbiological reference criteria for L. monocytogenes” require that all ready-to-eat foods and those that undergo a listericidal step meet a zero tolerance (absence in five samples of 25g). Foods exempt from this requirement include:

• raw fruits, vegetables, meats and seafoods;
• foods produced in accordance with Good Manufacturing Practice (GMP) that will not support the growth of L. monocytogenes;
  o pH <4.6 or >9.0, and/or
  o aw <0.9, and/or
  o are stored or displayed below 1°C; and
• foods recommended for consumption within four days of manufacture and clearly labelled as such, provided they are produced in accordance with GMP.

The zero tolerance applies to ready-to-eat foods and foods that are given a mild (ie non-listericidal) heat treatment before consumption, such as:

• cooked meals;
• cooked meats and their products;
• cooked seafoods and their products;
• seafood products that are likely to be consumed in that state, such as cold smoked salmon, smoked mussels;
• prepared desserts and bakery products containing cream or other fillings of high water activity; and
• dairy products including soft cheeses.

Australia

In Australia, the Food Standards Code contains a few food categories that require a zero tolerance. These foods include meat paste and pâté, smoked fish products, marinated smoked mussels and cheeses with a moisture content equal to or greater than 40% and a pH greater than or equal to 5.0.

These regulations apply only at the end of the production process or at the wholesale retail stage. In addition guidelines have been drafted to assist with recall procedures for packaged ready-to-eat foods found to contain L. monocytogenes at point of sale. This allows for low levels of Listeria (<100) in foods that have not been implicated in human listeriosis and are not capable of supporting the growth of L. monocytogenes (ANZFA, in press).
Joint Australia New Zealand Food Standards Code

The joint Australia New Zealand Food Standards Code microbiological standards for Listeria apply to foods sampled at any point during their stated shelf life. Zero tolerance applies to butter made from unpasteurised milk, soft and semi-soft cheeses, all raw milk cheeses, unpasteurised milk, packaged cooked cured/salted meat and heat treated paste and pâté, cooked crustacea and processed molluscs. For processed ready-to-eat finfish a level of up to 100 in one of 5 samples applies.

The microbiological risk assessment for processed finfish completed during the review of food standards recommended that low levels of Listeria should be permitted in processed finfish (smoked salmon being the key food in this category), as this type of product does not always receive a listericidal treatment during processing. However, some concerns have been expressed about the ability of the standard to provide the required level of protection for public health, since it may be possible under some packaging regimes that growth of Listeria could occur during storage prior to consumption.
**FAO / WHO, Codex**

The Food and Agriculture Organization of the United Nations (FAO) and the World Health Organisation (WHO) convened an Expert Consultation on Risk Assessment of Microbiological Hazards in foods in July 2000, with an aim of developing an international strategy and identified mechanisms required to support risk assessment of microbiological hazards in foods (FAO/WHO 2000).

The Codex committee on Food Hygiene is currently developing a document entitled “Guidelines for the control of *Listeria monocytogenes* in foods”. The draft document suggests that the most effective means of controlling *L. monocytogenes* in foods is through the implementation of HACCP principles. It also suggests that the management for preventing contamination and/or introduction of *L. monocytogenes* should start at primary production level, and be carried on throughout food processing and distribution. The role of consumer education is also discussed (Codex Committee on Food Hygiene 2000).

**United States of America**

The United States of America has established a zero tolerance for *L. monocytogenes* in ready-to-eat foods. The United States Food and Drug Administration has recently completed draft risk assessments for a variety of selected ready-to-eat foods (US FDA 2001). This concluded that new risk management options for the following food categories should be considered. What these risk management options should be was not discussed.

- Pâté and meat spreads
- Fresh soft cheese, such as queso fresco (particularly those made with unpasteurised milk)
- Smoked seafood
- Deli meats
- Deli salads
- Unpasteurised fluid milk.

Furthermore, the draft report concluded that information on the following food categories is not sufficient to allow a thorough assessment:

- Preserved fish
- Dry/semi dry fermented sausages
- Cooked ready-to-eat crustaceans
- Miscellaneous dairy products
- Vegetables

**Canada**

Canada has implemented a three-tiered system to regulate *L. monocytogenes* in ready-to-eat foods (Health Canada 1994).

