RISK PROFILE:
LISTERIA MONOCYTOGENES
IN ICE CREAM

Prepared as part of a New Zealand Food Safety Authority
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by

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RISK PROFILE: *LISTERIA MONOCYTOGENES* IN ICE CREAM

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EXECUTIVE SUMMARY

The purpose of a Risk Profile is to provide contextual and background information relevant to a food/hazard combination so that risk managers can make decisions and, if necessary, take further action. Risk Profiles include elements of a qualitative risk assessment, as well as providing information relevant to risk management. Risk profiling may result in a range of activities e.g. immediate risk management action, a decision to conduct a quantitative risk assessment, or a programme to gather more data. Risk Profiles also provide information for ranking of food safety issues.

The food/hazard combination addressed by this Risk Profile is *Listeria monocytogenes* in ice cream. This document represents an update on the Risk Profile completed in 2003.

The NZFSA commissioned this Risk Profile to address the following risk management question:

- This food/hazard combination has been removed from the high risk list for imported foods. Is there any recent evidence that this status should not continue?

The rate of reported invasive listeriosis in New Zealand is similar to that found in other developed countries. However, there is no epidemiological or surveillance evidence to link cases of *L. monocytogenes* infection in New Zealand with ice cream. Data on the prevalence of *L. monocytogenes* in ice cream from limited testing of imports and local samples by ESR, as well as end product testing by some manufacturers, indicate that contamination rates are very low. This is consistent with findings from other developed countries.

There are no data to suggest that *L. monocytogenes* in ice cream in New Zealand currently represents a significant risk to human health. Other potential food vehicles, which support the growth of the organism, represent a more important potential route of exposure.

Although there are no human illness data indicating problems, soft serve ice cream is a product with greater potential for *L. monocytogenes* growth between preparation and consumption, since the mix is stored at refrigeration temperatures and only aged and frozen at the retail point of sale.

Within the context of a Hazard Analysis Critical Control Point (HACCP) based Risk Management Programme (or Food Safety Programme) that controls pasteurisation and ingredients added after pasteurisation, ice cream can be considered a low risk product. Bacteria will not grow in properly stored frozen ice cream.

1 STATEMENT OF PURPOSE

The purpose of a Risk Profile is to provide contextual and background information relevant to a food/hazard combination so that risk managers can make decisions and, if necessary, take further action. Risk Profiles are part of the Risk Management Framework (http://www.nzfsa.govt.nz/about-us/risk-management-framework/index.htm) approach taken by the New Zealand Food Safety Authority (NZFSA). The Framework consists of a four step process, as shown in Figure 1.

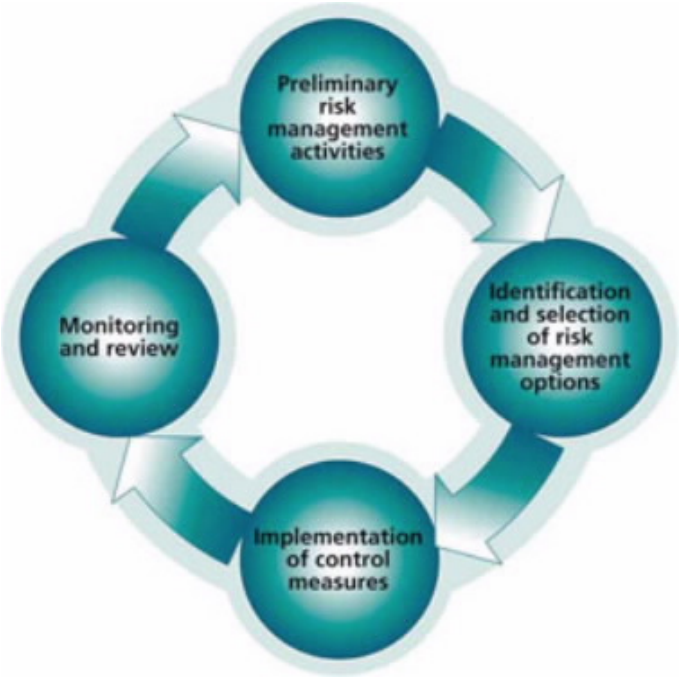


Figure 1: The four steps of the Risk Management Framework

This initial step in the RMF, Preliminary Risk Management Activities, includes a number of tasks:

- Identification of food safety issues
- Risk profiling
- Establishing broad risk management goals
- Deciding on the need for a risk assessment
- If needed, setting risk assessment policy and commissioning of the risk assessment
- Considering the results of the risk assessment
- Ranking and prioritisation of the food safety issue for risk management action.

Risk profiling may be used directly by risk managers to guide identification and selection of risk management options, for example where:

- Rapid action is needed
- There is sufficient scientific information for action
- Embarking on a risk assessment is impractical.

1.1 Food/hazard Combination and Risk Management Questions

NZFSA has recognised *Listeria monocytogenes* as one of the three most important foodborne pathogens in New Zealand and have developed a *Listeria monocytogenes* Risk Management Strategy (NZFSA, 2009). A number of risk profiles have been commissioned as part of the preliminary risk evaluation activities underpinning this strategy.

The food/hazard combination addressed by this Risk Profile is *Listeria monocytogenes* in ice cream. This document represents an update of the Risk Profile completed in 2003 (Lake *et al.*, 2003).

NZFSA commissioned this Risk Profile to address the following risk management question:

- This food/hazard combination has been removed from the high risk list for imported foods. Is there any recent evidence that this status should not continue?

2 HAZARD AND FOOD

2.1 *Listeria monocytogenes*

The information contained in this Risk Profile is current to the date of publication. Please be aware that new information on the subject may have become available since the document was finalised.

The following information is taken from a number of sources but, unless otherwise referenced, is derived from a data sheet prepared by ESR under a contract for the Ministry of Health in 2000-2001. The data sheets are located on the NZFSA website and are intended for use by regional public health units. The datasheets will be updated from time to time, and placed on this website: http://www.nzfsa.govt.nz/science/data-sheets/index.htm.

Six species of *Listeria* bacteria have been recognised (ICMSF, 1996). Two are considered non-pathogenic, while *L. seeligeri*, *L. ivanovi*, and *L. welshimeri* rarely cause human infection. *L. monocytogenes* is the most important species with respect to human health.

Two forms of disease caused by this organism are now recognised: a serious invasive disease and a non-invasive gastroenteritis (see Sections 4.1 and 4.2). While the invasive form of disease is uncommon, the clinical consequences are often serious. The organism's ability to grow at refrigeration temperatures is a significant factor, as chilling is often used as a control measure in the food industry.

Note that in the following text the term "D" is used. In microbiological terms "D" refers to a 90% (or decimal or 1 log cycle) reduction in the number of organisms.

2.1.1 Growth and survival

Growth:

Temperature: Optimum 37°C, range -1.5 to 45°C. Grows at refrigeration temperatures (4°C).

pH: Optimum 7.0, range 4.4-9.4.

Atmosphere: Grows optimally under microaerophilic conditions, but grows well both aerobically and anaerobically. Can grow in relatively high (e.g. 30%) CO_2, but is inhibited under 100% CO_2. Growth was not retarded by a 5-10% CO_2 atmosphere.

Water activity: Minimum a_w permitting growth = 0.92 (≡11.5 % NaCl).

Survival:

Temperature: Survives freezing very well.

Atmosphere: Not influenced by atmosphere.

2.1.2 Inactivation (CCPs and Hurdles)

Temperature: Rapidly inactivated at temperatures above 70°C. D time at 50°C can be in the order of hours, at 60°C 5-10 minutes, 70°C approximately 10 seconds.

pH: Inactivated at pH values less than 4.4 at rates depending on the acidulant and temperature. Organic acids, such as acetic, are more effective than mineral acids (e.g. hydrochloric). Inactivation proceeds faster at higher temperatures.

Water activity (a_w): Can remain viable in dry environments for long periods.

Preservatives: Inactivated on vegetables by lysozyme (100 mg/kg), 0.2% sodium benzoate at pH 5, 0.25-0.3% sodium propionate (pH 5, and less effective at lower temperatures), and 0.2-0.3% potassium sorbate (pH 5.0).

Radiation: D values depend on the food and temperature and range from 0.34 to 2 kGy. In ice cream exposed at –72°C, a D value of 0.38 kGy was noted, and a dose of 1 kGy for ice cream recommended (Kamat *et al.*, 2000). *L. monocytogenes* is more sensitive than other Gram positive bacteria to UV radiation.

2.1.3 Sources

Human: *L. monocytogenes* is carried asymptomatically in the faeces of 2-6% of the population. Person-to-person spread (other than mother to foetus) is not often recorded but has been recognised. Up to 30% of case contacts may carry the organism. *L. monocytogenes* is shed in high numbers ($\geq 10^4$/g) in the faeces of infected people.

Animal: Can cause disease in animals. Veterinarians were originally considered to be an at risk group, but the World Health Organization have stated that animals are not considered to be important as direct sources of human infection. Occasional incidents of cutaneous infection in livestock handlers have been reported. *Listeria* spp. present in animal faeces can contaminate milk or red meat. Improperly made silage can be a source of domestic animal infection.

Food: Should be considered as potentially present in all raw foods and ingredients. May be present in cooked foods as a result of post-cooking contamination. Risk posed is likely to be greatest in ready-to-eat cooked foods with long shelf lives on which *L. monocytogenes* can grow. Has been isolated from a wide variety of ready-to-eat and raw foods in New Zealand studies. Little information regarding numbers exists, but is generally considered to be present in low numbers (<10/g) on most foods, although it has been detected at numbers far in excess of this.

Environment: Is widespread in the environment including soil, vegetation, water and sewage. Has been isolated from toothbrushes and other domestic environments.

Transmission routes: One study estimates that one third of cases are foodborne. Other reports describe foodborne transmission as the primary source of human infections. Alternative routes include infections acquired in hospital and occupational exposure.

2.2 Ice Cream

The foods covered by this Risk Profile are those referred to in the New Zealand Ice Cream Manufacturers' Code of Practice i.e. ice cream, as defined by the Australia New Zealand Food Standards Code, and frozen dessert systems, which include: gelato and sorbet, water ices, frozen yoghurts, milk ices, ice confections, and soft serve wet mixes with frozen step.

In the Australia New Zealand Food Standards Code, Standard 2.5.6 Ice cream states:

> "ice cream means a sweet frozen food made from cream or milk products or both, and other foods, and is generally aerated."

In terms of composition:

> "Ice cream must contain no less than –
> (a) 100 g/kg of milk fat; and
> (b) 168 g/litre of food solids."

2.2.1 The food supply in New Zealand

2.2.1.1 Production

According to the New Zealand Ice Cream Manufacturers' Association (NZICMA) website (http://www.nzicecream.org.nz/industryfacts.htm, accessed 30 October 2008) New Zealand production of ice cream and related products is 90 million litres per annum by volume.

