Improving the Management of the Risk of Human Enteric Viruses in Shellfish at Harvest

Case Studies of Oyster Growing Areas Implicated in Norovirus Illness Events

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EXECUTIVE SUMMARY

INTRODUCTION

Most countries in the developed world use classification systems to determine where it is safe to commercially harvest shellfish. Countries have developed their own specific programmes, but most follow a combination of the following features:

a) A public health sanitary survey of the shellfish catchment area to assess the potential pollution risks.
b) Water and shellfish samples (using maximum limits of microbial indicator organisms, heavy metals and marine biotoxins).
c) Control of harvest times.
d) Labelling of shellfish so that people know the origin of the product.

Such classification systems and associated management of shellfish quality at harvest have been very effective in preventing food-borne illness associated with chemical contamination and bacterial pathogens. However there is now a large amount of documented epidemiological evidence indicating that shellfish consumers are not always protected from illnesses arising from human enteric viruses such as Hepatitis A virus and noroviruses.

Both Australian and New Zealand shellfish industries and regulatory authorities share an interest in improving their shellfish programmes to reliably manage the risk of viral contamination of shellfish, and this study is a collaborative project between the Australian and New Zealand industries. The project represents the first step in a wider project responding to the need to develop better management strategies to protect consumers from shellfish-borne viral pathogens. The aims of the project are to:

- Identify the fundamental reasons why the current bivalve shellfish classification and management systems used in Australia and New Zealand can fail to protect consumers from viral contamination in shellfish;
- Identify and evaluate potential frameworks for improved management strategies for shellfish growing areas, and their barriers to implementation, including any information gaps;
- Make recommendations on priorities for future work to develop and implement improved management strategies to protect shellfish from viral contamination.

The basis of the research is retrospective analysis across eight case studies drawn from New Zealand and New South Wales between 1990 and the present, each based on a norovirus (NoV) illness event associated with the consumption of oysters that were identified as having been contaminated with NoV before harvest. At the outset of this project a review of current information was undertaken to provide contextual information for the case studies.

METHODOLOGY

The broad framework for case study-based research used in this project was adapted from methodologies set out in Eisenhardt (1989), Kohn (1997) and Baxter & Jack (2008). The research question for this aspect of the project was defined as: *What key factors result in failure to prevent norovirus contamination of oysters in growing areas and resultant norovirus illness outbreaks in consumers?*
As the aim of the research was to identify the common and divergent factors that fail to prevent norovirus events across different sites, a multi-case study using cross-sectional analysis based on a sample of events from two countries (New Zealand and New South Wales, Australia) was considered appropriate. In order to maintain relevance to current conditions, the sample was temporally bounded to events since 1990, and bounded in scope to shellfish growing areas with an operative Shellfish Quality Assurance Programme (SQAP) at the time of the illness outbreak. (This latter condition restricted the temporal range of cases from NSW, since the SQAP was not introduced to NSW oyster growing areas until late 1990s-early 2000s). Based on this selection process, eight case studies across five oyster growing areas were selected.

Multiple data collection methods were used. The primary sources of information were reports written about each growing area and case, including Growing Area Sanitary Survey reports, Growing Area Annual Review reports, epidemiological reports of illness outbreaks, and reports of growing area investigations following illness outbreaks. These were supplemented by Council reports provided to the Food Authorities at the time of growing area investigations, and copies of correspondence and monitoring data provide to us by the Food Authorities. Additional information was provided to us by Food Authorities, Councils and oyster farmers either verbally or by email on request.

In order to provide a systematic process of data collection and subsequent analysis, a guiding framework comprised of potential control points was developed and documented. Data analysis consisted of two phases: analysis of within-case data; and cross-case analysis. Within-case analysis comprised detailed case study descriptions for each site, followed by analysis using the framework. Cross-case analysis by examining cases in groups was undertaken to determine whether there were some fundamental issues common to different growing areas. Differences between cases were also explored. Data analysis and data collection were interlinked iterative processes: any data gaps highlighted in the data analysis process were filled by further data collection where possible, and themes or issues that emerged were tested within and across all cases.

**CONCLUSIONS FROM CASE STUDY ANALYSIS**

Following is a very brief summary of the conclusions drawn from the study:

- The study demonstrates that the manner in which *E. coli* /faecal coliform indicators are used in the current shellfish quality assurance programme fails to consistently predict the risk of enteric virus contamination in shellfish harvested for market. This places a high reliance on the other components of the Shellfish Quality Assurance Programme in managing the risk of enteric viruses.

