



**RISK PROFILE:  
NORWALK-LIKE VIRUS  
IN MOLLUSCA (RAW)**

Prepared as part of a New Zealand Food Safety Authority  
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**RISK PROFILE:  
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## 1 INTRODUCTION

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. The place of a risk profile in the risk management process is described in “Food Administration in New Zealand: A Risk Management Framework for Food Safety” (Ministry of Health/Ministry of Agriculture and Forestry, 2000). Figure 1 outlines the risk management process.

**Figure 1 Risk Management Framework**

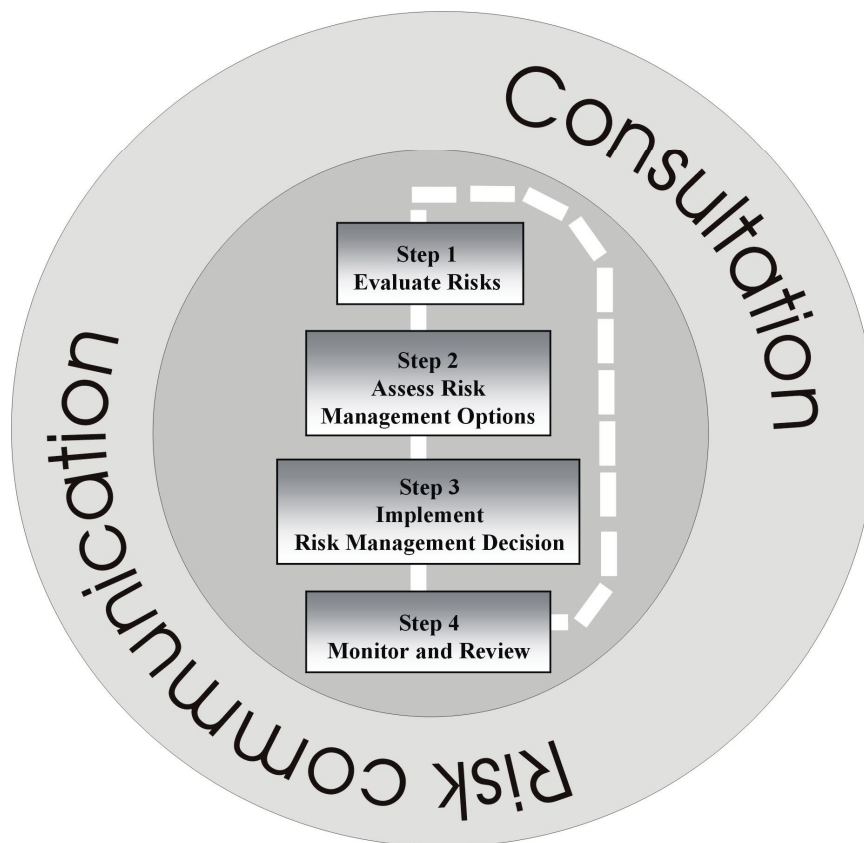


Figure reproduced from “Food Administration in New Zealand. A risk management framework for food safety” (Ministry of Health/Ministry of Agriculture and Forestry, 2000).

In more detail, the four step process is:

### *1. Risk evaluation*

- identification of the food safety issue
- **establishment of a risk profile**
- ranking of the food safety issue for risk management
- establishment of risk assessment policy
- commissioning of a risk assessment
- consideration of the results of risk assessment

## 2. Risk management option assessment

- identification of available risk management options
- selection of preferred risk management option
- final risk management decision

## 3. Implementation of the risk management decision

## 4. Monitoring and review

The Risk Profile informs the overall process, and provides an input into ranking the food safety issue for risk management. Risk Profiles include elements of a qualitative risk assessment. However, in most cases a full exposure estimate will not be possible, due to data gaps, particularly regarding the level of hazard in individual foods. Consequently the parts of a Risk Profile that relate to risk characterisation will usually rely on surveillance data.

The Risk Profiles also provide information relevant to risk management. Based on a Risk Profile, decisions are made regarding whether to conduct a quantitative risk assessment, or take action, in the form of gathering more data, or immediate risk management activity.

This Risk Profile concerns Norwalk-like virus (NLV) in raw mollusca, or shellfish. This food/hazard combination was chosen for preparation of a detailed risk profile because infection with this organism consistently causes the highest proportion of cases reported to the outbreak module of the notifiable disease database EpiSurv (Perks *et al.*, 1999; Kieft *et al.*, 2000, Lopez *et al.*, 2001). Of the outbreaks of NLV infection in New Zealand that have been associated with food, the most common food type has been raw seafood (including both domestic and imported shellfish).

The sections in this Risk Profile are organised as much as possible as they would be for a conventional qualitative risk assessment, as defined by Codex (Codex, 1999).

### *Hazard identification, including:*

- A description of the organism
- A description of the food group

### *Hazard characterisation, including:*

- A description of the adverse health effects caused by the organism.
- Dose-response information for the organism in humans, where available.

### *Exposure assessment, including:*

- Data on the occurrence of the hazard in the New Zealand food supply.
- Data on the consumption of the food group by New Zealanders.
- Qualitative estimate of exposure to the organism (if possible).
- Overseas data relevant to dietary exposure to the organism.

*Risk characterisation:*

- Information on the number of cases of adverse health effects resulting from exposure to the organism with particular reference to the identified food (based on surveillance data)
- Qualitative estimate of risk, including categorisation of the level of risk associated with the organism in the food (categories are described in Appendix 1).

*Risk management information:*

- A description of the food industry sector, and relevant food safety controls.
- Information about risk management options.

*Conclusions and recommendations for further action*

Note: Earlier versions of this document were produced as part of a project undertaken by ESR and jointly directed by the Ministry of Health and the Ministry of Agriculture and Forestry. Ministry responsibilities for food safety were combined into the New Zealand Food Safety Authority (NZFSA) in July 2002.

The Australia New Zealand Food Authority (ANZFA) became Food Standards Australia New Zealand (FSANZ), also in July 2002.

Information and reports published by the older organisations have been referenced to those names.

## 2 HAZARD IDENTIFICATION: THE ORGANISM

The following information is adapted from a data sheet prepared by ESR under a contract for the Ministry of Health. The data sheet is intended for use by regional public health units.

### 2.1 Norwalk-like viruses

#### 2.1.1 The Organism

The Norwalk-like viruses (NLVs) were renamed Noroviruses by the International Viral Taxonomy Committee in August 2002. These viruses, including Norwalk virus itself, are now the most widely recognised viral agents associated with food and waterborne outbreaks of non-bacterial gastroenteritis world-wide. They were previously known as small round structured viruses (SRSVs). The identification of the NLV has been difficult prior to development of molecular methods because they are non-culturable, there is no animal model, and they show great genetic diversity. These factors limit the use of traditional immunology and serotyping assays. A large number of genetically diverse NLV strains associated with gastroenteritis outbreaks have now been characterised. NLV strains are named after the location of the outbreak from which they were first derived e.g. Norwalk virus, Mexico virus, Hawaii virus, Bristol virus, Southampton virus.

#### 2.1.2 Growth and Survival

##### **Growth:**

Norwalk-like viruses cannot be grown in cell culture or human embryonic intestinal organ culture, and there is no known animal model. Detection and characterisation of NLV strains are carried out using molecular methods, including DNA sequencing. They cannot grow in food.

##### **Survival:**

Based on infectivity in human dose response research studies the virus is stable and resistant to heat, acid and solvents, as described below.

#### 2.1.3 Inactivation (CCPs and Hurdles)

Only limited information is available.

Temperature: The virus retained infectivity after incubation at 60°C for 30 min. Pasteurisation is not sufficient to eliminate viruses. Resistance is reported to be greater in foods and shellfish. Steaming of oysters may not inactivate NLV.

Under refrigeration and freezing conditions the virus remains intact (and presumably viable) for several months, possibly years. Freezing generally does not inactivate viruses.

pH: Resists gastric acids at pH 3-4. The virus retained infectivity after exposure to pH 2.7 for 3 hours at room temperature. It is believed to be sensitive to pH >9.0 but this is unproven.

Drying: Resistant. Infectious NLV were detected on environmental surfaces, including carpets, for up to 12 days after NLV outbreaks in institutions.

Preservatives: Since the organism does not grow in food, this will not be controlled by preservatives.

Radiation: Unknown

#### 2.1.4 Sources

Human: The only known reservoir for NLV is the human gastrointestinal tract. Other reservoirs could be shellfish, animals and the environment but currently there is no definitive evidence to support this.

Animal: Related caliciviruses are found in various animal species, but cross-species transmission has not been reported.

Food: Contaminated bivalve shellfish, salads, water and ice. Manually prepared food products (including bakery items) contaminated via food handlers. Poor hygiene practices are a major factor.

Environment: Excreta from infected humans may contaminate soil or water. Environmental survival is considered to be good. Faecal pollution from sewage discharges, septic tank leachates and boat discharges has caused contamination of shellfish beds, recreational water, irrigation water and drinking water. Few published data are available but it is probable that NLV persist in waters and shellfish for extended periods (possibly weeks or months).

One infection cluster occurred among carpet layers lifting carpet which had become contaminated 12 days earlier in a rest home outbreak (Cheesborough *et al.*, 1997)

Transmission Routes: The faecal/oral route is the established route of transmission and infection occurs following ingestion of faecally-contaminated food and water. Other routes are also implicated; these help explain the explosive outbreaks that cannot be attributed to faecal/oral spread alone and which occur in semi-closed communities such as rest homes, cruise ships, and camps. Person-to-person spread via aerosolised vomit following projectile vomiting is another route of spread. The role of asymptomatic carriers is unclear, but there is evidence that asymptomatic foodhandlers can cause infection. Direct transmission via contaminated surfaces, especially carpets and toilet seats, is also now considered a significant route.