New Zealanders are amongst the highest per capita consumers of ice cream in the world, lying either 2nd or 3rd (with Australia), behind the USA. New Zealand per capita consumption of ice cream and related products was 22-23 litres per annum as at 31 Dec 2006. In the year to March 2007, approximately 11,900 tonnes (approximately 23.6 million litres) of this production was exported, approximately half of which went to Japan and Korea.

2.2.1.2 Imported foods

New Zealand is both a significant exporter and importer of ice cream. According to the NZICMA website (http://www.nzicecream.org.nz/industryfacts.htm, accessed 30 October 2008) for the year to 31st March 2007 2,800 tonnes of icecream was imported, principally from Australia (1,900 tonnes) and the People's Republic of China (440 tonnes).

Import statistics obtained from Statistics New Zealand showed a significant increase in ice cream imports, from approximately 3,000 tonnes in the year ending September 2007 to more than 4,000 tonnes in the year ending September 2008. This increase included increased quantities from both Australia (2,800 tonnes) and China (670 tonnes). Significant quantities of ice cream were also imported from Korea (180 tonnes), Germany (120 tonnes) and Chile (100 tonnes) (data from custom data sets supplied annually by Statistics New Zealand).

The period 2001-2008 has seen a general increase in the quantity of ice cream imported into New Zealand, from 2,900 tonnes to more than 4,000 tonnes. This period has seen the emergence of China as a supplier of ice cream.

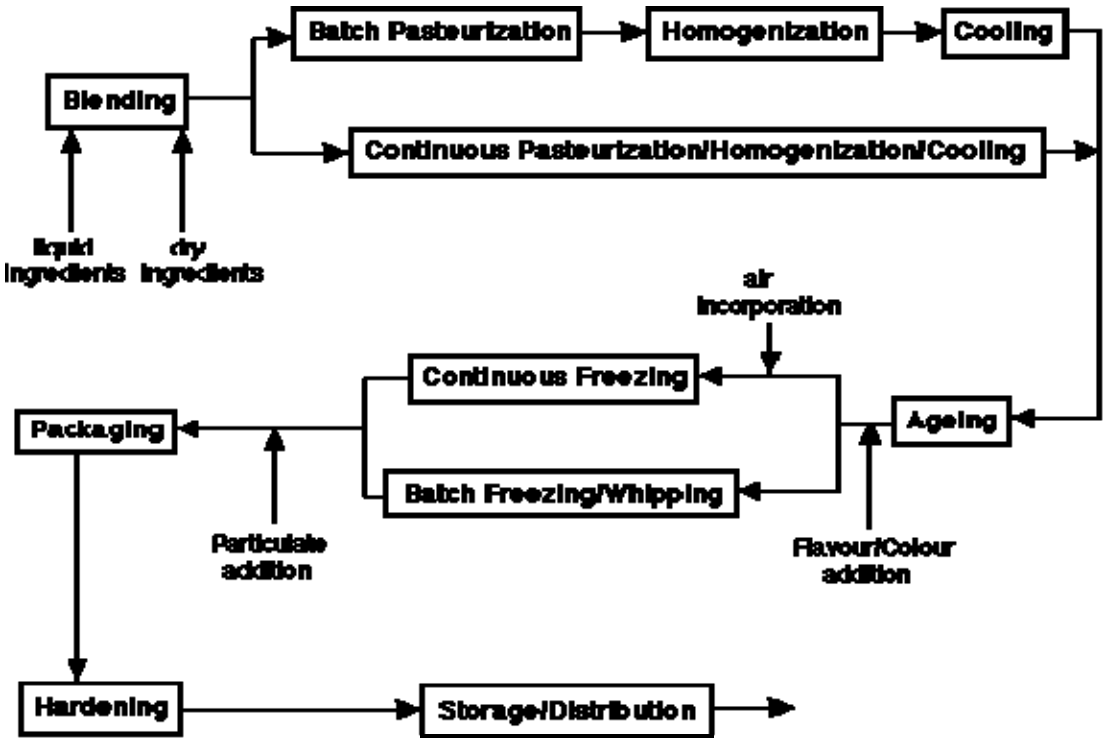
In 2003, when this Risk Profile was originally prepared, ice cream was a prescribed food under the New Zealand (Mandatory) Food Standard 1997 and therefore the importer was required to demonstrate the safety of the product, which may have required testing for the absence of pathogenic bacteria, specifically *Salmonella* and *Listeria*.

In September 2006, following a review by NZFSA, ice cream was removed from the list of prescribed foods.

2.2.2 Relevant characteristics of the food: Ice cream

Figure 2 shows a general schematic for the process of manufacturing ice cream.

Figure 2: Manufacturing process for ice cream – general features



Reproduced from: (Goff, 1997)
'Particulates' or 'inclusions' refers to additions such as ripples, chunks, fruit, nuts or hokey pokey

The process flow for soft serve ice cream is essentially the same as for hard ice cream, except for the exclusion of a hardening step. Soft serve ice cream mix is usually drawn from the freezer at about minus 6°C to minus 7°C. The wet mix is packed off after the initial freeze of the ice cream making process and does not undergo a hardening process (NZICMA, 2004). The wet mix is stored and transported at refrigeration temperatures. However, potential for contamination and temperature abuse occur and application of HACCP procedures may be required to control and monitor temperatures of equipment and product (NZICMA, 2004).

2.2.2.1 Ingredients

The principal components of ice cream are milk fat, non fat milk solids, sugar, and emulsifiers/stabilisers. The latter include polysaccharides to bind free water and retard ice crystal growth during freezing and storage, while emulsifiers are incorporated to stabilise fat droplets (Belitz and Grosch, 1987). In some ice creams eggs are used as a source of emulsifying agents.

The raw material from which ice cream is made, i.e. milk, should be considered a potential source of *L. monocytogenes*. Faecal contamination of milk is the most likely cause, and healthy dairy cows may shed the bacterium after being infected e.g. from silage. Dairy cattle can also intermittently shed *L. monocytogenes* in their milk as a consequence of listerial mastitis, encephalitis or a *Listeria*-related abortion, although instances of these diseases in New Zealand are rare (Lindsay Pearce, Fonterra Research Centre, pers. comm.). Although milk from obviously sick animals is unlikely to reach consumers, mildly infected or apparently healthy cows can shed *L. monocytogenes* in their milk for many months (Ryser, 1999b). Overseas testing has shown that up to approximately 10% of raw milk samples contain *L. monocytogenes* (Ryser, 1999b).

A survey of raw whole milk in New Zealand in 1986/87 found that, while none of 71 New Zealand raw milk samples tested contained *L. monocytogenes*, 14.1% contained *L. innocua* (Stone, 1987). This non-pathogenic *Listeria* species is very similar to *L. monocytogenes* and can be regarded as indicating that *L. monocytogenes* could originate from the same source. Pasteurisation of raw milk is therefore an important step in assuring the safety of ice cream.

After pasteurisation and homogenisation, ice cream and frozen novelty products may be altered with additional ingredients. These may include flavourings, ripples (syrups or other coloured liquid preparations that produce wavy lines or ripples in the finished ice cream), chocolate, fruit, nuts, confectionery etc. While these additional ingredients will generally not support microbial growth, due to their low water activity, low pH or high sugar content, microbial survival is possible.

L. monocytogenes has been isolated from a range of fruits, but fruit has not been associated with any outbreaks of listeriosis (McIntyre *et al.*, 2008). A survey in the UK isolated *L. monocytogenes* from 7.8% of 997 fresh cut fruit samples (Little and Mitchell, 2002), while a similar survey in Ireland isolated *L. monocytogenes* from 4.1% of 513 fresh cut fruits (FSAI, 2002). One sample from each of these two surveys was reported to contain *L. monocytogenes* at concentrations greater than 100 CFU/g (maximum 260 CFU/g). Incorporation of fruit in ice cream is likely to results in, at worst, a low level of contamination.

While no listeriosis outbreaks have been associated with chocolate or nuts, the organism has been isolated from commercially-produced chocolate (Kenney and Beuchat, 2004). There is less evidence for the presence of *L. monocytogenes* on nuts and nut products (Candlish *et al.*, 2001; Kenney and Beuchat, 2004). However, *L. monocytogenes* demonstrated longer survival at 60ºC in peanut butter or chocolate-peanut spread, than in whole-fat milk (Kenney and Beuchat, 2004).

While information was not found on *Listeria* contamination of sugar confectionery, this appears to be an unlikely source for introduction of the organism into the ice cream making process.

2.2.2.2 Processing

The major points of pathogen control are the pasteurisation, freezing and hardening steps, although the latter two will not reduce levels of *L. monocytogenes*. Post-pasteurisation ingredient additions may occur at two points, after ageing and after dynamic freezing. Following ageing, the mix is drawn into a flavour tank where any liquid flavours, fruit purees, or colours are added. The mix then enters the dynamic freezing process, which both freezes a portion of the water and whips air into the frozen mix. Ice cream contains a considerable quantity of air (up to half of its volume) which gives the product its characteristic lightness. As the ice cream is drawn with about half of its water frozen, particulate matter such as fruits, nuts, candy, cookies, etc., is added to the semi-frozen slurry which has a consistency similar to soft serve ice cream. Ice cream is frozen and hardened at this point whereas soft serve is drawn into packaging and is subsequently stored and transported at refrigeration temperatures.

In addition to hard and soft serve ice cream, a number of other dairy-based frozen products may be manufactured e.g. frozen yoghurts, milk ices. These include a freezing step and the same legislative requirements generally apply.

Some specific data are available concerning thermal inactivation of *L. monocytogenes* in ice cream mix (Holsinger *et al.*, 1992). In this work the concentrations of milk fat and high-fructose corn syrup (HFCS) were varied and the effect on thermal inactivation of *L. monocytogenes* measured at 60^{o}C. Thermal destruction curves were observed with lag and tailing periods complicating the calculation of D times. Instead a value of F (equivalent to the lag plus 7D) was calculated. An approximate two-fold difference was observed between the lowest (18.8 minutes) and highest (37.3 minutes) values for F, which was related to improved thermal resistance of the organism at higher HFCS contents (7%). However, it was concluded that pasteurisation guidelines for ice cream are adequate to ensure the destruction of *L. monocytogenes*.