- The case studies suggest that the implementation of the sanitary survey components of the programme failed to adequately protect consumers from illness arising from NoV contamination as a result of:
  - Insufficient reliable information gathered during the sanitary survey process to allow an adequate assessment of the risk of virus contamination of shellfish in the growing area, driven by
- Reliance on other agencies such as Councils to provide key information about growing areas and their catchments, and difficulties in obtaining sufficient reliable, high quality information;

- Assumptions by Food Authorities made about the quality of management of potential contamination sources by Councils and other parties without detailed information to support these assumptions;

- Barriers to accessing private properties in some cases prevent Food Authority officers inspecting potential contamination sources themselves;

- In some cases there is a lack of environmental information – particularly regarding the hydrodynamics of the growing area, movement of groundwater into coastal waters etc.

  - The design of the Shellfish Quality Assurance Programme, which incorporates infrequent detailed sanitary surveys and minimal field observation by the Food Authority in the catchment annually, assumes little change will occur in the risk of viral contamination in the growing area through time. The case studies suggest that this assumption is not correct, and that change may be impacted by the following:

    - There are increasing pressures from competing resource uses, including urbanisation of coastal areas. Particularly in New Zealand, there is little cross-agency planning and environmental policy is not well-designed to protect water quality in shellfish growing areas, especially with respect to the cumulative impact of many small changes. In New Zealand, the shellfish industry faces high costs in protecting their water quality through the processes available through the Resource Management Act.

    - The implementation of existing environmental policies by Councils (including both in New Zealand and Australia) can be very poor, driven by lack of resources (a key factor), poor management (resulting in inadequate management systems), and lack of technical competence and expertise.

    - Lack of expertise and uncritical reliance on standards and guidelines in the design of wastewater management systems by consultants and Council officers can result in systems that are inadequately designed to prevent viral contamination of growing areas.

- Failure to continue to manage the risk of sources of viral contamination that have previously been implicated in NoV illness events increases the risk of recurrence of viral contamination. In some cases this was evident in:

  - Inadequately detailed documentation of investigations (which potentially limits the transfer of institutional knowledge when personnel change, and inhibits the
continued monitoring of potential sources that history showed may be higher risk than others);

○ Failure to institute and sustain management plans to ensure that issues that caused virus contamination are not repeated.

• Because *E. coli* and faecal coliform indicators do not reliably predict the risk of human enteric virus contamination, there is a need for a feedback mechanism within the shellfish programme to confirm the validity of the conclusions drawn in the sanitary survey component of the programme with respect to the risk of viruses.

○ The absence of a universal indicator of the risk of virus contamination is a key information gap that acts as a significant barrier to this.

• In the absence of a universal viral indicator, feedback mechanisms may be able to be designed using a combination of techniques:

○ Viral indicators such as male-specific bacteriophage that could be used as predictors of risk within a defined set of circumstances.

○ Microbial source tracking applied close to the potential sources of contamination that might impact on growing areas, to determine whether human faecal contamination sources are present.

○ Testing for specific viruses of concern under specific circumstances (e.g. to identify whether shellfish are implicated in an illness outbreak, or to confirm that known contamination has cleared from shellfish in a growing area).

Key information gaps relevant to this include:

○ A NoV test method that distinguishes between infective and non-viable viruses;

○ Lack of knowledge about the effectiveness of male-specific bacteriophage as an indicator of risk of viral contamination in oyster growing areas in New Zealand and Australian conditions.

○ Sensitive and specific markers for human faecal contamination able to be reliably detected in a medium that captures information about water quality over a period of time (e.g. in shellfish, adsorbent media).

• The reluctance to sample shellfish for viruses in commercial shellfish growing areas means that it is difficult to place the results from testing that is occasionally undertaken into context. This reluctance arises from an uncertainty as to the regulatory response if the results are positive. (Anonymised harvest area and product surveillance would not provide the area-specific data required to improve risk management in specific growing areas). The interpretation of virus test results within the context of other concurrent factors (such as other indicators) could overcome this problem.

• Other information gaps relevant to improving the management of risk of virus contamination of growing areas include:
The length of time noroviruses remain infective within the marine environment;
The length of time noroviruses remain infective in shellfish;
The effectiveness of various wastewater treatment processes in reducing the level of infective NoV.