## 2.2 **Detection methods**

NLV cannot be detected by conventional microbiological methods. The introduction of reverse transcriptase polymerase chain reaction methods (RT PCR) over the last few years has offered the means to directly detect contamination, although the method remains labour intensive.

Over the past five years there have been a number of projects conducted by public health service providers and ESR for the Ministry of Health to improve the testing capability for

NLV in foods, and the recognition and investigation of outbreaks of viral infection. An overview of foodborne viral gastroenteritis, diagnostic practices, and testing capability (Wong *et al.*, 1996) was followed by an intensive study of 18 outbreaks (Wong *et al.*, 1997) which included the development of an investigation protocol for use by regional public health units.

Detection of NLVs in faecal specimens from outbreaks has been carried out by ESR for the Ministry of Health since 1996. Development of molecular methods for typing of these viruses took place in 1997 (Meekin and Low, 1997). Further method development provided techniques for the detection of Norwalk-like virus, Sapporo-like viruses, and hepatitis A virus in shellfish (Meekin and Dawson, 1998) and other foods (Greening and Dawson, 1999).

Analysis of faecal samples for NLV has now been established in two ESR laboratories (Norwalk-like Virus Laboratory, ESR Kenepuru Science Centre, Porirua, and Auckland Public Health Laboratory, ESR Mt Albert Science Centre). The ESR Kenepuru Science Centre also has the capability to analyse shellfish and other foods (water, fresh fruits and vegetables, salads and meats) for NLV and to genotype the strains associated with outbreaks so that sources of infection can be traced. It is likely that these improved capabilities will provide better data on the prevalence of NLV infection and its association with the contamination of foods in the future.

### 3 HAZARD IDENTIFICATION: THE FOOD

The shellfish group consists of members of the phylum mollusca. This includes easily recognised bivalve molluscs, as well as the cephalopods such as squid and octopus (New Zealand Fishing Industry Board, 1981). This risk profile will focus primarily on oysters, but will also consider other marine bivalve molluscs which are also filter feeders, and thus able to accumulate pathogenic microorganisms. These include:

- Clams, including:
  - Cockle
  - Pipi
  - Toheroa
  - Tuatua
- Mussel, blue
- Mussel, green
- Oyster, dredge
- Oyster, Pacific
- Oyster, rock
- Scallop

New Zealanders will consume shellfish from imports, local commercial farming operations, and recreational gathering from the shore.

The shallow waters and poor flushing of estuaries in certain areas present the greatest risk of viral contamination. Faecal contamination is believed to enter via influxes of fresh water into the marine environment near the surface, so the depth at which shellfish are grown is important.

Both blue and green mussels occur widely on New Zealand rocky coasts, as well as in dense beds on the bottom in moderately protected areas (Hay *et al.*, 2000). Mussels are commercially grown on ropes in deep water, so present less risk.

Scallops occur on soft bottoms in open water and harbours, and are mostly collected by diving or dredging. Scallops are grown in 10-12 metres of water, are usually cooked and are consumed with the gut and feeding parts removed. This habitat at greater depth reduces the risk of viral contamination.

There are three oyster species of significance. The native rock oyster and the introduced Pacific oyster occur most frequently in harbour or estuarine intertidal areas, principally in the North Island. Oysters are generally consumed raw and whole, including the gut, so present the greatest risk to public health if contaminated with pathogens prior to harvest.

Dredge oysters occur in subtidal water off the South Island. They are mainly abundant in the Foveaux Strait, although a small fishery for this species exists in Tasman and Golden Bays. Dredge oysters are not considered to be at risk of NLV infection, because they grow in deep water offshore rather than on racks in the coastal zone. Most New Zealand oysters are rack-farmed in the inter-tidal zone close to the coast.

Of these shellfish types, the most likely to be consumed raw (or lightly cooked e.g. steamed) are mussels and oysters. Steaming or freezing for storage are unlikely to inactivate Norwalk-like viruses.

Shellfish gathering in New Zealand can be regarded in terms of commercial and non-commercial (recreational) activities.

New Zealand's marine farming industry is based primarily on the green-lipped mussels. Other less important species include pacific oyster, paua (abalone) and salmon. Techniques are also being developed to introduce a variety of new species, such as dredge oysters, kina (sea urchin), scallops, seaweed, snapper and sponges. In 1995, aquaculture export earnings were approximately NZ\$160 million.

Commercial shellfish harvesting is organised under nine Shellfish Quality Assurance Delivery Centres (SQAPDCs) and specified growing areas. The largest number of leases, licences or permits are within the Marlborough Sounds SQAPDC and mainly relates to the farming of mussels.

Non-commercial shellfish gathering patterns in New Zealand are dictated by local availability of desirable shellfish species. Information on the distribution of non-commercial shellfish and amounts gathered (where information is available) has been reviewed by Hay *et al.* (2000). The limited data available suggested that over all areas, scallops were the most actively targeted species, followed by mussels and pipi. Oysters were the species least frequently targeted.

### **3.1 Relevant Characteristics of the Food: Raw Mollusca**

Shellfish are typically 70-80% water, 10-20% protein with small amounts of fat and carbohydrate. They generally contain high levels of metallic elements, due to their ability to bio-accumulate.

Bivalve molluscs feed and respire by inducing a current of water to flow over a series of complex gill structures and capture suspended particulate matter, passing it towards the mouth where it may be ingested or rejected as pseudo-faeces. Oysters can filter 10-20 litres of water per hour. These shellfish are capable of concentrating viruses that may be present in water, resulting in viral concentrations far exceeding those of the surrounding water (Grohmann, 1997).

### **3.2 The Food Supply in New Zealand**

New Zealand's domestic market for fish is about \$NZ120 million per year and the seafood sector is predominantly an export industry.

With exports in the region of \$NZ1.43 billion in 2000, the seafood sector ranks amongst the top five export sectors in the New Zealand economy, with Japan, the USA and the European Union being the largest markets. In the 2000 year the largest component of the shellfish export market was for mussels, of which 27,149 tonnes were exported, worth \$157 million. Other relevant shellfish exports were: oysters 1,183 tonnes (worth \$11 million); scallops 427 tonnes (worth

\$10 million) and “other” shellfish (excluding squid) 1,132 tonnes (worth \$15 million).

(Information from the New Zealand Seafood Industry website: <http://www.seafood.co.nz/>)

Little information is available on the amount of shellfish which enter the domestic market. However, the Ministry of Fisheries website gives the Total Allowable Catch (TAC) for some shellfish species (<http://www.fish.govt.nz/>). The dredge oyster catch in 1999 for Nelson/Marlborough and Foveaux Strait combined was approximately 1860 tonnes. Given the export figures for 2000 above, this suggests that approximately 700 tonnes remained for the domestic market.

### 3.2.1 Imported food

New Zealand imports significant quantities of shellfish and shellfish meat. Data obtained from Statistics New Zealand show that in the year to September 2001, New Zealand imported approximately 500 tonnes of oysters (mainly from Korea), 250 tonnes of scallops (mainly from Japan) and small quantities of mussels, abalone and clams. From the import statistics it is uncertain what proportion of this material was cooked, although the majority of it was frozen.

It is difficult to determine what proportion of shellfish consumption by New Zealanders these amounts represent, as there are no details on whether the weights include shells or just flesh.

Molluscs (cooked and raw) including clams, cockles, mussels, oysters and scallops are prescribed foods under the New Zealand (Mandatory) Food Standard 1997. This means that imports of these products can be required to demonstrate compliance with conditions related to the presence of heavy metals, marine biotoxins and pathogenic bacteria. Details of specific import requirements are given in section 7.1.3 of this report or on the Auckland District Health Board Central Clearing House website ([http://www.akhealth.co.nz/akphp/Services/ImportedFood/imported\\_foods.htm](http://www.akhealth.co.nz/akphp/Services/ImportedFood/imported_foods.htm)).

### 3.3 **Monitoring of Feral Shellfish Gathering**

In the 1999/2000 year a survey of public health service providers and regional councils regarding the safety of feral shellfish gathering was conducted by ESR (Thomson, 2000). Information on monitoring of the microbiological quality of shellfish and marine waters was reviewed. Some form of routine monitoring of feral shellfish for bacterial microbiological quality is performed by three Health Districts, while routine monitoring of marine waters is conducted by all twelve Districts, mostly for recreational bathing reasons. The report commented that indicators of microbiological quality in terms of bacteria do not provide information on viral contamination.

## 4 HAZARD CHARACTERISATION: ADVERSE HEALTH EFFECTS

Norwalk-like viruses colonise the proximal region of the small intestine and cause development of mucosal lesions. Short-term malabsorption of fats and some sugars has been reported. The exact mechanism of pathogenesis remains unclear.

### 4.1 Symptoms

*Incubation:* Gastroenteritis caused by Norwalk-like virus has an average incubation period of 12-48 hours (CDC, 2001).

*Symptoms:* Vomiting, often projectile, is generally the predominant symptom and is present in > 50% of cases. Stomach cramps, diarrhoea, abdominal pain, low-grade fever and headache are other common symptoms. Vomiting is more common amongst children, whereas adults usually experience diarrhoea.