The growth of *Listeria monocytogenes* in vanilla cream (a traditional milk-based dairy product popular in Mediterranean countries, with typical final composition of 4.6% fat, 2.9% protein, 17.8% carbohydrate and a neutral pH of 6.3-6.7) stored at refrigeration temperatures has been studied (Panagou and Nychas, 2008). Pasteurised vanilla cream was inoculated with a five strain cocktail of *L. monocytogenes* (10^2 $\log_{10}$ CFU/g) and stored at 3, 5, 10 or 15°C for 36 days. At 3 and 5°C, the lag phase exceeded 100 hours, after which there was rapid growth (maximum specific growth rates of 0.027 and 0.038 log CFU/hour at 3 and 5ºC respectively). At 10 and 15°C growth was almost immediate and rapid (maximum specific growth rates of 0.074 and 0.139 log CFU/hour at 10 and 15ºC respectively). The experimental data were fitted to growth models and, while vanilla cream is not a frozen product, these models may be useful in predicting growth in ice cream in the event of a temporary period of non-frozen storage. This may be particularly relevant for assessing the potential for *L. monocytogenes* growth in soft serve ice cream mixes, stored at refrigeration temperatures. It should be noted that the formulation of vanilla cream differs significantly from ice cream in the inclusion of a significant proportion of starch from tapioca, wheat or

corn (Panagou and Nychas, 2008).

2.2.2.3 Storage and distribution

In normal circumstances ice cream is stored and sold in the frozen state. While *L. monocytogenes* is known to grow at temperatures below 0°C, no growth should occur at the temperatures at which ice cream is normally stored (Dean and Zottola, 1996). However, any *Listeria* present as a result of post-pasteurisation contamination are likely to survive freezing. One study has shown that essentially 100% viable cells of *L. monocytogenes* could be recovered from ice cream after 14 weeks of storage at -18°C (Palumbo and Williams, 1991). The pH of ice cream is close to neutral (Nichols and de Louvois, 1995) and so provides no barrier to the growth of *L. monocytogenes*.

A more recent study has examined the kinetic behaviour of *L. monocytogenes* in icecream stored under static and dynamic chilling and freezing conditions (Gougouli *et al.*, 2008). The organism grew well at all static chilled temperatures (4, 8, 12, 16 °C). At static freezing temperatures (-5, -15, -23, -33 °C) there was no decline in bacterial numbers up to 90 days. Under simulated temperature abuse conditions fluctuating between chilled and freezing temperatures there was steady growth during the periods of chill temperature. The results showed that the pathogen was able to initiate growth after a temperature upshift from freezing to chilling temperatures within a very short time (12 hours or less). This indicated that freezing did not cause a significant additional lag phase.

For soft serve ice cream, pre-made ice cream mix is supplied to retail outlets under refrigeration (<5ºC). Aging and freezing are carried out in the vending machines at the retail premises. The study of Gougouli *et al*. (2008) confirms the potential for listerial growth in these products if post-pasteurisation contamination occurs.

A survey of ice cream, soft serve ice cream and milkshakes was conducted in Christchurch in 1996 (Sheat, 1996). The temperatures at which "hard scoop" ice cream samples were served were:

Temperature (°C)	No. of samples
>-4.9	0
-5.0 to -9.9	1
-10.0 to -14.9	10
-15.0 to -19.9	20
-20.0 to -25.0	9

Of the soft serve ice cream samples, fourteen were served at temperatures in the range of -5 to -9.9°C, and the other six for which data were recorded were in the range of 0 to -4.9°C (Sheat, 1996).

Data on ice cream temperatures are also available from Western Australia (Health Department of Western Australia, 1992). Recorded temperatures for dispensed soft serve ice cream were:

Temperature (°C)	No. of samples
0.1 to 4.0	1
-4.9 to 0	16

-9.9 to -5.0	87
-15.0 to -10.0	20

All hard scoop ice cream was held at <-5^{o}C.

It should be noted that soft serve ice cream is frozen at the point of sale. The mix used to make the ice cream is stored at <5^{o}C, temperatures that might allow growth of this organism.

3 EXPOSURE ASSESSMENT

3.1 The Hazard in the New Zealand Food Supply: *Listeria monocytogenes* in Ice Cream

3.1.1 Domestically-produced ice cream

No surveys of New Zealand ice cream for *L. monocytogenes* contamination have been located in the scientific literature or other extant sources.

Sporadic testing of domestic ice cream by Health Protection Officers has been carried out. However, none of the 93 tested samples on the ESR laboratory database were positive for the presence of *L. monocytogenes*. The samples were a mixture of soft-serve and hard ice creams.

The 2003 Risk Profile included results from testing conducted by ice cream manufacturers. Testing results were supplied by six ice cream manufacturers in New Zealand, in either summary form or as copies of test reports from the external laboratories conducting the testing. The manufacturers involved represented the majority of the ice cream produced in this country. The bulk of the results were from the previous three years (2000 – early 2003), while the others covered shorter periods up to early 2003. The results included both environmental and finished product testing. Testing was conducted according to either of the methods included in New Zealand Technical Manual 2 i.e. either the Section 53.1 (FDA BAM 8th edition 1995) method or the Section 53.2 (IDF) method.

Approximately 2280 test results from finished product were included in the data supplied, with no positive results for *Listeria monocytogenes* reported.

Environmental samples are taken from the manufacturing environment as swabs from sites at three different hygiene levels. The generally accepted dairy industry definitions of Pathogen Environmental Surveillance levels are:

- Level 1 - External non-critical environment, e.g. roofs, gutters, tanker bays and vehicle access ways.
- Level 2 - Internal non-critical environment, e.g. all areas inside buildings where product or product contact surfaces are not exposed to the surrounding environment on a daily or routine basis. This may be split between the clean and dirty side of the redline within a manufacturing building, e.g. Level 2a external environment, dirty side of redline) and Level 2b (internal environment, clean side of the redline).
- Level 3 - Internal critical environment, all areas where product or product contact surfaces are exposed to the surrounding environment on a daily or regular basis.

Results from 1750 environmental tests were supplied. Of these, 204 were positive for a *Listeria* species other than *L. monocytogenes* (principally *L. innocua*). Fifty-nine environmental samples were positive for *L. monocytogenes,* of which 39 were from swabs taken from Level 1 areas, 9 from Level 2 areas, and 11 from Level 3 areas.

Further data from manufacturers were not solicited for this update.

3.1.1.1 Recalls and incidents

Data concerning food recalls are posted on the NZFSA website: (http://www.nzfsa.govt.nz/recalls/consumers.htm). From 2001 – 2008 two recalls involved ice cream: both were for foreign material, not microbiological contamination.

In some cases *L. monocytogenes* is detected in ice cream prior to the product reaching the market. This usually results in destruction of the affected product. One such incident occurred during the period 2000-2008 (Shona Scott, NZFSA, pers. comm.; Alisa Bradley, NZFSA, pers. comm.). However, four notifications have been received by NZFSA during the 2009 year (Kathleen Shaw, NZFSA, pers. comm.).

3.1.2 Imported ice cream

The ESR laboratory database contains monitoring information from 1997 to 2000 for approximately 80 imported shipments of ice cream and related frozen confectionery products (no samples have been received by ESR for testing since that time). Ice cream products were principally from Italy, Sweden and the United Kingdom. Of these, only one, an ice cream confectionery bar from Sweden, was found to be positive for the presence of *L. monocytogenes* (serotype 1/2).

From 2001 to 2002 approximately 100 consignments of ice cream were imported into New Zealand. The majority of these consignments (77) were from Australia and enter New Zealand without a requirement for pathogen testing. All consignments from Thailand, Malaysia, Korea and Switzerland received during this period (16 consignments) were tested for *L. monocytogenes* – all tested negative. Consignments from the Netherlands, France, Denmark and Japan were not tested for pathogens at importation.

From the end of 2002 to 2006, 15 consignments of imported ice cream were tested, all from Korea or Malaysia. All were negative for *L. monocytogenes*. As noted above, as of September 2006, imported ice cream was removed from the prescribed list, and so is no longer subject to testing at the time of importation.

3.2 Food Consumption: Ice cream

The following information is taken from the New Zealand National Nutrition Survey (NNS) conducted in 1997 (Russell *et al.*, 1999) and the 2002 Children's National Nutrition Survey (CNS) (Ministry of Health, 2003).

3.2.1 Proportion of population consuming ice cream

For the adult New Zealand population, 14.4% of survey respondents reported consuming ice cream in the previous 24-hour period. Of approximately 700 servings of ice cream reported in the NNS, only 18 (2.5%) were described as 'cream freeze/soft serve'. Using data from the qualitative food frequency questionnaire (QFFQ), administered as part of the NNS, a slightly higher estimate of 15.6% of respondents consuming ice cream on any given day is obtained. However, 7% of respondents reported 'never' eating ice cream, while a further 28% reporting consuming ice cream less often than once per month. The QFFQ made no distinction between hard and soft serve ice cream.

Those aged over 65 years of age are approximately as likely (13.8%) to consume ice cream in any given 24 hour period than those aged under 65 years of age (14.5%).

Children aged 5-15 years are more frequent consumers of ice cream, with 24.4% of respondents in the 2002 CNS reporting consumption of ice cream in the previous 24-hour period (the survey was conducted over 12 months and so is not subject to seasonal fluctuation). Of approximately 680 servings described, 27 (3.9%) were described as soft serve. The qualitative food frequency questionnaire (QFFQ), administered as part of the CNS suggests a similar frequency of ice cream consumption of approximately 27.3% consuming on any day.

These figures are similar to those observed in the 1995 Australian NNS (Australian Bureau of Statistics, 1999), which reported 15.4-23.0% of respondents consuming frozen milk products, depending on the age group. The pattern of respondents with respect to age is similar to that seen in Australia, with the younger age groups more commonly consuming ice cream.

3.2.2 Mean daily consumption of ice cream

Analysis of data from the 1997 NNS gave a mean daily intake for consumers of ice cream of 99.1 g/person/day and a mean across the whole study population (consumers and non-consumers) of 14.2 g/person/day. The corresponding data for the child population (5-15 years) gave a mean daily consumption for consumers only of 128.9 g/person/day and for all respondents of 31.4 g/person/day. This confirms that children not only eat ice cream more frequently, but eat more ice cream on a consumption day than adults.

The mean amounts of ice cream eaten by persons in New Zealand (total population, not just consumers) are very similar to those reported for the Australian NNS (Australian Bureau of Statistics, 1999). The Australian study reported an overall mean (males and females) for respondents aged 19 and over of 17.6 g/day, compared to 14.2 g/day from the New Zealand NNS (1997).

These figures are consistent with those for the simulated typical diets formulated for the 2003/04 New Zealand Total Diet Survey (Vannoort and Thomson, 2005), which used an average daily intake of ice cream for adult males of 16 g/day, adult females of 10 g/day, 1-14 year male of 34 g/day, 11-14 year female of 26 g/day and 5-6 year child of 26 g/day.