RECOMMENDATIONS

As a result of this study we recommend the following:

Growing Area Management

- A review of the management of sources of contamination that were implicated in previous NoV outbreaks in each impacted growing area to ensure that appropriate management of risk is on-going – the on-going use of microbial source tracking techniques could be useful in confirming the absence of human contamination close to the source.
- A review designed to identify cost-effective ways of ensuring that the assessment of the risk of virus contamination in growing areas stays current.
- An initiative to improve linkages between Councils and Food Authorities, perhaps through joint training initiatives, Memoranda of Understanding etc.
- Development of detailed procedures and training initiatives for Food Authority and Council officers to follow in the event of suspected viral illness outbreaks implicating shellfish growing areas – including templates on what should be documented.
- Introduction of a peer review process of the shellfish quality management in each growing area (possibly across states, Australia/New Zealand?).
- An initiative to increase the technical competence of Council and Food Authority officers in assessing the suitability and efficacy of WWTPs and on-site sewage systems, through targeted training initiatives.
- Use of *E. coli*/faecal coliform testing, then appropriate microbial source tracking tools (i.e. the best available at the time) to detect human sewage contamination close to source in the wider catchment of growing areas to provide confirmation of observations made in the shoreline survey, and in investigation following non-compliant sample results.
- The development of a science-based policy for determining the actions to be taken in the event that enteric viruses are detected in a growing area in the absence of illness (for example, during research studies), using other indicators to support decision-making processes.

Science/Technical Issues

- Continued development of NoV test method that distinguishes between infective and non-viable viruses.
- A study of the effectiveness of male-specific bacteriophage as an indicator of risk of viral contamination in oyster growing areas in New Zealand and Australian conditions, taking into account different potential sources of contamination.
- Continued development of improved, reliable, validated faecal/microbial source tracking methods to detect human sewage contamination over an extended time period and including the “viral toolbox” and quick, cheap methods of confirming the absence of human faecal contamination close to source.
• Development of laboratory capability and capacity to undertake analysis of samples using existing and new microbial source tracking tools to provide reliable results in a timely manner.
• A science-based review of standards and guidelines for on-site sewage systems.
• A review of the commonly used on-site sewage systems in Australia and New Zealand to assess their performance in preventing viral contamination of waterways under a variety of environmental conditions, including saturated soil conditions, and the development of new technology if required.
• Development of science-based guidelines to assist Councils in identifying the minimum quality of effluent after treatment in a WWTP to ensure protection of shellfish growing areas from viral contamination (i.e. guidelines to determine how much is enough in any situation).

Environmental Policy Issues:
• In New Zealand particularly, the development of public policy that protects water quality in shellfish growing areas in both short and long term. Consideration of:
  o Policy linking environmental quality to commercial shellfish harvest areas;
  o Increased cross-agency planning and cooperation;
  o Improved protection against water quality degradation arising from the cumulative impact of many small changes in the catchment of shellfish growing areas;
  o Development of science-based marine pollution regulations with respect to shellfish growing areas.
• The introduction of mandatory audited quality management programmes for Councils with respect to all aspects of their operations with the potential to impact on water quality in shellfish growing areas.
• A review of the use of standards and guidelines in on-site wastewater management, and the alternatives in sensitive areas in shellfish growing catchments.
• Inclusion of science-based State of the Environment monitoring of water quality in shellfish harvesting areas (commercial & recreational), designed to detect degradation in water quality over time – possible information-sharing of industry data.
• A Government review of the funding of wastewater management systems.
• Regulation to allow Food Authority officers to gain access to private properties for the purposes of investigation of potential sources of growing area contamination.
• The introduction of policy to facilitate the transfer of information relevant to assessment of the risk of contamination of shellfish growing areas, from Councils to Food Authorities.
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SECTION 1  INTRODUCTION

Bivalve shellfish such as mussels, oysters and clams are a desirable food source in many countries. They are commercially harvested from the wild and increasingly they are farmed to supply both local and global markets.

One of the features of bivalve shellfish is their filter feeding system, which results in their accumulation of hazardous materials such as marine biotoxins, heavy metals and microbial contamination from their growing waters. Consequently bivalve shellfish pose a high food safety risk, and therefore receive special consideration in food safety laws throughout the world.

Most countries in the developed world use classification systems to determine where it is safe to commercially harvest shellfish. Countries have developed their own specific programmes, but most follow a combination of the following features:

a) A public health sanitary survey of the shellfish catchment area to assess the potential pollution risks.

b) Water and shellfish samples (using maximum limits of microbial indicator organisms, heavy metals and marine biotoxins).

c) Control of harvest times.

d) Labelling of shellfish so that people know the origin of the product.