The duration of illness is usually between 24-60 hours. Excretion of the virus in stools occurs from onset for up to 1-2 weeks following infection. High levels of virus may also be discharged in vomit. The disease is generally mild and self-limiting. Hospitalisation is not generally required, but has been reported in some outbreaks. US data assumes NLVs account for 11% of 452,000 annual hospitalisations for viral gastroenteritis. The attack rate is generally around 40-60%. The overall attack rate in New Zealand outbreaks is estimated at 40%, but may be higher as many cases are unreported.

It is generally believed that people infected with NLV remain contagious for 48-72 hours after recovery. However, it has since been found that both viral RNA and viral antigen may be present in faeces for up to 2 weeks following illness (CDC, 2001). The significance of this finding is unclear and does not establish that the person is infectious for this longer period (CDC, 2001). There are now several studies (Parashar *et al.*, 1998; Daniels *et al.*, 2000) that show presence of viral RNA in faeces 7-10 days after onset of symptoms. ESR has detected NLV in specimens collected 10 days after the onset of symptoms (G Greening, unpublished results).

*At Risk Groups:* Affects all age groups, but the elderly and the immunocompromised are particularly susceptible.

*Long Term Effects:* Fatality may be caused by severe dehydration but this is very rare and only occurs in people with existing health conditions. Elderly and frail people are most at risk. No long term sequelae have been reported (CDC, 2001).

*Treatment:* Usually none, but fluids may be given to reduce the risk of dehydration.

### 4.2 Dose Response

The consumption of small numbers of NLV particles can result in disease (Moe *et al.*, 2000). One estimate of a dose capable of causing infection has been reported as approximately 10-100 viral particles (Caul, 1994), while consumption of 1 virus particle in drinking water has been reported to cause infection on approximately 20% of occasions (Moe *et al.*, 1999). The dose-response relationship is still being elucidated but is not simple (Moe *et al.*, 2000).

Infected individuals produce large numbers of viruses in faeces and vomit. The levels of viral particles shed in faeces are  $\sim 10^6$  viruses/g. An estimated  $10^5$ - $10^6$  potentially infectious doses can also be generated per vomiting incident (Moe *et al.*, 1999).

Graham *et al.* (1994) administered an inoculum of Norwalk virus to 51 volunteers (21 females, 30 males; 19-39 year old medical students). All subjects received the same dose, which was not quantified. Of the 51 subjects 36 became infected (70% attack rate).

## 5 EXPOSURE ASSESSMENT

### 5.1 The Hazard in the New Zealand Food Supply: NLV in Raw Mollusca

#### 5.1.1 Prevalence of Norwalk-like viruses in molluscs in New Zealand: Survey data

There is little survey information on the prevalence of NLV in New Zealand shellfish; most of the information has come from the investigation of outbreaks.

During NLV detection method development at ESR, a pilot study was conducted into the prevalence of viral pathogens in feral and farmed New Zealand shellfish (Scales *et al.*, 2000). From 17 samples, this survey found Norwalk-like virus in one commercial oyster sample, and in one sample of oysters from recreational gathering, a total prevalence of 12%. This small sample size needs to be interpreted cautiously. The samples were all from the North Island and principally from Northland. Thus the survey may not reflect the national situation, and it has been shown that contamination of shellfish with NLV is site specific (Doré *et al.*, 2000).

Enteroviruses have been detected in shellfish samples (mussels and oysters) collected in the Manukau Harbour (Lewis *et al.*, 1996; Green and Lewis, 1999) indicating contamination from sewage and the potential presence of NLV.

### 5.2 Food Consumption: Shellfish

The following information is taken from the New Zealand National Nutrition Survey (NNS) conducted in 1997 (Russell *et al.*, 1999).

Summary food consumption statistics can be expressed in terms of ‘consumer’ (just those people reporting to eat a particular food) or ‘persons’ (the whole population). Both will be presented here. The age groups used by the Australian National Nutrition Survey (1995; Australian Bureau of Statistics, 1999) will initially be used so that an easy point of comparison can be made. These are 16-18 years, 19-24 years, 25-44 years, 45-64 years, 65 years and over. Comparisons with the Australian National Nutrition Survey are complicated as shellfish are part of a category with the description ‘Crustacea and Molluscs’, which will also contain prawns, shrimps, lobster, crayfish and snails.

It should be noted that the analysis of shellfish consumption based on the 1997 NNS involves very small numbers of respondents (102 total) and the analyses should be viewed with a corresponding degree of caution. Table 1 summarises the percentages of respondents in each age-gender group who reported consuming shellfish during the previous 24 hour period.

**Table 1: Total shellfish – percentage of respondents consuming**

Age (years)	16-18	19-24	25-44	45-64	65+	Total
Male	0.0	2.1	3.2	3.6	2.5	2.9
Female	0.7	1.4	2.0	1.9	1.0	1.7
Total	0.4	1.7	2.4	2.7	1.6	2.2

In the Australian NNS the percentage of respondents eating crustacea and molluscs were; males 2.7%, females 2.8%, all 2.7%. A recent FSANZ assessment of the 1997 NNS data, using a series of standard recipes to determine quantities of commodities in compound food, estimated the proportion of respondents consuming mussels, oysters and scallops as 1.9, 0.6, and 0.3% respectively. USA statistics suggest that raw oysters are consumed on average once every six weeks (2.4% of the population consume on any given day; FDA, 2001). This suggests a higher overall level of shellfish consumption than that reported for New Zealand or Australia.

Table 2 gives the median amount of shellfish consumed by respondents reporting consumption of shellfish in the previous 24 hour period. These amounts will usually relate to serving sizes, although in some cases respondents may have consumed more than one serving of shellfish during the 24 hour period.

**Table 2: Total shellfish – median consumption by consumers (g/day)**

Age (years)	16-18	19-24	25-44	45-64	65+	Total
Male	0*	80	100	80	83	96
Female	49	75	96	64	251	93
<b>Total</b>	49	77	96	80	102	96

\*No reported consumption by this consumer group

The median amounts of shellfish eaten by New Zealand consumers are higher than those reported for the Australian NNS (1995). The Australian study reported an overall median (males and females) for respondents aged 19 and over of 69.5 g/day (crustacea and molluscs), compared to an overall median of 96 g/day from the New Zealand NNS (1997). Overall figures for males and females are; males; Australia 80.0 g/day, New Zealand 96 g/day, females; Australia 52.7 g/day, New Zealand 93 g/day.

The FSANZ assessment of the 1997 NNS data reported a median amount eaten by consumers of 38.4, 45.9, 54.4 g/day respectively for mussels, oysters and scallops. The lower estimates made by ANZFA are due to their use of standard recipes, for instance, a recipe for a seafood pizza may include several grams of mussel or scallop. The lower weights of shellfish associated with recipes will result in the lower median intake values observed.

These figures are comparable to those obtained in the Life in New Zealand (LINZ) survey (the previous National Nutrition Survey) which reported mean (not median) intakes of shellfish of 70 g/day for all males, 99 g/day for all females, and 84 g/day for all consumers. The percentages of respondents consuming shellfish were slightly higher in the LINZ survey (4% of males and 3% of females).

The USFDA reported a mean value for a single serving of raw oysters of 110 g (FDA, 2001). Given that more than one serving of shellfish per day is likely to be a very rare event and extrapolating this figure to other shellfish, this figure is similar to the median daily consumption for New Zealand consumers.

Table 3 gives the 95<sup>th</sup> percentile level of consumption of shellfish for the various age-gender groups. These high percentile consumption levels are often used to represent a high level consumer of the particular food. These 95<sup>th</sup> percentiles could not be calculated for all age-gender groups due to the low numbers of respondents consuming these foods.

**Table 3: Total shellfish – 95<sup>th</sup> percentile consumption by consumers (g/day)**

Age (years)	16-18	19-24	25-44	45-64	65+	Total
Male	NA	NA	364	250	NA	331
Female	NA	NA	280	NA	NA	311
Total	NA	NA	350	272	NA	316

NA Not applicable, insufficient data points to calculate a 95<sup>th</sup> percentile value

These results are consistent with ANZFA's assessment of the 1997 NNS data, which reported 97.5<sup>th</sup> percentile intakes of mussels, oysters, and scallops of 378.3, 600, and 163.2 g/day respectively.

Table 4 summarises the mean consumption of shellfish for all respondents in the NNS, not just those reporting consumption of shellfish – these figures are generally considered to be population averages.

**Table 4: Total shellfish – mean consumption by persons (g/day)**

Age (years)	16-18	19-24	25-44	45-64	65+	Total
Male	0.0	1.3	4.4	4.8	2.6	3.7
Female	0.4	1.6	2.0	1.9	2.1	1.9
Total	0.2	1.5	2.9	3.3	2.3	2.7

The Australian NNS reports an overall mean consumption of 2.7 g/day of crustacea and molluscs. Unfortunately, although this appears to be similar to New Zealand figures, this does not allow a direct comparison to be made. The ANZFA assessment of the 1997 NNS data produced an estimate for mean consumption of mussels, oysters and scallops by persons totalling 3.1 g/day.

Analysis of the data from the 1997 NNS suggests that Maori respondents, on average, consume larger amounts of shellfish (average daily consumption of 160 g as compared to 113 g for non-Maori), although the data available do not suggest that they eat shellfish more frequently.