Data from the Australian NNS suggest even higher levels of ice cream consumption by children, with the 12-15 year age group age group consuming the highest daily amount (58.8 g/day of frozen milk products) (Australian Bureau of Statistics, 1999).

The estimate for adult New Zealand mean consumption of ice cream of 14.2 g/day is slightly lower than that for the US population for whom a per capita daily consumption of 20.3 g/day was reported (EPA (US Environmental Protection Agency), 1997).

3.2.3 Serving sizes for ice cream consumption

Analysis of data from the 1997 NNS gave mean, median and 95th percentile serving sizes for ice cream of 92.8, 73.0 and 245.6 g. Child servings, as reported in the 2002 CNS are generally higher, with corresponding values of 112.8, 100.0 and 234.0 g.

Based on import statistics for the year ending September 2008 (see Section 2.2.1.2), the per capita consumption of imported ice cream would be approximately 2.8 g/day.

3.3 Overseas Context

Information from the scientific literature on the prevalence of *L. monocytogenes* in ice cream overseas has been summarised in Appendix 1. Overall, the prevalence is low (often less than one percent of samples). However, the result from the National Food Authority (the predecessor organisation of FSANZ) in Australia is anomalous. The large number of samples with <1/ *L. monocytogenes*/g results may arise from the "Most Probable Number" method used, and may actually include 0 CFU/g, but nevertheless these results show an unusually high proportion of samples containing 1-10 CFU/g and 11-100 CFU/g.

Very few reports were found in the literature to supplement the summary prepared for the previous version of this Risk Profile. Those that were found (Abrahão *et al.*, 2008; Busani *et al.*, 2005; Chen *et al.*, 2009; Moharram *et al.*, 2007) supported the conclusion that overall the prevalence in branded retail products is very low (aggregate prevalence 16/2610 or 0.61%; 95th percentile confidence interval 0.35-0.99%).

The study of Chen *et al*. (2009) is of interest given the recent increase in imports of ice cream to New Zealand from China. The prevalence of *Listeria* spp. found (1.4%) is low, but not as low as generally observed in Europe and North America (less than 1%). Of *Listeria* isolates recovered from ice cream, 75% were *L. monocytogenes* and 25% *L. welshimeri.*

The survey from Belgium (De Reu *et al.*, 2004), examined raw milk and a range of derived dairy products. Although a small survey, (143 samples of raw milk, 100 samples of raw milk products) it did indicate a higher prevalence of *Listeria monocytogenes* in such products (6.3% in raw milk, 18.7% in butter) than is usually found for pasteurised milk and products.

4 EVALUATION OF ADVERSE HEALTH EFFECTS

There are two types of disease associated with infection by *L. monocytogenes*; invasive and non-invasive.

4.1 Invasive Listeriosis

The populations most at risk from this disease are the elderly, the immunocompromised, and the perinatal. Perinatal infections occur primarily as a result of transplacental transmission of the organism to the foetus, following infection of the mother. The perinatal group includes foetuses and neonates, and infection can occur before or after birth. The symptoms experienced by the mother are usually restricted to a mild fever.

Incubation: 1-90 days, mean 30 days.

Symptoms: Include 'flu'-like symptoms (e.g. fever, headache), diarrhoea, vomiting. In perinatal cases clinical outcomes for the foetus or newborn include general septicaemia, intrauterine death, premature birth, stillbirth. In non-perinatal cases symptoms commonly include bacteraemia and meningitis.

Long term effects: In one outbreak neurological problems (cranial nerve palsies) developed in 30% of the survivors of meningitis. Pre-term infants may suffer from excess fluid in the brain and partial paralysis.

Treatment: L. monocytogenes is susceptible to a number of antibiotics, but penicillin and ampicillin optionally with an aminoglycoside (e.g. gentamicin) is considered to be the combination of choice.

4.2 Non-Invasive Febrile Gastroenteritis

The non-invasive form of listeriosis was first recognised during the 1990s. It is usually called febrile gastroenteritis i.e. gastroenteritis associated with mild 'flu-like' symptoms, and can occur in healthy people if large numbers of *L. monocytogenes* cells are consumed.

Incubation: 11 hours to 7 days, median 18 hours.

Symptoms: Diarrhoea, fever, muscle pain, headache, and less frequently with abdominal cramps and vomiting. Attack rate reported to be more than 74%.

4.3 Dose Response

It is becoming increasingly apparent that there is no threshold dose of *L. monocytogenes* for listerial infection and very low doses will carry a low, but non-zero, risk of infection, even in healthy people. The probability of invasive disease following exposure to even moderate levels of cells is very low. For example, the current dose-response model indicates that doses up to 10^6 cells will result in less than a one in a million probability of disease (see Appendix 1, Figure 3).

Dose response data for febrile gastroenteritis are limited. Outbreak data suggest that consumption of more than 10^6- 10^7 cells appears to be sufficient to cause *L. monocytogenes* febrile gastroenteritis, at a high infection rate in some circumstances.

Further data on dose-response, and the size of high risk groups in the New Zealand population are given in Appendix 1.

4.4 Adverse Health Effects in New Zealand

Listeriosis is a notifiable disease in New Zealand, and it is generally assumed that the severity of the disease means that there are no unreported cases. However, the non-invasive febrile gastroenteritis form of infection is not notifiable, and the only information on its incidence comes from an outbreak (Sim *et al.*, 2002). Consequently this section is principally concerned with invasive listeriosis.

4.4.1 Incidence

Notification and mortality data from the EpiSurv database for listeriosis for the years 1997 to 2007 are given in Table 1. It is important to note that these are total cases, rather than cases associated with any specific transmission vehicle. Perinatal refers to the period after 28 weeks of pregnancy and up to one week after birth.

Table 1: Number of reported cases of invasive listeriosis and mortality from 1997 to 2007

Year	Listeriosis cases	Rate (per 100,000)	Deaths (perinatal)	Deaths (non-perinatal)
1997	35	1.0	6	2
1998	17	0.5	0	0
1999	19	0.5	2	1
2000	22	0.6	4	2
2001	18	0.5	1	1
2002	19	0.5	3	0
2003	24	0.6	2	2
2004	26	0.7	2	3
2005	20	0.5	0	1
2006	19	0.5	1	0
2007	24	0.6	2	2

The number and rate of reported listeriosis cases has been reasonably stable over the last ten years with no apparent trend. Hospitalisation rates for notified cases are high; often 100%.

Case reports from notified cases of listeriosis from 1998-2007 were reviewed for risk factors, and suspected or confirmed food vehicles. No foods were confirmed as sources during that time, and amongst suspected foods, ice cream was not mentioned.

4.4.2 Information from Ministry of Health's suspect foodborne illness investigation programme

The Ministry of Health's Suspect Foodborne Illness Investigation Programme provides investigative analyses to Public Health Units and provides a means of collating such investigations. The programme is funded by the Ministry of Health and provided by ESR. It contains information relating particular foods to episodes of suspected foodborne illness. This may be due to the fact that it is a genuine risk factor related to the symptoms presented, or may be due to preconceptions of the person experiencing the illness or the investigating officer. If the laboratory investigation identifies a known food pathogen in the suspect food at levels sufficient to cause illness and the symptoms known to be caused as a result of infection by the organism are consistent with the case details then the food may be identified as confirmed. Less compelling evidence may be provided in cases where a known pathogen is identified in faecal specimens associated with the suspected foodborne illness episode but not from the food samples provided (in some cases food samples may not have been provided, but a food may still be suspected). In many cases a food may be implicated by the case or by the investigating officer, as a result of questioning the case. Implication of a food in a suspect food poisoning may reflect true risk factors, but may equally reflect personal bias on the part of the case or the investigating officer.

Despite suspicions of *Listeria monocytogenes* infections associated with ice cream and testing of some samples, ice cream was not confirmed as the cause of any cases investigated under the Ministry of Health programme between July 1997 and June 2008.

4.4.3 Outbreaks

Attribution of outbreaks to *L. monocytogenes* is complicated by the generally long incubation time for this organism (mean 30 days).

Outbreaks of infection with *L. monocytogenes* in New Zealand are rare. From 1997 to 2001 only three were recorded in the national surveillance system. None of these outbreaks were linked with the consumption of ice cream, although in one of these outbreaks no food vehicle was identified (Anonymous, 1998).

L. monocytogenes was not identified as the causative organism in any reported outbreaks between 2001 and 2007.

4.5 Adverse Health Effects Overseas

4.5.1 Incidence

Comparisons of listeriosis rates between countries must be made cautiously, as reporting practices may differ. However, the data in Table 2 indicate that New Zealand's rate is similar to that of other developed countries.

Table 2: Comparison of listeriosis incidence between countries

Country	Period	Rate /100,000	Reference
New Zealand	**2007**	**0.6**	**(ESR, 2008)**
Australia	2006	0.3	(OzFoodNet, 2007)
USA	2006	0.3	(FoodNet, 2008)
Europe	2006	0.3 – 1.0	(Goulet *et al.*, 2008)

4.5.2 Contributions to outbreaks and incidents

Association of listeriosis cases or outbreaks to specific foods is complicated by the relatively long incubation time (mean of 30 days for invasive listeriosis).

No published instances of *L. monocytogenes* causing outbreaks or incidents where ice cream was identified as the vehicle have been located, apart from the possible link found in the case-control study discussed below.

Despite the numerous recalls of ice cream and other frozen dairy products, particularly in the United States, the only instance of a case of listeriosis linked to consumption of ice cream occurred in Belgium. An immunocompromised 62-year-old man developed listerial meningitis after consuming commercially prepared ice cream containing 10^4 CFU/g *L. monocytogenes* serotype 4b (Ryser, 1999a). However, reference to the original paper (in French) states that the case was immunocompetent and suggests that the most likely source of the high levels of *L. monocytogenes* in the ice cream (up to 10^6/g) was from a crème fraiche topping applied to the ice cream. It is also possible that crème fraiche was mixed in with the ice cream, as judged by the fact that the fat content of the implicated container of ice cream was higher than unopened product (Andre *et al.*, 1990). This case can be regarded as a "red herring" in terms of this risk profile, but is interesting as it represented an outbreak of 12 cases who dined together at a restaurant and where 11 people reported 'flu'-like symptoms and only one was hospitalised.

4.5.3 Case-control studies

An incident in the U.S. where multiple subtypes of *Listeria monocytogenes* were associated with a number of cases is reported in the literature. A case control study was undertaken, and consumption of a range of foods, including ice cream, may have linked the cases. Salami was the favoured vehicle in this incident (Schwartz *et al.*, 1989) (Farrag and Marth, 1992).

4.6 Health Burden of Infection with *Listeria monocytogenes*

The annual health burden of invasive listeriosis for New Zealand has been estimated in terms of both Disability Adjusted Life Years (DALYs) and Cost of Illness (see: http://www.nzfsa.govt.nz/science/research-projects/FW0724_DALY_estimates_August_2007_final.pdf).