Such classification and associated management systems have been very effective in preventing food borne illness associated with chemical contamination and bacterial pathogens\(^1\). However there is now a large amount of documented epidemiological evidence indicating that shellfish consumers are not always protected from illnesses arising from human enteric viruses such as Hepatitis A virus and noroviruses. The problem has been recognised since 1956 when the first viral Hepatitis A outbreak associated with shellfish in the USA was recorded. In developed countries such as the USA, European Union, Australia and New Zealand, it seems that there has been an increasing number of viral illness outbreaks associated with shellfish consumption documented since then. It is acknowledged that this increasing trend could arise for a variety of reasons including more consumer complaints about illness events, better epidemiological sentinel practices and improved scientific techniques. However, while the current management procedures are adequate to control other sewage-linked pathogens, enteric viruses have now become the leading cause of shellfish-borne illness amongst consumers.

The current classification programmes and management systems therefore appear to be inadequate in reliably preventing viral illness, and it is necessary to develop a new management framework to protect consumers. This is a significant food safety problem for the shellfish industry internationally, and will pose on-going human health and market access issues unless the problem is remedied.

The cost of viral illness associated with shellfish consumption is not just that associated with personal morbidity and mortality issues. Illness events can also quickly and adversely affect the

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\(^1\) The risks of some species of *Vibrio* bacteria that are pathogenic to humans and which occur naturally in the marine environment can be managed using environmental indicators (e.g. temperature, salinity) in some places. Consideration of the management of the risk of pathogenic *Vibrio* species is beyond the scope of this project.
public confidence in the industry to supply safe food products. The loss of this reputation in today’s global food market is economically significant.

Both Australian and New Zealand shellfish industries and regulatory authorities share an interest in improving their shellfish programmes to reliably manage the risk of viral contamination of shellfish, and this study is a collaborative project between the Australian and New Zealand industries. The project represents the first step in a wider project responding to the need to develop better management strategies to protect consumers from shellfish-borne viral pathogens. The aims of the project are to:

- Identify the fundamental reasons why the current bivalve shellfish classification and management systems used in Australia and New Zealand can fail to protect consumers from viral contamination in shellfish
- Identify and evaluate potential frameworks for improved management strategies for shellfish growing areas, and their barriers to implementation, including any information gaps;
- Make recommendations on priorities for future work to develop and implement improved management strategies to protect shellfish from viral contamination

The basis of the study is analysis across eight case studies drawn from New Zealand and New South Wales, each based on a norovirus (NoV) illness event associated with the consumption of oysters that were identified as having been contaminated with NoV before harvest. At the outset of this project a review of current information was undertaken to provide contextual information for the case studies. This is presented in the Section 2 of the report. The cases from each oyster growing area are presented in separate sections (Sections 3-8) followed by a cross-case analysis in Section 9. Discussion, conclusions and recommendations are presented in the final two sections.
SECTION 2 BACKGROUND

2.1 Introduction

The following section outlines the background information that provides an introduction to the context of the case studies undertaken in this project. This has been collected by reviewing current literature. It encompasses the biological basis for the issue of viral contamination in shellfish, the history and outline of the Shellfish Food Safety Programmes in USA, Europe, New Zealand and New South Wales, Australia, and epidemiological trends associated with the consumption of shellfish in those same countries. Lastly, the framework for environmental policy in New Zealand and Australia is briefly summarised to provide the basis for comment on comparisons provided in case analysis later.

2.2 Biological Background to Viral Contamination in Shellfish

2.2.1 Enteric viruses

The pathogenic viruses of concern to the shellfish industry, such as norovirus and hepatitis A, are included within human enteric viruses. Human enteric viruses are those which enter the body through the oral route and infect the alimentary canal (i.e. the gut). Infection by some enteric viruses is localised to the gut (e.g. NoV), but others produce generalised or systemic disease (e.g. hepatitis A virus) (Pommerville, 2001). Enteric viruses multiply in the gut and are excreted in faeces at very high concentrations. An infected individual can shed millions of virus particles. Viruses may be shed in the faeces before the onset of any symptoms, as in the case of hepatitis A, which is excreted in large numbers about two weeks before any symptoms appear (Pommerville, 2001). Virus shedding may also continue after the symptoms have disappeared - for example, Marshall et al. (2001) found high level excretion of NoV after the clinical symptoms of illness had resolved, and Rockx et al. (2002) found that shedding of NoV continued for up to 22 days after the onset of illness.