There is some evidence to suggest that certain ethnic groups in New Zealand (Maori, Pacific Islanders, Asians) are over-represented in non-commercial harvesting of shellfish (see studies reviewed in Hay *et al.*, 2000). The harvesting of Kaimoana by Maori, particularly in the far north, is an important cultural and dietary component. A survey in this region found that 11% of households reported collecting seafood more than once a week, 31% collected seafood at least weekly, and 52% reported collecting seafood at least fortnightly (reported in Hay *et al.*, 2000).

The total consumption of shellfish is made up of:

- Mussels 44%
- Oysters 24%
- Paua 14%
- Scallops 13%
- Pipis 3%
- Tuatuas 2%

### **5.3 Qualitative Estimate of Exposure**

#### **5.3.1 Number of servings and serving size**

Consumption of shellfish in New Zealand is relatively uncommon with only about three percent of the population reporting consumption of shellfish on any particular day. The data from the National Nutrition Survey suggest that shellfish are as commonly consumed as foods such as parsnip, chilli peppers, spring onions or mandarins.

Of the servings of shellfish identified in the 1997 National Nutrition Survey, 57% identified the product as being cooked, 20% raw, 19% marinated, 3% canned and 2% smoked.

Serving sizes for shellfish are similar to those for medium-sized fruit such as figs or kiwifruit, mammalian offals or vegetables such as brussel sprouts, pumpkin or spinach. These foods form a 'medium' serving size group below the dietary staples such as meats and common fruits and vegetables, but above meal ingredients such as herbs, fats and oils, seeds and nuts.

#### **5.3.2 Frequency of contamination**

Information on the frequency of NLV contamination in New Zealand (or overseas) shellfish is scant. Overseas contamination frequencies in the range 0-56% have been reported, with an overall prevalence of 25%. A small New Zealand survey gave a lower prevalence rate of 12%.

Either of these figures would be high enough for NLV contamination of shellfish to be considered a common occurrence.

#### **5.3.3 Predicted contamination level at retail**

The highly infective nature of NLV means that any level of contamination in a food must be considered to be potentially infective.

#### **5.3.4 Growth rate during storage and most likely storage time**

NLVs are unable to replicate outside the human body and, consequently, will not grow during storage.

### 5.3.5 Heat treatment

As this risk profile is for raw shellfish thermal inactivation through a cooking process is not relevant.

### 5.3.6 Exposure summary

Raw molluscan shellfish are an infrequently consumed food in New Zealand. This is consistent with findings from normal 'benchmark' countries such as Australia and the US. The limited New Zealand information suggests that raw oysters may be commonly contaminated with NLV, which is consistent with most of the reported international studies, although it may not reflect the national situation (see Section 5.1.1). No assessment can be made with respect to other shellfish species.

While, overall, the exposure to NLV through consumption of raw shellfish will be a relatively rare event, due to the low level of consumption of this food, there is evidence to suggest that consumption of raw oysters (other than dredge oysters) may carry a relatively high risk of exposure to NLV.

## 5.4 **Overseas Context**

### 5.4.1 NLV in mollusca

The limited data from the scientific literature concerning surveys of shellfish for NLV are summarised in Table 5.

**Table 5: Reported Prevalence of NLV in overseas raw mollusca**

Country	Mollusc species	Samples tested	Positive for NLV (%)	Year	Reference
France	Oysters	108	23	1995-1998	Le Guyader <i>et al.</i> , 2000
France	Mussels	73	35.6	1995-1998	Le Guyader <i>et al.</i> , 2000
Greece	Oysters, mussels	144	1.4	2000-2001	Formiga-Cruz <i>et al.</i> , 2002
Spain	Oysters, mussels	104	25	2000-2001	Formiga-Cruz <i>et al.</i> , 2002
Sweden	Oysters, mussels	54	76	2000-2001	Formiga-Cruz <i>et al.</i> , 2002
UK	Oysters	32	56 (prior to depuration)	1995-6	Henshilwood <i>et al.</i> , 1998
UK	Oysters	32	38 (after depuration)	1995-6	Henshilwood <i>et al.</i> , 1998
UK	Oysters	32	73 (summer)	1995-6	Henshilwood <i>et al.</i> , 1998
UK	Oysters	32	31 (winter)	1995-6	Henshilwood <i>et al.</i> , 1998
UK	Oysters	3 (site 1 summer)	0	1995-1997	Doré <i>et al.</i> , 2000
UK	Oysters	4 (site 1 winter)	0	1995-1997	Doré <i>et al.</i> , 2000
UK	Oysters	5 (site 2 summer)	0	1995-1997	Doré <i>et al.</i> , 2000*
UK	Oysters	10 (site 2 winter)	0	1995-1997	Doré <i>et al.</i> , 2000*
UK	Oysters	6 (site 3 summer)	0	1995-1997	Doré <i>et al.</i> , 2000*
UK	Oysters	7 (site 3 winter)	0	1995-1997	Doré <i>et al.</i> , 2000*
UK	Oysters	14 (site 4 summer)	0	1995-1997	Doré <i>et al.</i> , 2000 *
UK	Oysters	21 (site 4 winter)	62	1995-1997	Doré <i>et al.</i> , 2000*
UK	Oysters, mussels	173	5.8	2000-2001	Formiga-Cruz <i>et al.</i> , 2002

\*These oysters were depurated for 42hr pre-analysis

## 6 RISK CHARACTERISATION

### 6.1 Adverse Health Effects in New Zealand

Intestinal disease caused by infection with NLV is not a notifiable disease and the only data reported by public health service providers to the surveillance system concern outbreaks.

There are no data on the incidence of sporadic NLV infection in the New Zealand. However, based on rates of NLV (SRSV) infection from a prospective population-based study in England (Wheeler *et al.*, 1999), approximately 46,000 community cases and 7,300 GP visits caused by NLV gastroenteritis a year have been estimated (Lake *et al.*, 2000). Of these, 33% were assumed to be due to foodborne transmission.

Infection with NLV is thus estimated to be the second most common foodborne cause of infectious intestinal disease in New Zealand (after campylobacteriosis) representing 15-20% of all foodborne cases.

#### 6.1.1 Outbreaks of infection with Norwalk-like virus

Table 6 gives the number of outbreaks and cases caused by infection with NLV for 1997 – 2001. In each of these years infection with NLV caused the highest number of cases of infectious intestinal disease of all the enteric pathogens implicated in outbreaks.

**Table 6: Numbers of outbreaks and cases caused by infection with Norwalk-like virus in New Zealand, 1997-2000**

Year	Number of outbreaks (% of total outbreaks)	Number of cases (% of total cases)	Reference
1997	13 (12.0%)	334 (21.4%)	ESR, 1998
1998	17 (5.4%)	334 (15.6%)	Naing <i>et al.</i> , 1999
1999	62 (17.2%)	875 (37.15)	Perks <i>et al.</i> , 2000
2000	34 (11.8%)	532 (23.2%)	Lopez <i>et al.</i> , 2001
2001	45 (11.6%)	541 (23.3%)	Thornley <i>et al.</i> , 2002

A retrospective analysis of NLV infection outbreaks in New Zealand from July 1997 to June 1999 found a hospitalisation rate of 1.4%. Two fatalities were attributed to NLV infection (case-fatality rate of 0.2%), although both cases who died were over 90 years old with pre-existing medical conditions (Greening *et al.*, 1999). For more recent NLV outbreak cases for which outcome data were available, 5.1% (4/78) and 43.2% (19/44) were hospitalised in 1999 and 2000 respectively (Perks *et al.*, 2000; Lopez *et al.*, 2001).

In contrast, an analysis of NZ Health Information Service hospitalisation data from 1991 – 1997 revealed no hospitalised cases attributed to infection with SRSV (Lake *et al.*, 2000). An analysis of 10 outbreaks in Auckland in 1999 found that six (7%) of 86 cases visited their GP because of their symptoms and no cases were hospitalised (Simmons *et al.*, 2001).

Between 1996 and 2000, most outbreaks occurred over the summer between October and March. This was similar to the pattern observed in Australia, where the seasonal peak occurs between August and December (Wright *et al.*, 1998), but differs from the United Kingdom where disease more commonly occurs in the winter months (Henshilwood *et al.*, 1998). However, in 2001 and 2002, New Zealand outbreaks have been reported throughout the year and there is no longer a clear seasonal peak.

The preliminary results of three gastroenteritis outbreak investigations in Northland between November 1994 and January 1995 were summarised by Jarman and Brown (1995). Oysters harvested from the Waikare Inlet of the Bay of Islands during a two-week period in November 1994 were implicated in all of the outbreaks. A viral aetiology was thought likely and this was supported by the detection of Norwalk-like virus in the stools of one patient. Northland Health requested a recall of products.

Jones and Graham (1995) reported that thirty-six (38%) of 95 people attending a Christmas party at a yacht club in December 1994 developed a gastrointestinal illness. Epidemiological and microbiological investigation indicated that oysters contaminated with NLV were the most likely cause of infection. The oysters were probably from a Bay of Islands farm.

An intensive study of 18 outbreaks of NLV infection was carried out by Wong *et al.* (1997). One of these 18 outbreaks was attributed to imported Chilean oysters based on a retrospective cohort epidemiological study. In total, seven outbreaks of acute gastroenteritis between June and December 1996 were associated with oysters imported from Chile (Bates, 1997). Investigations were carried out for four of these, and while there was insufficient evidence to draw conclusions for two of the outbreaks, for the other two there was strong evidence to implicate imported Chilean oysters. Human enteroviruses were detected in the oysters, indicating faecal contamination, but at that time methods to specifically detect NLV in shellfish were not available.