The total burden of foodborne perinatal listeriosis was 195 DALYs (95% CI 110-290) and for foodborne non-perinatal listeriosis the burden was 22 DALYs (95% CI 8 – 45). The burden of perinatal listeriosis is high due to the years of life lost due to mortality, and makes this

illness third highest in the ranking (after foodborne campylobacteriosis and norovirus infection). In addition the proportion of listeriosis cases considered to be foodborne (on the basis of an expert elicitation) was high at 85% (minimum 78%, maximum 92%).

The annual cost of foodborne perinatal listeriosis to New Zealand society was estimated to be $2.3 million (95% CI $0.7 – 4.8 million) and 0.2 million (95% CI $0.1 – 0.5 million) for non-perinatal listeriosis (Cressey and Lake, 2008). The full report is available from: http://www.nzfsa.govt.nz/science/research-projects/FW07102_COI_estimates_final.pdf.

These estimates concern listeriosis in total, not the proportion (if any) due to transmission in ice cream.

5 EVALUATION OF RISK

5.1 Risk Assessments

Two risk assessments for *L. monocytogenes* in ready-to-eat foods have been produced, one by the FDA and USDA/FSIS in January 2001 (and updated in September 2003):

http://www.foodsafety.gov/~dms/Lmr2-toc.html

and the other by FAO/WHO, published in 2004 (FAO/WHO, 2004):

http://www.fao.org/ag/agn/agns/jemra_riskassessment_listeria_en.asp

The USDA/FSIS document is a North American risk assessment. It is reasonable to assume that the hazard characterisation (dose response) would be similar in New Zealand, but the exposure assessment is particular to North America (even though data from diverse sources were used to calculate prevalence in food), so the risk characterisation will not necessarily reflect the risk to consumers in New Zealand.

Relative risks predicted for ready-to-eat food categories considered as part of the FDA/FSIS risk assessment are given in Table 5 (see Appendix 1). These risk rankings are quite consistent with results from case control studies, in giving high rankings to foods that have been identified in available studies.

Ice cream and frozen dairy products were ranked amongst the lowest of the identified risks for all three population groups (perinatal, elderly and intermediate aged).

The WHO/FAO risk assessment addressed four food examples selected to exemplify the difference between foods that do (fluid milk and cold-smoked fish) or do not (ice cream and semi-dry fermented meats) support growth of *L. monocyoigenes* during storage. An exposure assessment for ice cream was conducted using international data for prevalence and concentration, and Canadian food consumption data. The results of the comparative exercise are shown in Table 3.

Table 3: Estimated risk of listeriosis per 100,000 population and per million servings for the four selected foods.

Food	Cases of listeriosis per 100,000 consumers*	Cases of listeriosis per 1 million servings
Pasteurised milk	0.091	0.005
Ice cream	0.00012	0.000014
Cold smoked fish	0.016	0.053
Fermented meat products	0.0000055	0.0000021

* Includes susceptible populations

This assessment concluded that the risk of listeriosis was greater from consumption of foods that could support growth of *L. monocytogenes* during storage (pasteurised milk, cold smoked fish) than from foods that would not support growth during storage (ice cream, fermented meat products).

In contrast, a review of ice cream technical issues by Dairy Food Safety Victoria (Australia) (DFSV) concluded that ice cream was a high risk product (Dairy Food Safety Victoria, 2001). This classification was based on consideration of all risks associated with ice cream, not only the presence of *L. monocytogenes*, and specifically it was based on the following:

- "ice cream is responsible for more product recalls for *L. monocytogenes* than any other non fermented dairy product;
- the dose of *Salmonella* spp. required to cause food poisoning is substantially lower than for other products;
- whilst all bacteria can't grow in ice cream in the frozen state, studies have shown that pathogens may survive in ice cream for years; and,
- Ice cream has been responsible for a number of food poisoning outbreaks."

The review noted that while ice cream had frequently been recalled due to the presence of *L. monocytogenes*, it had also been involved in numerous outbreaks of salmonellosis in the US (See; http://www.cspinet.org/reports/outbreak_alert/appendix_a.htm). These outbreaks were associated with the presence of (or contamination from) shell eggs, presumably unpasteurised. It was also concluded that *Salmonella* in ice cream was able to cause disease at very low doses (as little as 25 cells), possibly due to the fat and sugar in ice cream protecting the organism from natural gastric barriers (Vought and Tatini, 1998). In contrast, only one case of listeriosis (in Belgium) has been linked to consumption of ice cream (or possibly crème fraiche – see Section 4.5.2). In this case the ice cream was contaminated with *L. monocytogenes* at a level of 10^4 cfu/g.

5.2 Estimate of Risk for New Zealand

The information summarised in this risk profile leads to the conclusion that, with respect to the transmission of *L. monocytogenes*, ice cream is a low risk food. Evidence for this conclusion comes from:

- Manufacturer testing data indicating a very low prevalence of contamination in ice cream products (see Section 3.1.1);
- Where data are available, the number of *L. monocytogenes* cells in contaminated ice cream overseas are low;
- Lack of a strong epidemiological or other link between the presence of *L. monocytogenes* in ice cream and clinical cases, either sporadic or outbreak;
- The inability of the organism to grow in frozen food. Although, it should be noted that soft serve mixes are an exception to this statement and may be held at refrigeration temperatures for extended periods, allowing potential for microbial growth;
- The very low values for R in the dose response model, even for "at risk" groups, which means that at low cell numbers the probability of infection is very low.

5.3 Description of Risks to New Zealand Consumers

5.3.1 Risks associated with ice cream

The populations most at risk from this disease are the elderly, the immunocompromised, and the perinatal. Perinatal infections occur primarily as a result of transplacental transmission to the foetus following infection of the mother. The perinatal group includes foetuses or neonates, and infection can occur before or after birth. The symptoms experienced by the mother are usually restricted to a mild fever. There is no evidence to suggest that these risk groups are any more or less likely to consume ice cream than the general population in New Zealand, although objective comparative data are only available for the elderly.

The rate of reported invasive listeriosis in New Zealand is similar to that found in other developed countries. However, there is no epidemiological or surveillance evidence to link cases of *L. monocytogenes* infection in New Zealand with ice cream. Data on the prevalence of *L. monocytogenes* in ice cream from limited testing of imports (1/111 samples positive for *Listeria*, 95th percentile confidence interval 0.02-5.0%) and local samples (0/93 positive, 95th percentile confidence interval 0.0-3.9%) by ESR, as well as end product testing by some manufacturers (0/2280 samples positive, 95th percentile confidence interval 0.0-0.2%), indicate that contamination rates are very low, which is consistent with product from other developed countries.

There are no data to suggest that *L. monocytogenes* in ice cream in New Zealand currently represents a significant risk to human health. Other food vehicles, which support the growth of the organism, represent a more important potential route of exposure.

Although there are no human illness data indicating problems, soft serve ice cream is a product with greater potential for *L. monocytogenes* growth between preparation and consumption, since the mix is stored at refrigeration temperatures and only aged and frozen at the retail point of sale.

Within the context of a HACCP-based RMP (or FSP) that controls pasteurisation and ingredients added after pasteurisation, frozen/hard ice cream can be considered a low risk product. Bacteria will not grow in properly stored frozen ice cream. The assessment by Dairy Food Safety Victoria that ice cream is a high risk product is at variance with the US FDA and WHO/FAO risks assessments, and the conclusion of this report for New Zealand, at least in terms of *L. monocytogenes*. There is potential for bacterial growth in soft serve ice cream mixes and the importance of HACCP-based controls of storage and transport, to prevent contamination and/or temperature abuse, has been identified by ice cream manufacturers.

This document is concerned with *L. monocytogenes* in ice cream, but some comment on the use of eggs by ice cream manufacturers is pertinent. Although eggs are not generally considered a source of *L. monocytogenes*, they have been a common source of *Salmonella* contamination in ice cream overseas. Although New Zealand is fortunate in that *S.* Enteritidis types which can infect eggs internally as well as externally are not endemic, eggs should still be considered a potential source of this organism. The potential for this contamination is likely to be small as most manufacturers are likely to use pasteurised egg ingredients, or conduct their own heat treatment of eggs.

5.3.2 Risks associated with other foods

Listeriosis is primarily considered a foodborne disease. Other potential routes of infection have been identified but most assessments assign the majority of cases to the foodborne route. It is likely that ready-to-eat foods contribute to foodborne listeriosis, but foods on which it cannot grow, e.g. cheddar cheese, or which have a short shelf life, e.g. pre-prepared salads, are less likely to contribute significantly to the disease burden, as the organism should not reach high numbers (FAO/WHO, 2004).

The USDA risk assessment listed as high (5 or above) relative risk of listeriosis for pâté and meat spread, delicatessen meats, fresh soft cheese, smoked seafood, cooked ready-to-eat crustaceans, deli salads. Non-reheated frankfurters were also ranked highly for relative risk in the USA. It is unlikely that this food is widely consumed in New Zealand, although saveloys and cocktail sausages may be eaten without reheating prior to consumption.

In New Zealand, an outbreak of invasive listeriosis was linked to smoked mussels, and an outbreak of non-invasive disease attributed to ham.

5.3.3 Risk assessment options

A quantitative risk assessment would be feasible for *L. monocytogenes* in ice cream, provided sufficient data on the prevalence of the organism in the product at a retail level could be obtained. However, it is difficult to see how the conclusions would be markedly different to those derived from the quantitative risk assessments conducted by the US FDA and WHO/FAO, and the lack of evidence for transmission of *L. monocytogenes* in ice cream in New Zealand argues against such an exercise.

A possible exception to this conclusion is the case of soft serve ice cream mixes, which are stored and transported at refrigeration temperatures. These products would be classified separately to hard ice cream under the FAO/WHO assessment (product able to support bacterial growth).

5.4 Data Gaps

The data gaps identified in this Risk Profile are:

- Prevalence of *L. monocytogenes* in New Zealand ice cream;
- Prevalence in soft serve ice cream mixes;
- Quantitative data on levels of *L. monocytogenes* in ice cream when contamination does occur;
- Types of products added to ice cream after pasteurisation and their potential to introduce *L. monocytogenes* contamination; and
- New Zealand ice cream industry practices with respect to the use of eggs.