Over the last 40 years, research contributing toward improving the management of the risk of human enteric viruses to shellfish consumers has included research on virus transport and survival in terrestrial and aquatic environments, survival through wastewater treatment processes, and research on the uptake and retention of viruses by shellfish. For logistical and technical reasons (such as the dangers associated with experimenting with infective viruses in the environment, and difficulties associated with detection methods for some viruses), a variety of virus types has been utilised in this research. These have included not only the enteric viruses of primary concern (such as hepatitis A, and more recently, norovirus), but also other viruses with a high prevalence in human sewage, which were of interest because of their potential to act as indicators of the risk of the enteric viruses commonly associated with disease outbreaks following shellfish consumption. These included the enteric virus poliovirus (the attenuated strain of poliovirus was commonly found in sewage in developed countries because of widespread vaccination programmes), and bacteriophages that infect bacteria found in human sewage. While some variation between different virus types has been observed, in general results have shown broad patterns that transcend all virus types. These are described below.

Enteric viruses are hardy and generally have a higher resistance to wastewater treatment than bacteria (e.g. Gomila et al., 2008; Jacangelo et al., 2003; Lewis et al., 1986; Ottoson et al., 2006a;
Ottoson et al., 2006b). They can be transported readily from effluent disposal fields through saturated soils and groundwater (e.g. Schaub & Sorber, 1977; Vaughn et al., 1978; Vaughn et al., 1983), and can survive for long periods of time in the environment.

Viruses can retain their infectivity for significant periods of time in dry and wet soil, although survival is lower under dry conditions (e.g. Lefler & Kott, 1974; Wellings et al., 1975; Jin & Flury, 2002). Survival of different virus types has been found to differ significantly in soil (e.g. Schaub et al., 1982) and in freshwater (e.g. Smith et al., 1978; Callahan et al., 1995; Enríquez et al., 1995). There are little data for NoV, primarily because of difficulties that have been faced with respect to developing detection methods that will determine whether NoV is viable or not. However a study by Seitz et al. (2009) using human volunteers found that NoV in groundwater retained infectivity for at least two months.

These characteristics of enteric viruses result in the risk of their transport into the marine environment, particularly in estuarine areas where freshwater, including run-off originating from the land, enters the coastal environment. Enteric viruses may also survive for long periods of time in the marine environment (e.g. Goyal et al., 1984, who observed the 17-month persistence of enteric viruses in sediments associated with sewage sludge disposal sites in the Atlantic Ocean), although a review by Ball et al. (2008) observed that the wide variation in survival times recorded by researchers following laboratory-based experiments (10 hours - 671 days) has been significantly influenced by experimental conditions. (For example, longer survival times have been observed under conditions such as within sterile seawater or in the dark, which differ significantly from conditions found in the marine environment). Adsorption to marine sediments prolongs virus survival times (e.g. Gerba & Schaiberger, 1975; Smith et al., 1978; Bosch, 1995), and survival decreases with increasing temperature (O’Brien & Newman, 1977; Yates & Gerba, 1984). Microbial activity in seawater is very significant in the inactivation of viruses (Magnusson et al, 1966; Katzenelson & Shuval, 1973; O’Brien & Newman, 1977; Patti et al., 1987; Bosch, 1995).

2.2.2 Enteric viruses in shellfish

The biological class of Bivalvia contains more than 20,000 species of marine and freshwater molluscs, including mussels, oysters and clams. These molluscs are commonly called bivalves. One of the distinguishing characteristics of this class is the presence of lamellibranch gills which allow filter feeding (Villee et al., 1978).

During filter feeding, large volumes of water pass across the gills to allow the shellfish to obtain oxygen and food. Particulate matter from the water, including microorganisms, is trapped in the mucus on the gills and transported to the mouth by ciliary action. As the mucus passes the labial palps, particles are sorted and non-food items are rejected as pseudofaeces. The remaining items, entrapped in the mucus, enter the mouth. The food then passes through the short oesophagus to the stomach where it is mixed with digestive enzymes released by the rotating crystalline style. Some intracellular digestion occurs in the stomach. Small food particles are transported into the blind tubules of the digestive diverticula and are ingested by phagocytosis. Particles that do not enter the digestive diverticula are passed out of the stomach into the mid-gut and are eventually discharged through the anus. This process requires <2 hours in actively feeding adult Pacific oysters (SITO, 2005). The feeding rates of Pacific oysters (Crassostrea gigas) vary with environmental factors such as temperature, concentration of particles in the water etc. (Ren et al., 2000).
Numerous studies have shown that shellfish rapidly accumulate microorganisms if they are present in polluted water (e.g. Eyles, 1980; Lees, 2000; Rose & Sobsey, 1993). Viral particles, which are much smaller than the typical food of bivalves, may be taken up coincidentally during the feeding process (Metcalf, 1982; Landry et al., 1983), although Burkhardt & Calci (2000) suggested a more complex process in describing the uptake of F+ coliphage by oysters \(\textit{Crassostrea virginica}\) as selective. These authors suggest that selective accumulation of viruses by shellfish is related to the way in which shellfish feed.