A retrospective analysis of 50 NLV infection outbreaks in New Zealand from 1997 to 1999 found that in 27 of these food was the predominant mode of transmission. A specific food or food type was epidemiologically implicated in 12 of these 27 outbreaks. The food type most commonly associated was seafood (5/12 outbreaks), and shellfish were implicated in three of these (Greening *et al.*, 1999).

Preliminary analysis of outbreaks of NLV infection reported to the surveillance system during 1999 and 2000 showed that the number of outbreaks in which oysters were reported as the food vehicle was quite variable. In 1999 oysters were cited as the food vehicle in 8 of 61 reported outbreaks, while in 2000 oysters were cited in only one of 32 outbreaks. In 2001 oysters were implicated (but not confirmed) in 2 of the 11 outbreaks of NLV infection for which an implicated food was determined (Thornley *et al.*, 2002)

Norwalk-like viruses have been identified in commercially farmed New Zealand oysters associated with outbreaks of viral gastroenteritis (Simmons *et al.*, 2001). During November-December 1999, ten outbreaks of viral gastroenteritis occurred in which epidemiological evidence implicated oysters as the source of infection. Stool samples from cases were available from nine of these outbreaks, and NLV were detected in all. Traceback of oyster supply chains located oysters from the same batches as those implicated in the outbreaks. NLV were identified in two batches of oysters harvested from different growing areas and

implicated in four of the outbreaks. Sewage effluent from recreational boats was identified as the likely source of contamination in growing waters at one site. Contamination by infected workers through the supply chain was thought unlikely, as no history of illness was identified amongst people involved. This was the first New Zealand report to identify NLV contamination in commercially harvested shellfish and to link their occurrence with outbreaks of viral gastroenteritis.

In August 2001 Auckland District Health Board was notified of three outbreaks of acute gastroenteritis involving 24 people (Jones and Simmons, 2001). Combined epidemiological and microbiological investigations identified Norwalk-like virus (NLV) as the likely pathogen. Fresh, raw Pacific oysters were determined to be the probable source of illness. Six of the 12 (50%) faecal samples obtained from cases in these outbreaks tested positive for NLV; no other pathogens were identified. The origin of the oysters was identified by trace back through the harvesting, processing, and distribution chain to two growing areas in Northland (the Waikare Inlet and Orongo Bay). No NLV were detected in any of the three batches of oysters associated with these outbreaks. However, oysters harvested from the Waikare Inlet a week earlier and associated with a Northland case tested positive for NLV. No source of contamination could be identified down the chain of processing and distribution. As a result of the initial investigation, the two growing areas were closed for a period of 21 days. This was the third cluster of NLV outbreaks implicating oysters harvested from the Waikare growing area since 1994.

As a result of these virus contamination events associated with the Waikare Inlet growing areas, the regulatory authorities made changes to the growing area classifications. Much of the area underwent a reclassification to “Restricted” – which means that oysters can only be harvested if processed by an approved method before consumption. Relaying of oysters to clean waters is an approved treatment. The current (January 2003) situation is that the Upper Waikare area is still classified as “Conditionally Approved”, and the Lower and Middle Waikare growing areas have been reclassified as “Restricted” growing areas. Some individual leases in Lower and Middle Waikare are currently classified “Prohibited”. Relaying of oysters from the “Restricted” and “Conditionally Approved” areas is permitted.

As a result of viral contamination, authorities in Hong Kong temporarily refused entry to farmed North Island Pacific oysters for several months from March 2001. They then established a sampling programme for New Zealand oysters on arrival before clearance. A number of batches were tested and found to be clear of virus. Consequently, Hong Kong now allows all product in except from the Waikare Inlet. US authorities have also reported NLV illnesses in Hawaii from New Zealand shellfish, resulting in recalls of product. These events have caused the closure of major oyster growing areas in Northland and the loss of several million dollars worth of exports.

#### 6.1.2 Information from Ministry of Health’s Investigation of Foodborne illness cases

Information collated through the Ministry of Health’s Investigation of Foodborne Illness programme contains two types of information relating particular foods to episodes of suspected foodborne illness. The food may be implicated as the cause of the 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 organisms known symptoms 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).

Table 7 summarises details of episodes in which molluscs were implicated during the 1997/98, 1998/99, 1999/00, 2000/01 and 2001/02 years.

**Table 7: Summary of results from the Ministry of Health’s Foodborne Illness Investigation Programme, 1997-2002: Episodes associated with shellfish**

Shellfish	Number of episodes	Number of cases	Number of confirmed episodes (faeces)	Number of confirmed episodes (food)
Oysters	49	214	18 (15 x NLV, 1 x <i>Clostridium perfringens</i> , 1 x <i>Campylobacter</i> , 1 x <i>Staphylococcus aureus</i> )	3 (NLV)
Mussels	30	50	1 ( <i>Clostridium perfringens</i> )	
Mussels and oysters	3	5	1 ( <i>Campylobacter</i> )	
Shellfish, unspecified	5	12	1 ( <i>Campylobacter</i> )	1 ( <i>Vibrio parahaemolyticus</i> )
Scallops	4	6	1 (NLV)	
Tuatuas	2	2		
Clam chowder	1	4		
Pipis	1	3		1 ( <i>Vibrio</i> species)
Cockles	1	1		

## 6.2 Adverse Health Effects Overseas

### 6.2.1 Incidence

A prospective population-based study in England found an annual incidence of NLV infection of 1250/100,000 community cases and 199/100,000 GP visits (Wheeler, 1999). No data were available to indicate how many of these were foodborne.

In the United States, foodborne NLV infection has been estimated to cause 9.2 million cases (3150/100,000) per year, representing 40% of the estimated 23 million cases (7900/100,000) of NLV infection per year (Mead *et al.*, 1999). This estimate derived from the assumption that 11% of all acute primary gastroenteritis cases were caused by NLV, based on relatively small studies in Europe and Australia.

## 6.2.2 Outbreaks of infection with Norwalk-like virus

An analysis of foodborne disease outbreaks in Australia found that 9% of outbreaks, making up 38% of cases, were caused by small round structured viruses (Crerar, 1996). For six of the seven NLV outbreaks for which a food vehicle was identified, the vehicle was seafood. In the other outbreak for which a food was identified the vehicle was orange juice served on domestic airline flights. Although NLV could not be found in the juice itself, the outbreak terminated after the juice was withdrawn (Fleet *et al.*, 2000).

A discussion of foodborne viral disease in Australia (Fleet *et al.*, 2000) indicates that a number of NLV outbreaks since 1977 have been associated with oysters, and these involved over 2000 consumers. In 1991 New South Wales made it mandatory for all oysters to be subject to a process of depuration before sale. Although depuration, combined with quality assurance programmes, has apparently markedly reduced further major outbreaks of oyster-associated NLV, the efficacy of depuration has been questioned, and research into this issue is being conducted at the University of New South Wales. An outbreak (97 cases) of NLV infection associated with supposedly depurated oysters occurred in 1996 (Stafford *et al.*, 1997). An outbreak of hepatitis A infection involving nearly 500 cases occurred in New South Wales in 1996-1997 and was traced to oysters, which conformed to bacteriological standards and supposedly had been subject to depuration (Fleet *et al.*, 2000).

Representative reports from the scientific literature concerning outbreaks of NLV overseas are summarised in Table 8.

**Table 8: Examples of overseas NLV outbreaks associated with raw mollusc consumption**

Country	Food implicated	No. ill	Attack rate	Evidence for food implicated	Reference
Australia	Oysters	97	NS	Epidemiological	Stafford <i>et al.</i> , 1997
England	Oysters	9	38%	Epidemiological, examination of stools	Ang, 1998
USA	Oysters and clams	1017 (813 assoc. with clams)	NS	Epidemiology, radioimmunoassay, seroconversion	Morse <i>et al.</i> , 1986
USA	Oysters, steamed and raw	>180	43-100%	Epidemiological, electron microscopy of stools	FDA, 1993
USA	Oysters	45	63%	Epidemiological, raised antisera, electron microscopy of stools	FDA, 1994
USA	Oysters	70	83%	Epidemiological, electron microscope and RT-PCR examination of stools.	Kohn <i>et al.</i> , 1995
USA	Oysters	171	NS	Epidemiological RT-PCR of viruses from oysters	Shieh <i>et al.</i> , 2000

NS = not stated

Some very large outbreaks of NLV infection have been reported overseas. Presumably this reflects either the greater scale of the food supply with large production by growing areas, or the widespread pollution of numerous smaller growing areas. Oysters are the shellfish most commonly implicated as the source of infection.

A review of outbreaks of nonbacterial gastroenteritis in the US from 1997 to 2000 found that for the 217/233 (93%) of the outbreaks, NLV could be detected in faecal samples by either PCR or electron microscopy (Fankhauser *et al.*, 2002). Restaurants and events with catered food were the most common settings, and contaminated food was the most common (57% of outbreaks) mode of transmission. This presumably included food contaminated by infected food handlers as the other modes of transmission were person to person contact (16% of outbreaks) and contaminated water (3%). It was noted that none of the infections was related to the consumption of contaminated oysters.

### 6.2.3 Contributions to outbreaks and incidents

The proportion of reported outbreaks due to infection with NLV are shown for the US and the UK in Table 9.