6 AVAILABILITY OF CONTROL MEASURES

6.1 Risk Management Strategy

In March 2009 NZFSA released their *Listeria monocytogenes* Risk Management Strategy 2008-2013:
http://www.nzfsa.govt.nz/foodborne-illness/listeria/strategy.htm

This document states that the strategy will:

- Ensure that risk management options for the control of *L. monocytogenes* are effective and applied consistently across all food businesses;
- Take account of international developments in *L. monocytogenes* risk management through involvement in international fora and collaborations;
- Provide enhanced and effective information to all stakeholders for reducing the potential for *L. monocytogenes* contamination of food and exposure of consumers to potentially contaminated food;
- Document a process that will monitor and review progress of the strategy to meet the SOI (Statement of Intent) performance target; and
- Identify and prioritise research needed to inform and support *L. monocytogenes* risk management options applied and proposed.

The SOI performance target is "no increase in reported incidence of foodborne listeriosis after five years".

The objectives of the strategy are:

- To achieve no increase in human foodborne listeriosis cases;
- To engage with industry, other stakeholders and consumers in order to ensure that any outcomes developed are practical, feasible and cost effective;
- To effectively communicate the strategy and outcomes to all stakeholders (including consumers);
- To make well informed risk management decisions on appropriate control measures and their implementation; and
- To design and implement an ongoing monitoring and review programme to assess the effectiveness of risk management decisions.

6.2 Relevant Food Controls

In New Zealand, food safety risk management for manufacturers of dairy products depends on whether the product is intended for export or domestic sale only. The domestic market is defined as including both New Zealand and Australia.

If some or all of the ice cream is intended for export a Risk Management Programme (RMP) must be registered under the Animal Products Act 1999. If the ice cream is for domestic consumption only (i.e. New Zealand and Australia), then an RMP may not be required, and instead a Food Safety Programme (FSP) approved under the Food Act 1981 may be appropriate.

A RMP template specifically for Dairy Processors producing ice cream for domestic supply has been developed by NZFSA:
http://www.nzfsa.govt.nz/dairy/publications/cop/template-icecream/rmp-temp-for-dairy-processors-ice-cream-domestic-supply.pdf

An associated guidance document, approval statement and waiver of the requirement to provide a copy of an independent evaluation report are also available:
http://www.nzfsa.govt.nz/dairy/publications/cop/template-icecream/dairy-processors-icecream-domestic-supply.htm

The RMP also includes process control requirements for heat treatment, in line with DPC 3: Animal Products (Dairy): Approved Criteria for the Manufacturing of Dairy Material and Product:
http://www.nzfsa.govt.nz/dairy/publications/approved-criteria/dcp3/dpc3-approved-criteria-for-the-manufacturing-of-dairy-material-and-product.htm

Options for times and temperatures for pasteurisation of ice cream mix prior to freezing are:

- not less than 69°C for at least 20 minutes;
- not less than 74ºC for at least 10 minutes;
- not less than 79.5ºC for at least 15 seconds;
- not less than 85.5ºC for at least 10 seconds; or,
- an equivalent heat treatment.

These times and temperatures are greater than those for pasteurisation of raw milk for consumption as milk (e.g. the most commonly used "high temperature short term" pasteurisation for milk is 72°C for at least 15 seconds). The reason is that other ingredients of ice cream mix such as fat, sugar, emulsifiers and stabilisers, can have a protective effect on pathogenic bacteria. With respect to *L. monocytogenes*, it has been found that increased thermal resistance is associated with higher sugar (high fructose corn syrup) and stabiliser content of an ice cream mix, but not the milk fat content (Holsinger *et al.*, 1992). As noted in Section 2.1.3 the D time for *L. monocytogenes* at 70°C is approximately 10 seconds.

The RMP template also includes Product Safety Limits (PSL), one of which is that *L. monocytogenes* is ND/25g. "ND = not detected in the volume tested. Composite of samples collected throughout the production run as defined by the manufacturer's RMP."

A footnote to this limit states: "A figure of 100/g has been proposed by the Joint FAO/WHO Food Standards Programme, Codex Committee on Food Hygiene in the "Draft Guidelines for the Control of *Listeria monocytogenes* in Foods" and is obtaining increasingly wide acceptance. In the future, it maybe appropriate to adopt a PSL of 100/g in circumstances where it can be shown that growth is extremely unlikely to occur during the life of the product. However, before this occurs, NZFSA and the dairy industry will need to be convinced that the 100/g figure has become accepted by reputable food safety authorities worldwide."

Ice cream is stored and displayed for sale in a frozen state. An exception is soft serve ice cream mixes, which are stored and transported in a liquid form, at refrigeration temperatures. The New Zealand Food Regulations 1984 defined "frozen" as being at or below –18°C, while

the New Zealand Hygiene Regulations 1974 Amendment No. 4 (1983, #2) required that any food sold by retail in a frozen condition must be stored at a temperature at or below –18°C, or, if displayed for sale, at a temperature of at or below –12°C.

Some manufacturers serving only the domestic New Zealand market may have a Food Safety Programme (FSP) registered under the Food Act instead of a RMP. A checklist (http://www.nzfsa.govt.nz/processed-food-retail-sale/dairy-fsps/icecream-checklist.pdf) has been prepared which assists dairy FSP auditors to assess FSPs developed by individual businesses.

6.2.1 Ice cream manufacturing Code of Practice

The New Zealand Ice Cream Manufacturers' Association represents thirteen producers, and has developed a Code of Practice on behalf of the local ice cream industry (http://www.nzicecream.org.nz/about.htm). This Interim Code of Practice for Ice Cream is available on the NZFSA website, (http://www.nzfsa.govt.nz/animalproducts/publications/code-of-practice/copicecreamfinal.htm) and is recognised as a document providing a sound basis for the design, implementation, and operation of a FSP or RMP, for a business processing those products referred to in the code.

6.3 Legislative Environment Overseas with Respect to *Listeria monocytogenes* in Ice cream

An important issue for food manufacturers and regulators is whether there should be a zero tolerance for the presence of *L. monocytogenes* in ready-to-eat foods, or whether a low level (usually 100 CFU/g) is tolerable in certain foods where growth of the bacteria is unlikely. This section collates information on the regulatory regimes in place overseas.

6.3.1 United States of America

The United States of America has a zero tolerance for *L. monocyt*ogenes in ready-to-eat foods, which will include ice cream.

In 2008 the United States Food and Drug Administration (FDA) conducted a consultation over the background and rationale for the establishment of an enforcement policy for *L. monocytogenes* in RTE foods based on whether the food does, or does not, support growth of the organism (http://www.cfsan.fda.gov/~lrd/fr08027a.html). Ice cream is mentioned as a food for which an extrinsic factor (frozen storage) prevents growth.

6.3.2 Canada

In 2004, the Food Directorate of Health Canada published a policy on *L. monocytogenes* in ready-to-eat foods (http://www.hc-sc.gc.ca/fn-an/legislation/pol/policy_listeria_monocytogenes_politique_05-eng.php). This includes Compliance Criteria, including "Ready-to-eat foods supporting the growth of *L. monocytogenes* with refrigerated shelf-life of <10 days and all other ready-to-eat foods not supporting growth. "

Ready-to-eat foods not supporting growth of *L. monocytogenes* include the following:

- pH 5.0 – 5.5 and $a_w < 0.95$
- pH <5.0 regardless of a_w
- $a_w \leq 0.92$ regardless of pH
- frozen foods

Ice cream falls into the last category. The applicable Compliance Criteria is ≤ 100/g (depending on the GMP status).

6.3.3 European Community

The European Commission Regulation 2073/2005 outlines microbiological criteria for foodstuffs, including *L. monocytogenes* in ready-to-eat foods. The UK Food Standards Agency (FSA) has published guidance for food business operators (http://www.foodlaw.rdg.ac.uk/pdf/uk-06001-micro-criteria.pdf) in relation to this Regulation.

Both documents describe three criteria for *L. monocytogenes* as:

- Food intended for infants or for special medical purposes (absent in 25 g during its shelf life);
- Shelf life 5 days or less (*L. monocytogenes* should not exceed 100 CFU/g during its shelf life); and,
- Foodstuffs unable to support growth of *L. monocytogenes* (*L. monocytogenes* should not exceed 100 CFU/g during its shelf life).

Foodstuffs in the third category are defined as:

- pH less than or equal to 4.4
- Water activity less than or equal to 0.92
- pH less than or equal to 5.0 and water activity less than or equal to 0.94.

The EC Regulation also comments that "Other categories of products can belong to this category, subject to scientific justification". This is apparently reflected in the UK FSA guideline by a fourth category "Has growth of *Listeria monocytogenes* been taken into account when setting shelf life" for which the criterion is 100 CFU/g. This latter category may include ice cream.

6.4 Overseas Environmental Control Requirements

Reports in the literature suggest that contamination of ice cream is associated with post-pasteurisation contamination, rather than a failure of pasteurisation to remove *L. monocytogenes* from the raw ingredient (Kozak *et al.*, 1996). Although cleaning and sanitation practices can minimise the presence of *L. monocytogenes* in the manufacturing environment, complete elimination is extremely difficult (Dean and Zottola, 1996).

Following a number of outbreaks of listeriosis in the USA in the mid-1980s the FDA implemented the Dairy Safety Initiatives from 1st April 1986 to 30th September 1988 (Kozak

et al., 1996). This involved the collection of both finished product and environmental samples for *Listeria* testing, as well as plant inspections. Because of funding limitations, environmental samples were collected only when a finished product tested positive. A total of 1370 inspections were carried out and 2.7% of the plants were manufacturing products positive for *Listeria* spp. Ice cream and novelty ice cream were the products responsible for 60% of the isolations. There was a clear correlation between *Listeria* in the plant environment and in the final product.

The result of this initiative was the production of guidelines for controlling environmental contamination in dairy plants (FDA, 1988). The focus of this document was preventing post-pasteurisation contamination by *L. monocytogenes*.

A study has been performed on the sources of *L. monocytogenes* in an ice cream production plant in Finland (Miettinen *et al.*, 1999). Pulsed field gel electrophoresis (PFGE) typing and serotyping was performed on the isolates obtained. Twelve PFGE types were identified, and 63% of the isolates were of a single type. This *L. monocytogenes* type had persisted in the plant for at least seven years and was never isolated from raw materials (although the number of samples tested was not large). The source of contamination was traced to a packaging machine and, in particular, a conveyor belt. Targetted cleaning and sanitation of the equipment and other sites resulted in eradication of the strain from the plant.

If this identification of the source of contamination is typical, then the ability of pasteurisation to provide *L. monocytogenes*-free raw ingredients for ice cream manufacture is supported. The numbers which may be present in the final product should therefore be low if they are the result of cross contamination from environmental sources.

6.5 Options for Control

NZFSA's *Listeria monocytogenes* Risk Management Strategy 2008-2013 recognises that the most effective risk management control is the application of a listericidal processing step that will inactivate all *L. monocytogenes* present and that heat treatment is the most commonly used listericidal process (NZFSA, 2009). Where a listericidal treatment is not possible, the most important risk management approaches are identified as:

- Reducing the amount and opportunity for contamination of food with *L. monocytogenes*;
- Minimising the potential for microbial growth to occur in the food; and
- Communicate to at-risk consumers the need to avoid foods that have greater potential to be contaminated.