Foods in Category 1 have been linked to outbreaks of listeriosis, and therefore are regarded as high risk ready-to-eat foods. This includes soft cheese, liver pâté, coleslaw mix with a shelf-life >10 days, and jellied pork tongue. A zero tolerance (absence in 50g) applies to foods in this category.
Foods in Category 2 are all other ready-to-eat foods that support the growth of *L. monocytogenes* with a refrigerated shelf-life of >10 days. A zero tolerance (absence in 25g) applies to foods in this category.

Foods in Category 3 are ready-to-eat foods that support the growth of *L. monocytogenes* but have a shelf-life of <10 days, and all other ready-to-eat foods that do not support the growth of *L. monocytogenes*. Foods in this category with <100cfu/g are permitted for sale, however follow-up at the plant level is required in order to reduce levels of *L. monocytogenes*. Foods in this category with >100cfu/g are not permitted for sale.

In order for ready-to-eat foods to be considered not able to support the growth of *L. monocytogenes*, they must meet the following criteria:

a) pH 5.0 – 5.5 and a_w < 0.95  
b) pH <5.0 regardless of a_w  
c) a_w ≤0.92 regardless of pH  
d) frozen foods

**European Union**

The European Union has established a zero tolerance for *L. monocytogenes* in soft cheese and pasteurised milk (absence in 25g), and for all other dairy products (absence in 1g). Currently, there are no other regulations for *L. monocytogenes* in foods in the European Union (European Commission 1999).

The European Commission released a consultation paper, prepared by the Scientific Committee on Veterinary Measures Relating to Public Health, on *L. monocytogenes* in ready-to-eat foods in September 1999. This paper concludes that the presence of *L. monocytogenes* in foods at <100cfu/g presents a low risk for all population groups. The paper also suggests three factors that might result in an increased incidence of listeriosis in the future:

- the increasing proportion of susceptible people be it due to old age or immunosuppressive treatments and/or diseases;  
- the increased use of cold storage to prolong the shelf-life of foods;  
- the possible emergence of non-classical listeriosis, such as *L. monocytogenes* food poisoning resulting in diarrhoea.

The European Commission is now conducting a risk assessment on *L. monocytogenes* in ready-to-eat foods
ATTACHMENT 3 - Codex General Principles for Conducting Microbiological Risk Assessment

1. Microbiological Risk Assessment should be soundly based on science.

2. There should be a functional separation between Risk Assessment and Risk Management.

3. Microbiological Risk Assessment should be conducted according to a structured approach that includes Hazard Identification, Hazard Characterization, Exposure Assessment, and Risk Characterization.

4. A Microbiological Risk Assessment should clearly state the purpose of the exercise, including the form of Risk Estimate that will be the output.

5. The conduct of a Microbiological Risk Assessment should be transparent.

6. Any constraints that impact on the Risk Assessment such as cost, resources or time, should be identified and their possible consequences described.

7. The Risk Estimate should contain a description of uncertainty and where the uncertainty arose during the Risk Assessment process.

8. Data should be such that uncertainty in the Risk Estimate can be determined; data and data collection systems should, as far as possible, be of sufficient quality and precision that uncertainty in the Risk Assessment is minimized.

9. A Microbiological Risk Assessment should explicitly consider the dynamics of microbiological growth, survival, and death in foods and the complexity of the

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**iii** Risk Assessment – a scientifically based process consisting of the following steps:

(i) Hazard identification (the identification of biological, chemical, and physical agents capable of causing adverse health effects and which may be present in a particular food or groups of foods);

(ii) Hazard characterization (the qualitative and/or quantitative evaluation of the nature of the health effects associated with the hazard. For the purposes of Microbiological Risk Assessment, the concerns relate to microorganisms and/or their toxins. Dose-response is an important aspect of hazard characterization. For chemical agents, a dose-response assessment should be performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable);

(iii) Exposure assessment (the qualitative and/or quantitative evaluation of the likely intake of biological, chemical, and physical agents via food as well as exposures from other sources if relevant); and

(iv) Risk characterization (the process of determining the qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse effects in a given population based on Hazard Identification, Hazard Characterization and Exposure Assessment).