**Table 9: Contribution of NLV to foodborne disease outbreaks and incidents overseas**

Country	Year	No. (%) Outbreaks	No. (%) of cases	Reference
UK	1995	366 (43.9)	11,215 (53.9)	Evans <i>et al.</i> , 1998
	1996	314 (42.8)	11,484 (58.9)	Evans <i>et al.</i> , 1998
USA	1993-1997	24 (0.9)	1,233 (1.4)	Olsen <i>et al.</i> , 2000
USA	1989	1 (0.2)	42 (0.3)	Bean <i>et al.</i> , 1996

The contribution of NLV to foodborne disease as reported is highly variable, from almost 60% of outbreak cases in the UK to less than 1% in the USA. However, these differences are likely to largely be explained by differences in surveillance systems.

### 6.3 **Qualitative Estimate of Risk**

Oysters have been linked to a number of outbreaks of NLV infection in New Zealand. This has largely been based on epidemiological association, although in some recent outbreaks new methodology has allowed the identification of NLV contamination in shellfish samples as well. It seems likely that these new molecular methods will continue to identify viral contamination in this food group. Other types of shellfish have not been reported as vehicles for NLV transmission in New Zealand although clams have been implicated in an outbreak in the United States and NLV contamination in mussels has been reported in France. It should be noted the mussels are rack farmed in France and the fact that they are grown in more shallow environments than normal in New Zealand may have contributed to the contamination reported.

The ability to concentrate the virus makes shellfish growing in seawater especially likely to be a transmission vehicle. In addition some types of shellfish are often consumed raw, or after light heating which is unlikely to inactivate the virus.

The presence of NLV in shellfish in New Zealand appears to be largely a result of faecal contamination of the growing environment, rather than contamination by harvesters or food handlers. A review of ten NLV outbreaks in Auckland concluded that contamination of seafood products during processing, distribution or food handling was unlikely (Simmons *et al.*, 2001). Instead, contamination of oysters at the growing site, probably by sewage discharge from boats was suspected as the source. However, overseas, infected harvesters have been implicated in contamination of shellfish by polluting the waters with faecal material during harvesting (Kohn *et al.*, 1995).

#### 6.4 Risk Categorisation

The rationale for categorisation of food/hazard combinations is presented in Appendix 1.

The proportion of severe outcomes (hospitalisation, long term sequelae, and death) resulting from NLV infection is considered to be very low. No long term illnesses resulting from NLV infection have been reported, and death from dehydration is very rare (CDC, 2001). Data cited in Section 6.1.1 on hospitalisation and fatality rates indicate that both are very low.

Although in one analysis of outbreaks (Greening *et al.*, 1999) hospitalisation rates are higher, NLV has been placed in the lowest severity category (<0.5% severe outcomes) as other analyses suggest lower rates, and outbreaks may not be indicative of rates amongst sporadic cases.

For the purposes of estimating the numbers of cases of foodborne disease in New Zealand (Lake *et al.*, 2000) it was assumed that 33% of NLV infections were due to foodborne transmission. The total rate of NLV infection (including unreported cases) attributable to food contamination in New Zealand was thus estimated to be of the order of 478 per 100,000 of population, although it should be noted that this is based on an English incidence rate for NLV, not New Zealand data.

A retrospective analysis of NLV outbreaks in New Zealand found that foodborne transmission was the predominant mode in 27 of 47 outbreaks (Greening *et al.*, 1999). The food involved was identified in 12 of these. The food type most commonly associated was seafood (5/12 outbreaks), and shellfish were implicated in three of these (Greening *et al.*, 1999). If it is assumed that these proportions will also be applicable to sporadic cases of NLV, then these data suggest that the estimated rate of NLV infection due to shellfish would be approximately 11% (3/27) of the total food rate or approximately 52/100,000 of population. This would place NLV infection due to consumption of shellfish in the second incidence category (10-100/100,000 of population).

#### 6.5 Summary

Food/hazard combination	Severity	Incidence	Trade importance	Other considerations
NLV in raw molluscan shellfish	3 (<0.5% serious outcomes)	2 (10-100 per 100,000)	Emerging – food poisoning outbreaks linked to NZ oysters have resulted in damage to the shellfish export industry	Implications for New Zealand's image as a tourist destination

## 7 RISK MANAGEMENT INFORMATION

### 7.1 Source Contamination and Other Transmission Routes

#### 7.1.1 Sewage

The discharge of sewage by commercial and recreational boats was suspected of causing the contamination of commercial oyster growing areas during the investigation into outbreaks in the Auckland area (Simmons *et al.*, 2001). Provisions in the Resource Management (Marine Pollution) Regulations 1998 and subsequent amendments aimed to reduce the impact of such contamination. From July 2002, the discharge of 'Grade A treated' sewage from boat holding tanks is permitted beyond 100 metres from marine farms, and 'Grade B treated' or untreated sewage discharge is permitted beyond 500 metres from marine farms or mataitai reserves in water depths greater than five metres. A rule may only be included in a regional coastal plan or a proposed regional coastal plan relating to the discharges under this regulation if the rule increases the distances seaward or increases the depth specified. Most recreational boats discharge either untreated or grade B treated sewage.

There has been increasing impact on shellfish growing areas from septic tank leachate, sewage discharges and boat sewage in the last few years and it is generally expected that this situation will get worse. Sewage contamination may arise from unexpected problems at sewage treatment plants or septic tank runoff. For example, oil contamination shut down the Warkworth sewage treatment in July 2002 causing untreated sewage to be discharged, requiring the closure of local oyster farms (New Zealand Herald 30 July 2002). Runoff from septic tank systems in Okiato Point is suspected of causing contamination of Waikare Inlet oyster farms (The Northern News 16 May 2002).

This suggests that bivalve shellfish farming and recreational shellfish gathering will be at increasing risk of viral contamination. To manage this problem additional information is needed in the following areas.

- Characterisation of the survival of NLV in boat and domestic sewage in order to define the contamination process.
- Determination of prevalence of NLV in key growing/recreational shellfish gathering areas, including sufficient coverage to define seasonality.
- Persistence of NLV in the environment and in shellfish.
- Characteristics of removal or natural depuration in the environment and in post-harvest treatment.

#### 7.1.2 Post harvest treatments: depuration and relaying

In New South Wales, depuration in tanks prior to sale appears to have reduced the number of oyster associated outbreaks, although this measure may not be completely effective (Fleet *et al.*, 2000). Depuration in tanks for short time periods is rarely used in New Zealand and no depuration of oysters is carried out (Dr Gail Greening, personal communication). The efficacy of depuration for virus removal has been questioned and research into this issue is being carried out at several overseas centres, including in Australia (University of New South Wales), United Kingdom (CEFAS) and France (IFREMER). Studies so far indicate that virus

elimination by tank depuration is of low efficacy (Muniain-Mujika *et al.*, 2002; Formiga-Cruz *et al.*, 2002). Bacterial removal is efficient, but viruses can persist in the shellfish gut for several days or weeks. Temperature has been reported to be a significant factor in virus and bacteriophage removal, with little removal at temperatures below 9°C (Doré *et al.*, 1998; 2000). There are also reports of viruses becoming sequestered in the shellfish flesh, but it is not known if they remain infectious in this state (Hay and Scotti, 1986).

Relaying of shellfish to clean growing waters is an approved treatment (under the New Zealand Shellfish Quality Assurance Circular 1995 (IAIS 005.1)) that is more successful for virus removal. EU Directive 91/492 for depuration of enteric viruses specifies that, for shellfish grown in heavily contaminated waters, a minimum relaying period of two months in clean waters is required. Research in progress in New Zealand investigating the removal of NLV from oysters during relaying supports this time frame for virus removal (Greening *et al.*, 2003; in press).

### 7.1.3 Imported shellfish

Molluscs (cooked and raw) including clams, cockles, mussels, oysters and scallops are prescribed foods under the New Zealand (Mandatory) Food Standard 1997. This means that imports of these products can be required to demonstrate compliance with conditions related to the presence of heavy metals, marine biotoxins and pathogenic bacteria. The application of this standard to imported molluscan shellfish resulted in a requirement to test for or provide test results from an approved overseas laboratory to demonstrate acceptable levels of *Listeria monocytogenes* and marine biotoxins (<http://www.akphp.co.nz/akphp/Services/ImportedFood/Molluscs.htm>). Specific conditions apply to shellfish imported from Chile ([http://www.akphp.co.nz/akphp/Services/ImportedFood/Molluscs\\_\(Chile\).htm](http://www.akphp.co.nz/akphp/Services/ImportedFood/Molluscs_(Chile).htm)), including:

- the provision of acceptable evidence that enterovirus contamination (by workers on harvest vessels and at the pack house) are being managed, prior to any consignments being shipped, and,
- in the absence of a finalised relationship with SERNAPESCA, the provision of acceptable evidence that only oysters harvested and packed in accordance with the NSSP (or an equivalent accepted by the New Zealand Food Safety Authority), and,
- testing of consignments on arrival in New Zealand will be required to verify the hazards in Chile are being managed. Compliance with both microbiological and marine biotoxin criteria is required.

Lots must also be tested, with specified microbiological criteria, for aerobic plate count at 35°C, faecal coliforms, coagulase-producing *Staphylococcus*, *Listeria monocytogenes* and *Salmonella*.

### 7.1.4 Food handlers and person-to-person transmission

Infected food handlers can contaminate foods during preparation. This is especially important for foods such as salads, which are consumed without further cooking. The exclusion of foodhandlers for 48-72 hours following gastrointestinal illness has been recommended to

prevent such contamination (CDC, 2001). Foodhandlers are not considered to be a major factor in the contamination of raw shellfish.