The application of Good Operating Practices (GOP) and HACCP were identified as approaches to prevent initial contamination or post-processing contamination of RTE foods (NZFSA, 2009).

Food safety risks from ice cream in New Zealand are currently managed under RMPs or FSPs developed for individual businesses.

Pasteurisation is an effective means of eliminating *L. monocytogenes* from ice cream. Consequently, provided pasteurisation practice is effective, any risk of contamination arises after that step. There are two important possible sources of *L. monocytogenes* contamination:

- Ingredients added after pasteurisation. Although the New Zealand Food Regulations require any additions to ice cream after pasteurisation to also be pasteurised (except fruit, fruit syrup, fruit juice), in practice a number of added ingredients, particularly to novelty products, will not be able to be heat treated.
- Environmental contamination. Studies in the USA during the 1980s showed the potential for this type of contamination (Kozak *et al.*, 1996), which was followed by control measures.

The NZICMA Code of Practice lists as a control for ingredients added post churn (page 32): "ensure ingredients are free of pathogens, foreign matter and chemical contamination". Test certification of raw materials is the usual control measure suggested for such ingredients (page 39). Processing of inclusions is covered (Section 17), and products that are unable to be heat treated before use are recommended to be subject to appropriate control measures at purchase, or subject to testing before use.

Environmental monitoring requirements for ice cream manufacturers are currently as for dairy factories generally and general requirements were set out in MRD-Standards 10. This has now been superseded, and replaced by guidance in pathogen management (http://www.nzfsa.govt.nz/dairy/publications/guidelines/pathogen/index.htm). Although *L. monocytogenes* is not mentioned specifically, the guidance does state:

"A risk assessment should have determined what control measures are necessary to prevent entry by these, or any other identified means. The sampling plan for the environmental surveillance programme should be developed to confirm the effectiveness of these controls. In general, surveillance can occur at three discrete levels of risk, based on the principle of zones described earlier.

• **Zone 1** encompasses the **outside** environment of the processing area.

• **Zone 2** encompasses those **inside** areas where product is not normally exposed (standard hygiene area), e.g. stores, or where there is exposed raw product (ie prior to a microbiocidal critical control point) e.g. raw milk prior to pasteurisation. These areas should be seen as a **buffer** between the outside environment or other high risk area and the critical hygiene area (Zone 3).

• **Zone 3** encompasses those **inside** areas where product, particularly product after a microbiocidal critical control point, is normally exposed (critical hygiene areas)."

6.6 Commentary on Risk Management Options

General measures of hygiene in ice cream, such as aerobic plate counts or coliform monitoring, are not indicative of the potential for the presence of *L. monocytogenes*. Although testing of product and in-process tests are described in the NZICMA Code of Practice (Section 20), the hygiene testing options given are not appropriate for indicating the potential presence of *L. monocytogenes*. However, they do indicate the effectiveness of plant cleaning and sanitation programmes. *Listeria*-specific tests would be required, since the presence of *L. monocytogenes* has not been found to be correlated with high bacterial counts in dairy plants (Cotton and White, 1992).

Ice cream can be accepted as a low risk product due to the very low risk of bacterial growth, even if post pasteurisation contamination has occurred. Post pasteurisation contamination is most likely to introduce only low numbers of cells. Assuming that growth of *L. monocytogenes* does not occur between pasteurisation and freezing, the frozen storage of ice cream offers the potential to consider this food as separate from the majority of unfermented dairy products which do not receive this storage treatment. The exception to this statement is soft serve ice cream mixes, which are stored and transported at refrigeration temperatures and, if contaminated, offer potential for microbial growth. Scientists in the United States and Canada have argued that an effective public health management strategy should be based on eliminating high concentrations of the bacterium in foods in which it is present and likely to grow, rather than trying to achieve zero prevalence of the organism in RTE foods (Chen *et al.*, 2003).

Controls on ingredients added after pasteurisation are considered in the NZICMA Code of Practice. Testing and/or listericidal processing (e.g. heat) may be applied depending on the composition of the particular ingredient e.g. for ingredients where bacterial growth is possible.

While manufacturers will have extensive environmental cleaning and sanitation programmes designed to minimise contamination by *L. monocytogenes*, occasional low level contamination of the processing environment and product may be detected by the manufacturer's microbiological monitoring programme. Bacteria do not grow in frozen foods, so low numbers of *L. monocytogenes* in frozen ice cream will not increase. However, it is still important that isolates from environmental and product sampling are fully identified (e.g. serotyping, PGFE) to facilitate identification and elimination of the source of contamination.

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APPENDIX 1 ANCILLIARY MATERIAL

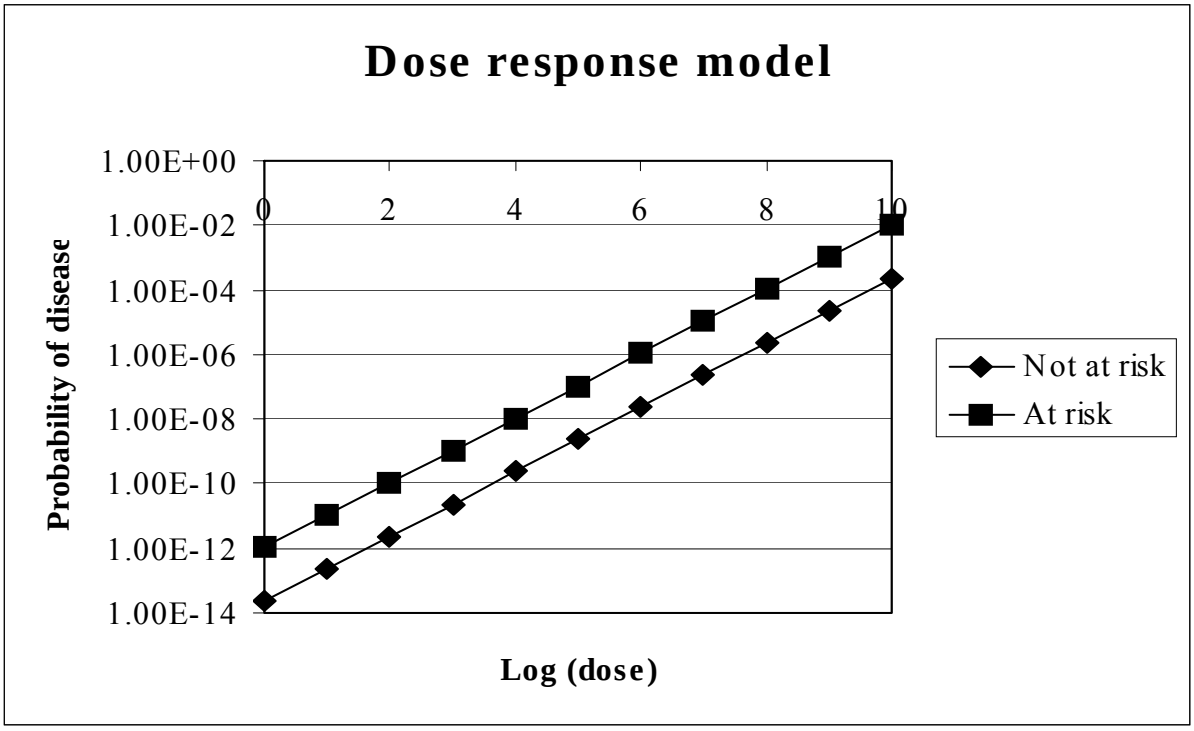
Dose Response: Invasive Listeriosis

The FAO/WHO risk assessment used a dose response model described by:

$P_{\text{health outcome}}=1-\exp^{-R*N}$

Where R is a variable that defines the dose/response relationship and N is the number of cells consumed. The values of R vary depending on population group (to reflect different susceptibilities) but are around the 10^{-12}-10^{-14} level. The model is a single hit model which means that there is a probability of illness associated with each cell consumed. It is therefore total consumption of cells that dictates risk; there is no "infectious dose", and there is no difference to risk if a small number of cells are eaten frequently or many cells eaten at the same time as long as the total eaten is the same. Figure 3 shows dose response curves for at risk and not at risk groups.

Figure 3: Dose response models at median values for R for invasive disease caused by *L. monocytogenes.**



***** Information provided by Dr. Tom Ross, University of Tasmania, and is that used in the FAO/WHO Listeria quantitative risk assessment.

The FDA/FSIS modelled value of R accounts for variation of virulence in the types of *L. monocytogenes* extant in the population. It is known that certain serotypes of *L. monocytogenes* appear to be associated with human disease, but there is no certainty that any one isolate will be pathogenic to humans just because it belongs to a particular serotype. A recent study has grouped *L. monocytogenes* into three distinct lineages (Jeffers *et al.*, 2001), and there did appear to be some differences between the contributions that the lineages made

to human disease. However, these lineages are not based on serotyping. The conservative approach is to treat all isolates as potentially capable of causing disease, but modelling of variability will be a more accurate reflection of real life.

Dose Response: Febrile Gastroenteritis

Dose response data for febrile gastroenteritis are limited. In a New Zealand outbreak involving ham, 21 of 24 (87.5%) people consuming the food contaminated with 1.8 x 10^7 *L. monocytogenes* cells/g became ill with symptoms of febrile gastroenteritis (Sim *et al.*, 2002). Assuming approximately 100g of ham was eaten by each person at the meal, then the dose ingested to produce this response was of the order of 10^9 cfu. In one outbreak (Dalton *et al.*, 1997) an attack rate of 75% was recorded where the median number of cells consumed was estimated as being as high as 2.9 x 10^{11} cfu. In other outbreaks it is difficult to estimate dose responses as portion sizes are not detailed or the number of cells present not accurately known. However, of all of the other outbreaks, the lowest number in food that has been shown to cause febrile non-invasive listeriosis is 1.9 x 10^5 cfu g^{-1} (Miettinen *et al.*, 1999), although the serving sizes were not detailed. In this incident all five people eating the contaminated fish became ill with gastroenteritis, nausea, abdominal cramps and diarrhoea. Therefore consumption of more than the order of 10^6- 10^7 cells appears to be sufficient to cause *L. monocytogenes* febrile gastroenteritis at a high infection rate in some circumstances. Given the currently accepted "single hit" non-threshold dose response models where the ingestion of a single cell is assigned a probability of causing infection, it is likely that foods contaminated with lower numbers of *L. monocytogenes* also cause febrile non-invasive gastrointestinal disease. As the dose decreases, so will the probability of illness. Because this organism is not routinely screened for by clinical laboratories in cases of gastroenteritis, sporadic cases of non-invasive listeriosis are likely to evade detection.