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**iv** Risk management is separate from Risk Assessment and is defined as the process of weighing policy alternatives in the light of the results of Risk Assessment, and if required, selecting and implementing appropriate control options (prevention, eliminating, or reduction of hazards and/or minimization of risks), including regulatory measures.

**v** Risk Estimate – output of Risk Characterization.
interaction (including sequelae) between human and agent following consumption as well as the potential for further spread.

10. Wherever possible, Risk Estimates should be reassessed over time by comparison with independent human illness data.

11. A Microbiological Risk Assessment may need re-evaluation, as new relevant information becomes available.

(Codex Alimentarius Commission 1999)
## ATTACHMENT 4 - Outbreaks of Foodborne Listeriosis

<table>
<thead>
<tr>
<th>Year</th>
<th>Number of cases</th>
<th>No. of deaths</th>
<th>Country</th>
<th>Possible vehicle of infection</th>
<th>Reference</th>
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<td>~100</td>
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<td>Possible vehicle of infection</td>
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*vi Predominantly gastrointestinal illness
<table>
<thead>
<tr>
<th>Year</th>
<th>Number of cases</th>
<th>No. of deaths</th>
<th>Country</th>
<th>Possible vehicle of infection</th>
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<td>Hot dogs</td>
<td>Graves et al 2001</td>
</tr>
<tr>
<td>1999</td>
<td>11</td>
<td>2</td>
<td>USA</td>
<td>Pâté</td>
<td>US FDA 2001</td>
</tr>
<tr>
<td>1999-2000</td>
<td>10</td>
<td>4</td>
<td>Finland</td>
<td>[Vacuum packaged fish]</td>
<td>Lyytikainen&lt;sup&gt;b&lt;/sup&gt; et al 2000</td>
</tr>
<tr>
<td>1999-2000</td>
<td>26</td>
<td>7</td>
<td>France</td>
<td>Pig tongue is aspic</td>
<td>Dorozynski 2000</td>
</tr>
<tr>
<td>2000</td>
<td>39</td>
<td>1</td>
<td>New Zealand</td>
<td>Sliced corned beef</td>
<td>Anon&lt;sup&gt;b&lt;/sup&gt; 2000</td>
</tr>
<tr>
<td>2000</td>
<td>26</td>
<td>7</td>
<td>France</td>
<td>Jellied pork tongue</td>
<td>Anon&lt;sup&gt;c&lt;/sup&gt; 2000</td>
</tr>
<tr>
<td>2000</td>
<td>29</td>
<td>7</td>
<td>USA</td>
<td>Turkey meat</td>
<td>Hurd et al 2000</td>
</tr>
<tr>
<td>2000-2001</td>
<td>12</td>
<td>5</td>
<td>USA</td>
<td>Mexican-style (soft) cheese</td>
<td>Boggs et al 2001</td>
</tr>
</tbody>
</table>

Adapted and updated from Rysera 1999

Foods listed in brackets [ ] in the column “Possible vehicle of infections” have not been conclusively shown to be the cause of the infection.
**ATTACHMENT 5 - Definition of diagnoses and syndromes associated with *Listeria monocytogenes***

Bacteraemia - Presence of bacteria in the blood stream.

Cholecystitis - Inflammation of the gall bladder.

Conjunctivitis - Infection of the conjunctiva

Cutaneous infections [in animal workers] – skin infection

Diarrhoea – abnormally frequent discharge from the bowels

Endocarditis - Infection of the valves in the heart

Endophthalmitis - Infection inside the eyeball

Granulomatosis infantiseptica - a form of infection in the newborn which is characterised by widespread abscesses

Hepatitis - Inflammation of the liver

Liver abscess – abscess of the liver

Meningitis - Infection of the membranes which surround the brain

Meningoencephalitis - Infection of the brain and its surrounding membranes

Mild, febrile gastroenteritis - Gastroenteritis means infection of the bowel

Oculoglandular listeriosis - an infection involving the eyes and lymph glands

Osteomyelitis - Infection in a bone

Pneumonia - Lung infection

Pneumonic listeriosis - Lung infection with listeria

Pyrexia - Fever

Septic arthritis - Infection within a joint

Septicaemia - Infection within the blood stream

Spontaneous abortion - Miscarriage

Spontaneous bacterial peritonitis - Infection within the abdominal cavity