Food handler contamination of food is considered to be foodborne transmission despite the human source. It is difficult to disentangle food handler contamination and source contamination of food vehicles, but the former is clearly significant. Contamination by an infected foodhandler was implicated in the foodborne transmission of seven of 27 foodborne NLV outbreaks in New Zealand between July 1997 and June 1999 for which a mode of transmission was identified (Greening *et al.*, 1999). In the analysis of outbreaks for 2001 (Thornley *et al.*, 2002) all of the eight NLV infection outbreaks with high level evidence for the mode of transmission identified infected food handlers as the source of infection.

A working group including staff from Public Health Units, the New Zealand Food Safety Authority, and ESR have developed a “Food Business Sickness Policy” and supporting material for the food industry. This is intended to be included in a Food Safety Programme and manage the risk from infected persons in food premises. It includes clearly defined minimum periods between symptoms of illness (diarrhoea or vomiting) and when the person can return to work activities that involve food handling. All foodborne pathogens are considered, including NLV. It was recommended that food handlers infected with NLV continue to be absent from work for a period of at least 48 hours after symptoms have ceased. This policy was trialled by several Public Health Units late in 2002, and has now been made available to the food industry.

Person-to-person transmission can also occur easily. In outbreaks primary cases are often associated with a food or water vehicle, whereas secondary and tertiary cases occur via person-to-person transmission. Vomiting, the faecal-oral route, and aerosols can all contribute to the spread of infection. The control of such transmission can be difficult, given the ability of viruses to spread via environmental surfaces, and possibly even aerosols generated by handwashing (CDC, 2001).

## 7.2 Relevant Food Controls

Bivalves produced commercially in New Zealand (for both local and export markets) are covered by the Ministry of Agriculture and Forestry Shellfish Sanitation Programme (responsibility for the programme was transferred to the New Zealand Food Safety Authority in July 2002). This programme requires products to meet quality standards for faecal coliform levels set out in the New Zealand Shellfish Quality Assurance Circular 1995 (IAIS 005.1). The Sanitation Programme is assessed regularly by the US Food and Drug Administration for compliance with their standards. The programme does not include virus testing. There are no international standard methods for virus testing. The European Union Community Reference Laboratories are developing and validating methods that will permit implementation of a viral indicator or standard. This is expected within 3-5 years (David Lees; EU EOI FP6.2002).

The seafood industry in New Zealand is mainly an exporting industry and compliance with Hazard Analysis and Critical Control Point (HACCP) based Risk Management Plans (RMPs) is compulsory. Generic models have been developed to assist the Seafood Industry with their own HACCP plans (FIICC & MAF RA (Meat and Seafood), 1997).

The Seafood Standards Council (formerly the Fishing Industry Inspection and Certification Council) has been established as a consultative forum between the seafood industry and the Ministry of Agriculture and Forestry. The Council's role is to prepare, and assist with implementation of standards to meet regulatory requirements for food safety and labelling associated with market access. Implementing HACCP-based RMPs is one means of meeting these regulatory requirements. The consultation process will include the regulatory standards, specifications and codes of practice to be promulgated under the Animal Products Act.

### 7.2.1 The Animal Products Act

The [Animal Products Act 1999](#) reforms the New Zealand law that regulates the production and processing of animal material and animal products (including marine species) to:

- manage associated risks; and
- facilitate overseas market access.

The Animal Products Act requires all animal products traded and used to be "fit for intended purpose". This means they must meet New Zealand animal product standards. The New Zealand animal product standards are contained in Part 1 of the [Animal Product Regulations 2000](#).

The Animal Products Act (except for Part 2) and the transitional Act commenced on 1 November 1999. Part 2 of the Animal Products Act commenced on 20 November 2000. Part 2 provides the requirements for risk management programmes.

The risk management system potentially applies anywhere in the value chain from production, through processing to the market. The risk management system comprises the following main types of controls:

- risk management programmes;
- regulated control schemes; and
- controls relating to the export of animal material and animal products.

By 1 November 2002, all animal product primary processing businesses, except those exempt under the Act or under the [Animal Products \(Exemptions and Inclusions\) Order 2000](#), must have a Risk Management Programme.

A Risk Management Programme is a documented programme to identify and manage biological, chemical and physical hazards. The programme is to be based on the principles of Hazard Analysis and Critical Control Point (HACCP): identifying the hazards, the systems of control, and demonstrating that the controls are effective. Risk management programmes are to be designed by individual businesses for the animal materials used, the processes performed and the product range produced.

In June 2002 MAF circulated a Public Discussion Paper (No. 32) entitled "Proposed Bivalve Molluscan Shellfish Regulated Control Scheme". This paper proposed that a regulated control scheme be established under the Animal Products Act, in preference to risk management programmes. The scheme would cover growing, harvesting, transport and

handling of bivalve molluscan shellfish, but not further processing which would be subject to risk management programmes developed by individual businesses. The proposal does not specifically address viral contamination. The details of the proposed Regulated Control Scheme are still being developed.

### **7.3 Economic Costs**

The annual economic cost to New Zealand of infection with NLV has been estimated as \$3,586,000, which represents 6.5% of the total economic cost of foodborne infectious disease (Scott *et al.*, 2000). The number of cases used for this estimate was based on the assumption that 33% of infections with NLV are foodborne (Lake *et al.*, 2000) and incidence data from a prospective study of infectious intestinal disease in England (Wheeler *et al.*, 1999). Due to the short duration of illness and rarity of hospitalisation the economic cost of NLV infected cases is frequently small in comparison with bacterial pathogens, and mostly comprises the cost of lost productive time. However, in 2002, NLV was the predominant cause of large gastroenteritis outbreaks both nationally (hospitals, rest homes, school camps) and internationally (cruise ships, hospitals, schools). As large numbers of staff, guests and patients became ill, hospital wards were closed and cruise ship vacations cancelled. The subsequent economic cost of these NLV outbreaks has been significant.

If it is assumed that approximately 11% of all foodborne cases of NLV are due to consumption of shellfish then the percent of the total cost of foodborne disease due to NLV derived from shellfish will be of the order of 0.65%.

## 8 CONCLUSIONS

### 8.1 Description of Risks to New Zealand Consumers

#### 8.1.1 Risks associated with raw mollusca

The current overall rate of NLV infection in New Zealand can only be approximated, due to the non-notifiable nature of these infections. However one estimate is approximately 478 cases per 100,000 population caused by foodborne transmission (based on an estimate that approximately 33% of cases are caused by foodborne transmission). Based on analyses of outbreaks in New Zealand (Greening *et al.*, 1999) and the US (Fankhauser *et al.*, 2002) this is probably an underestimate.

A significant number of outbreaks, as well as some sporadic cases, of NLV infection have been reported to the surveillance system where shellfish, specifically oysters, were implicated as the food vehicle. An analysis of outbreaks of NLV infection in New Zealand from 1997 to 1999 suggested that shellfish may be the vehicle in approximately 11% of outbreaks, and oysters have been implicated in several outbreaks since then.

The limited survey work carried out in New Zealand suggests that NLV contamination of shellfish is not uncommon and it appears likely that shellfish account for a significant proportion of foodborne cases of NLV. While the clinical consequences of NLV infection are generally not severe, the high number of cases of NLV infection in New Zealand, as indicated by outbreak data, means that NLV infection will still constitute a significant public health concern.

Despite representing the bulk of New Zealand's shellfish aquaculture industry, mussels do not appear to be an important vehicle for NLV transmission. This is probably because they are grown in deeper water where viral contamination is less likely, and they are more likely to be cooked before consumption.

The very limited information available suggests that oysters are not a common target for recreational gathering of shellfish. This indicates that risk management measures should focus mainly on the oyster aquaculture industry, but also recognise that there may be particular groups, such as Maori or people in Northland, who are at greater risk from recreational shellfish gathering.

Shellfish exports represent a significant amount of earnings for New Zealand, and although oysters are a much smaller component of shellfish exports than mussels, any contamination of shellfish with NLV would be detrimental to our seafood export industry. There also appears to be real potential for damage to New Zealand's reputation as a tourism destination as many shellfish growing areas are also popular tourist destinations (Bay of Islands, Coromandel, Waiheke, Marlborough, Mahurangi, etc.).

While New Zealand produced oysters clearly represent a risk for NLV infection, it should be remembered that reasonably large quantities of shellfish are imported and outbreaks of acute gastroenteritis in 1996 were associated with imported oysters. It is uncertain what impact testing requirements for imported shellfish under the New Zealand (Mandatory) Food Standard 1997 has had on the quality of imported shellfish.

### 8.1.2 Risk associated with other foods

Other foods implicated in outbreaks of NLV infection in New Zealand have included dairy products, fruit and vegetables, and meat (Greening *et al.*, 1999).

Contamination by food handlers means that theoretically any food can be a vehicle for NLV transmission, but this is unlikely to be a major source of contamination for shellfish. Nevertheless, infected food handlers are a major source of contamination of foods implicated in outbreaks (see Section 7.1.4).

Person-to-person spread of NLV infection is common, often occurring as a secondary transmission route after primary infection via food.

The recently developed ability to detect NLV contamination in foods will provide much needed information on sources of infection, as well as helping to gain an estimate of the relative importance of these differing transmission routes. Data have only been available for a few years, but regular analysis of reported outbreak information should be conducted to build up and improve the picture of NLV transmission in New Zealand.