High Risk Groups in the New Zealand Population

There are some high risk (susceptible) groups in the population for listeriosis (Sutherland and Porritt, 1997). The well-categorised risk groups for listeriosis include pregnant women and their foetuses, neonates, the elderly, and adults with a compromised immune system e.g. renal transplant patients, patients on corticosteroid treatment, and HIV/AIDS patients. However, it should be noted that these groups will not be homogeneous with respect to their susceptibility, either within a group or between groups. The following sections provide information on the New Zealand population of these groups.

Perinatal population

Live births data for the 2007 Calendar year were 64,040 (http://www.stats.govt.nz/). This represents 1.5% of the 4.23 million population in December 2007.

Elderly population

According to estimates based on the 2006 Census of New Zealand, in 2007 724,330 New Zealanders were aged 60 years or over. This is 17.1% of the total population (up from 16.0% in 2001). The aged population is 46.1% male and 53.9% female. The population 80 years and over is 136,640 (3.2% of the population, up from 2.6% in 2001) (http://www.stats.govt.nz/).

Immune compromised

Persons at high risk of developing listeriosis often have deficient immune systems (immune compromised). Actual numbers of people fitting this description are difficult to determine as the individuals belong to a diverse range of groups (e.g. cancer and transplant patients, people suffering from immunosuppressive diseases, the elderly) and the fact that definition of an immune compromised state is often based on qualitative or circumstantial criteria. Available statistics on some identifiable groups usually associated with compromised immune states are summarised in the following section.

HIV/AIDS: During 2007, 156 people were diagnosed with HIV through antibody testing. A further 39 were reported with HIV through viral load testing (http://www.moh.govt.nz/aids.html). During the same period 31 people were notified with AIDS. While these figures represent a decrease compared to previous years, the number of people receiveing care for HIV in New Zealand has increased from 593 in 2000 to an estimated 1230 in 2007. This is considerably less than the number of people ever diagnosed with HIV in New Zealand (2,872), due to deaths from AIDS and other causes, emigration and decisions not to receive treatment. This figure of 1230 people represents 0.03% of the total New Zealand population.

Cancer: The most recently available statistics on the incidence of cancer and cancer mortality in New Zealand are from the 2005 year. In that year, 18,610 new cases of cancer were registered (340.3 cases per 100,000 population), made up of 9,647 males (376.3 cases per 100,000) and 8,963 females (312.7 cases per 100,000). During the same period mortality due to cancer was 7,970 (133.6 cases per 100,000) made up of 4,184 males (156.6 per 100,000) and 3,786 females (116.8 per 100,000). It is uncertain what proportion of the New Zealand population are suffering from cancer at any particular time.
Source:
http://www.nzhis.govt.nz/moh.nsf/pagesns/32/$File/Cancer_Deaths_New_Registrations2005v3.doc

Recipients of organ or tissue donations:

In 2007, 126 kidney transplants were performed on New Zealanders (http://www.donor.co.nz/donor/statistics/transplants.php). The total number of surviving New Zealand kidney transplant recipients at the end of 2006 was 1,253 (http://www.anzdata.org.au).

In 2007, 39 liver transplants were performed at the Auckland liver transplant unit (http://www.donor.co.nz/donor/statistics/transplants.php).

The New Zealand Organ Donation website gives the following numbers for other major organ transplants performed in 2007; heart 12, lungs 13, pancreas 1 (http://www.donor.co.nz). It appears likely that the total New Zealand population of surviving major organ transplant recipients is less than 2000 people (0.05% of the total population).

Overseas Data on Prevalence/Concentration of *L. Monocytogenes* in Ice Cream

Table 4: Overseas prevalence and quantitative data for *L. monocytogenes* in ice cream

Country	Food	No. samples tested	No. (%) positive for *L. monocytogenes*	Reference
Australia	Domestic and imported ice cream	495	[413 (83.8)] [< 1/g approx 310] [1.0-10/g approx 60] [11-100/g approx 119]	(NFA (National Food Authority), 1992)*
Australia, Western	Ice cream Soft serve ice cream	15 114	2 (13.3) *L. innocua* 1 (0.9)	(Health Department of Western Australia, 1992)
Belgium	Raw milk ice cream	7	1 (14.3)	(De Reu *et al.*, 2004)
Brazil	Ice cream	60	0	(Abrahão *et al.*, 2008)
Canada	Ice cream from manufacturers Ice cream mix from manufacturers Ice cream novelties from manufacturers	394 85 51	1 (0.3) 0 1 (2.0)	(Farber *et al.*, 1989)
Chile	Ice cream, scooped Ice cream, factory packed	68 535	5 (7.4) 16 (3.0)	(Cordano and Rocourt, 2001)
China (13 provinces)	Ice cream	796	11 (1.4) *Listeria* spp.	(Chen *et al.*, 2009)
Costa Rica	Pasteurised ice cream	50	1 (2.0)	(Monge *et al.*, 1994)
England and Wales	Ice cream bars (branded) Other hard ice cream Soft ice cream	87 1000 964	0 2 (0.2) 2 (0.2)	(Nichols and de Louvois, 1995)
England and Wales	Ice cream	150	3 (2.0) < 500/g (detected by enrichment only)	(Greenwood *et al.*, 1991)
Europe	Ice cream, finished product 1996 1997 1998 1999	 32040 22753 27177 17246	 32 (0.01) 10 (0.04) 7 (0.03) 7 (0.04)	International Dairy Federation (pers. comm)
Finland	Ice cream 1994 1995 1996 1997	 603 188 264 74	 4 (0.7) 0 2 (0.8) 0	(Miettinen *et al.*, 1999)
Hong Kong	Soft serve 1998 1999 2000 Pre-packed ice cream 1998 1999 2000	 40 41 13 27 39 38	 0 0 0 0 0 0	http://www.info.gov.hk/fehd/safefood/report/icecream/report.html
India	Icecream (branded)	20	0	(Moharram *et al.*,

Country	Food	No. samples tested	No. (%) positive for *L. monocytogenes*	Reference
	Icecream (unbranded)	60	3 (5)	2007)
Italy	Artisanal ice cream	396	0	(Maifreni *et al.*, 1993)
Italy	Icecream (2001-2002)	1,734	5 (0.3)	(Busani *et al.*, 2005)
Korea	Unspecified imports from the USA	132	8 (6.1)	(Baek *et al.*, 2000)
Oceania/Asia/ Africa	Ice cream, finished product 1996 1997 1998 1999	 15 5286 7395 8720	 0 0 3 (0.04) 0	International Dairy Federation (pers. comm)
Singapore	Ice cream	61	0	(Ng and Seah, 1995)
United Kingdom	Soft ice cream Powdered ice cream mix Liquid pasteurised mix Liquid UHT mix Liquid mix, treatment not specified	1214 14 200 248 50	10 (0.8) all < 100/g 0 0 1 (0.4%) <100/g 1 (2/0%) <100/g	(Little and de Louvois, 1999)
USA	Ice cream, finished product 1996 1997 1998 1999	 4606 4039 2301 5441	 0 0 0 5 (0.09)	International Dairy Federation (pers. comm)
USA	Ice cream	43	0	(Schwartz *et al.*, 1989)
USA	Ice cream (1986) Novelty ice cream (1986) Ice cream (1987) Novelty ice cream (1987) Ice cream (1987)	232 145 427 206 57	6 (2.6%) 10 (6.9%) 19 (4.4%) 20 (9.7%) 3 (5.3%)	(Kozak *et al.*, 1996)
USA	Quantitative data for dataset in line above		Levels: 15/g and 1-5g for two samples	(Ryser, 1999b)

* Given the uncertain presentation of data in this report the figures quoted may not be reliable. The question is whether a value of <1 has been interpreted as "detected".

Frozen dairy products as a potential vehicle for listeriosis infection have been the subject of intense scrutiny in the United States after a 1986 perinatal case was suspected of being caused by transmission in ice cream sandwiches (Ryser, 1999a). Since then enhanced surveillance by the US dairy industry has resulted in over 50 recalls of frozen dairy products due to *Listeria* contamination. However, not a single case of listeriosis in the United States has been linked to consumption of contaminated ice cream.

A survey of raw milk and milk filters in 17 states in the USA was undertaken as part of the National Animal Health Monitoring and Surveillance programme conducted by the USDA (Van Kessel *et al.*, 2008). *Listeria* spp. were detected in 7.8% of the milk samples and 26.8% of the filters, while *Listeria monocytogenes* was detected in 4.3% of the milk samples and 6.5% of the filters.

FDA/FSIS Ranking of the Risk of Listeriosis from Consumption of Various RTE Foods

Table 5: Predicted relative risk rankings for listeriosis based on the North American sub-population using median estimates on a per serving basis

Food Categories[a]	Sub-Population			
	Intermediate Age[b]	Elderly[b]	Perinatal[b]	Total [b,c]
	Relative Rank (1- 23)			
SEAFOOD				
Smoked seafood	6	5	5	5b
Raw seafood	12	12	12	13d
Preserved fish	13	13	13	12d,e
Cooked ready-to-eat crustaceans	5	6	6	6b
FRUIT AND VEGETABLES				
Vegetables	18	18	18	18
Fruits	15	15	15	14e
DAIRY PRODUCTS				
Fresh soft cheese (e.g. queso fresco)	10	10	10	10
Soft ripened cheese, >50% moisture	17	17	17	17f
Soft unripened cheese, >50% moisture	8	8	8	8c
Semi-soft Cheese, 39-50% moisture	16	16	16	16f
Processed cheese	20	20	20	21g
Hard cheese <39% moisture	23	23	23	23
Fluid milk, pasteurised	9	9	9	9c
Fluid milk unpasteurised	4	4	4	4b
Ice cream and frozen dairy products	21	21	21	20g
Cultured Milk Products	22	22	22	22g
High Fat and Other Dairy Products	7	7	7	7
MEATS				
Reheated frankfurters	11	11	11	11
Non-reheated frankfurters	2	2	2	2a
Dry/semi dry fermented sausages	14	14	14	15d
Deli meats	1	1	1	1a
Pâté and meat spread	3	3	3	3
COMBINATION FOODS				
Deli salads	19	19	19	19

[a] Food categories are grouped by type of food but are not in any particular order.
[b] A ranking of 1 indicates the food category with the greatest predicted relative risk per serving of causing listeriosis and a ranking of 23 indicates the lowest predicted relative risk of causing listeriosis.
[c] Ranks with the same letter are not significantly different based on the Bonferroni Multiple Comparison Test (alpha = 0.05).
Source: FDA/FSIS 2003 (http://www.cfsan.fda.gov/~dms/lmr2-5.html)