### 8.1.3 Quantitative risk assessment

The principal barrier to the development of a quantitative risk assessment for NLV in raw molluscan shellfish is the shortage of data on the prevalence of contamination of shellfish. As well as information on prevalence, it would be important to understand the seasonal and geographical distribution of contamination. A major barrier to collection of good quality quantitative data is also the lack of a culture system for the virus. Thus it is not possible to determine levels of infectious virus present in shellfish or the environment. Most data are based on molecular detection of NLV. The advent of real time PCR assays has enabled semi-quantitative estimates of viral RNA present in shellfish samples to be made, but this does not relate to infectivity. The only measure of infectivity currently available is by human dose response experiments. However, NLV is known to be environmentally resistant and retain infectivity for prolonged periods. Naked RNA is rapidly degraded in the environment, therefore detection of viral RNA in environmental samples indicates that the viral particle is still intact and therefore is potentially infectious.

## 8.2 **Commentary on Risk Management Options**

From analysis of outbreak data it seems likely that, as a risk management measure for NLV infection in the New Zealand population, control of infected food handlers is likely to have a greater effect on the number of local cases than further controls on shellfish. Nevertheless, improved control of NLV contamination in shellfish is desirable for both public health reasons and to protect New Zealand shellfish exports.

The control of contamination of molluscan shellfish in the growing environment is currently managed by growing water monitoring and shellfish monitoring. None of this monitoring includes mandatory testing for viruses (New Zealand Shellfish Quality Assurance Circular 1995 -IAIS 005.1). Indeed, the recent closure of oyster farming waters in the north of New

Zealand was in response to identification of oysters from the region as causative agents in viral food poisoning outbreaks, not due to detection of a water quality concern. The waters in this area met statutory requirements for bacterial contamination. Risk management could obviously be improved by addition of viral parameters to the water quality requirements, but routine methods for the monitoring of viruses in shellfish or water are not yet available.

Shellfish from lightly polluted water may be depurated to decrease their contaminant loading. This was made a statutory requirement in New South Wales in 1991 for farmed oysters, due to concerns over high numbers of cases of viral gastroenteritis attributed to oysters. However, outbreaks of NLV and hepatitis A infection from apparently depurated oysters have occurred in New South Wales since this measure was introduced. Depuration has been shown to be an inefficient means of removing viruses from shellfish. One recent study reported elimination of both human viruses and F-RNA bacteriophage after 5 days tank depuration at 17-18°C (Muniain-Mujika *et al.*, 2002) but in another study F-RNA bacteriophage was still detected after 7 days depuration at 18°C (Doré *et al.*, 1998). Depuration is allowed under the New Zealand Shellfish Quality Assurance Circular 1995-IAIS 005.1, following registration of the depuration facility. However, current indications are that this would not be an effective risk management strategy for New Zealand, and as such the NZFSA has prohibited depuration as a means of treatment of viral contaminated shellfish.

Relaying of product from 'restricted' growing areas to clean waters is a more appropriate option that is currently practised in New Zealand. Relaying of shellfish to clean growing waters is an approved treatment that has been shown to be successful for virus removal. The EU Directive 91/492 for depuration of enteric viruses specifies that, for shellfish grown in heavily contaminated waters, a minimum two months relaying period in clean waters is required and that the relay area must be a minimum of 300 metres from any production area. Current New Zealand research investigating the removal of NLV from oysters under relaying conditions supports this time frame for virus removal (Greening *et al.*, 2003, in press). The EU directive is based on data for bacterial depuration but may not be optimum for viral depuration; to date there are no published data on virus removal under relaying conditions. The NZFSA has approved relaying as a process for virus cleansing with the requirements that the relay period be for a minimum of eight weeks and the relay area be a minimum of 300 metres from other production areas.

Researchers in the US and Europe have proposed the use of F-RNA bacteriophage as a viral indicator. Published reports (Henshilwood *et al.*, 1998; Doré *et al.*, 1998, 2000) have indicated a correlation between the occurrence of NLV and F-RNA bacteriophage in shellfish, especially from shellfish gathered from Category B and C waters. The limited amount of New Zealand data does not support this finding, and so the use of F-RNA bacteriophage in New Zealand may not be useful for industry or regulators.

Adenoviruses, which are frequently present in shellfish, are alternative human viruses which are also now being considered as a potential indicator virus (Formiga-Cruz *et al.* 2002). It is planned to address this lack of data on viral prevalence within the next 2-3 years through a comprehensive prevalence study of viruses (NLV, enterovirus, adenovirus and F-RNA bacteriophage) in commercially farmed and feral shellfish from growing areas around New Zealand. This research project is currently being reviewed by FRST and, if funded, will be carried out at ESR Porirua.

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## APPENDIX 1: CATEGORIES FOR RISK PROFILES

The assignment of a category for a food/hazard combination uses two criteria: incidence and severity.

### 1. Incidence

The incidence is an estimate of the proportion of the foodborne disease rate due to an individual hazard, that is transmitted by a single food or food group.

The overall rate of foodborne disease caused by individual hazards can be derived from information in the published estimate of foodborne disease (Lake *et al.*, 2000). This estimate has been updated to reflect more recent notifications rates for the 12 months to June 2001, but still using 1996 census figures (3,681,546 population). Rates include estimates for unreported cases who do not present to a GP.

Disease/organism	Food rate (/100,000 population) Calculated for 12 months to June 2001	Food rate (/100,000 population) Calculated for 12 months to December 1998
Campylobacteriosis	1320	2047
Listeriosis	0.4	0.4
VTEC/STEC	1.9	1.4
Salmonellosis	176	230
Yersiniosis	38	62
Shigellosis	7	7
NLV*	478	478
Toxins*	414	414
Typhoid*	0.3	0.3
Hepatitis A*	0.4	0.4

\* not recalculated.

These are **total** foodborne rates, so it is probably safe to assume that in most cases the rates associated with a particular food are likely to be an order of magnitude lower. For instance, a category of “>1000” would only be assigned if it was decided that all campylobacteriosis was due to a single food/food type.

The following categories are proposed for the rates attributable to a single hazard/food (or food group) combination:

Category	Rate range	Comments/examples
1	>100	Significant contributor to foodborne campylobacteriosis Major contributor to foodborne NLV
2	10-100	Major contributor to foodborne salmonellosis Significant contributor to foodborne NLV
3	1-10	Major contributor to foodborne yersiniosis, shigellosis
4	<1	Major contributor to foodborne listeriosis

A further category, of “no evidence for foodborne disease in New Zealand” is desirable, but it was considered more appropriate to make this separate from the others. Also separate is another category, of “no information to determine level of foodborne disease in New Zealand”.

The estimation of the proportion of the total foodborne disease rate contributed by a single food or food group will require information from a variety of sources including:

- exposure estimates
- results from epidemiological studies (case control risk factors)
- overseas estimates

For illnesses where the rate is <1 per 100,000 the ability to assign a proportion is unlikely to be sensible. For such illnesses it may be more useful to consider a Risk Profile across the range of all high risk foods, rather than individual foods or food groups.

## 2. Severity

Severity is related to the probability of severe outcomes from infection with the hazard.

The outcomes of infectious intestinal disease are defined in the estimate of the incidence (Lake *et al.*, 2000) as:

- death
- hospitalised and long term illness (GBS, reactive arthritis, HUS)
- hospitalised and recover
- visit a GP but not hospitalised
- do not visit a GP

The first three categories of cases were classed as severe outcomes. Some hospitalisations will result from dehydration etc. caused by gastrointestinal disease. However, for infections with *Listeria* and STEC hospitalisation will result from more severe illness, even if recovery is achieved.

The proportion of severe outcomes resulting from infection with the hazards can be estimated from the proportion of cases hospitalised and recover, hospitalised and long term illness, and deaths (Lake *et al.*, 2000).

Disease/organism	Percentage of outcomes involving death or long term illness from foodborne cases
Campylobacteriosis	0.3
Listeriosis	60.0
VTEC/STEC	10.4
Salmonellosis	1.0
Yersiniosis	0.4
Shigellosis	2.7
NLV	Assumed to be <0.5%
Hepatitis A	15.4
Typhoid	83.3
Toxins	Assumed to be <0.5%

Categories for the probability of severe outcomes are suggested as follows:

Severity Category	Percentage of cases that experience severe outcomes	Examples
1	>5%	listeriosis, STEC, hepatitis A, typhoid
2	0.5 – 5%	salmonellosis, shigellosis
3	<0.5%	campylobacteriosis, yersiniosis, NLV, toxins

There are a number of hazards for which the incidence of foodborne disease is uncertain. These have been assigned to the above severity categories as follows:

### Severity category 1:

#### Bacteria

*Clostridium botulinum*

#### Protozoa

*Toxoplasma*

### Severity category 3:

#### Bacteria

*Aeromonas/Plesiomonas*

*Arcobacter*

*E. coli* (pathogenic, other than STEC)

*Pseudomonas*

*Streptococcus*

*Vibrio parahaemolyticus*

#### Viruses

Others (e.g. rotavirus)

#### Protozoa

*Giardia*

*Cryptosporidium*

*Cyclospora*

Others (e.g. *Entamoeba*)

### Proposed Category Matrix

<b>Incidence</b>	<b>&gt;100</b>	<b>10-100</b>	<b>1-10</b>	<b>&lt;1</b>
<b>Severity 1</b>				
<b>Severity 2</b>				
<b>Severity 3</b>				

Alternatives:

No evidence for foodborne disease in New Zealand

No information to determine level of foodborne disease in New Zealand