A more recent study found that NoV uptake by Pacific oysters \(\textit{Crassostrea gigas}\) is also related to the specific binding of NoV to the oyster digestive tract through an A-like carbohydrate structure indistinguishable from human blood group A antigen (Le Guyader et al., 2006). This type of specific binding has subsequently been confirmed for several oyster species, mussels, and clams for various NoV strains (Tian et al., 2006; Tian et al., 2007). Differences in the bioaccumulation efficiency and tissue distribution of three strains from the two principal human NoV genogroups have also been noted in oysters (\(C.\ gigas\)), and may be attributable to differences in recognition of different ligands between different NoV strains (Tian et al., 2008; Maalouf et al., 2010; Maalouf et al., 2011).

Viruses may accumulate in shellfish to concentrations which exceed the concentration of the virus in seawater (e.g. Mitchell et al., 1966; Hamblet et al., 1969; Hoff and Becker, 1969; Canzonier, 1971; Enriquez et al., 1992; Burkhardt & Calci, 2000). The accumulation factor (i.e. the ratio of the concentration of virus in shellfish compared to the concentration in seawater) varies widely among studies reported in the literature, from less than one-fold to over 1000-fold.

Initially the uptake of viral particles by shellfish appears to be rapid with most accumulation occurring during the first few hours (Mitchell et al., 1966 (working with poliovirus); Enriquez et al., 1992 (Hepatitis A)). Studies using culturable viruses show viral concentration then appears to reach a plateau (see Sobsey and Jaykus, 1991 for review). Mitchell et al. (1966) suggested that this plateau in the concentration of virus in shellfish is a state of equilibrium between uptake and elimination, suggesting that viral levels in shellfish are maintained as long as exposure is maintained.

While it is fairly well established that bacteria can be removed from shellfish by placing them in clean water under specified environmental conditions in a process known as depuration (see Richards, 1988 for review), numerous studies have established that viruses are not necessarily removed under the same conditions (e.g. Canzonier, 1971 (working with somatic coliphages); Metcalf et al., 1980 (poliovirus); and see Richards, 1988; Lees, 2000 for reviews). Depuration rates can vary by shellfish species (e.g. Dore & Lees, 1995), with virus type (e.g. Sobsey et al., 1987; Enriquez et al., 1992; Bosch et al., 1995) and with environmental conditions such as temperature (e.g. Dore, 2012).

Norovirus appears to be one of the viruses that persist in oysters for long periods of time, and it has been suggested by several researchers (e.g. Maalouf et al., 2010) that this might be attributable to its binding using specific glycan ligands in oysters. Ueki et al. (2007) observed virus levels in Pacific oysters by RT-PCR (reverse transcriptase polymerase chain reaction) over a 10-day depuration period at 10 °C in clean water following contamination with NoV(GII) and feline calicivirus (FCV) in the laboratory. While FCV depurated to undetectable levels within 3 days, NoV levels did not reduce significantly over 10 days. In an investigation of the persistence of NoV in Pacific oysters, NoV was detected by RT-PCR in oysters held in their natural environment for over 8 weeks (Greening et al., 2003). The viability of the virus was not able to be determined in either of these
experiments. Commercial depuration processes, which involve placing shellfish in clean seawater for 36-48 hours, are effective in removing some bacteria (including faecal coliforms and *E. coli*, which are commonly used as indicators of the effectiveness of the process), but do not reliably prevent NoV illness in shellfish consumers (e.g. Grohmann et al., 1981).

The duration of exposure to contaminants may affect the ability of shellfish to depurate contaminants. Canzonier (1971) suggested that with prolonged exposure, small numbers of viral particles may be sequestered in shellfish tissues rather than eliminated in faeces and pseudofaeces. Schwab et al. (1998) found that the likelihood of detecting Norwalk virus in the tissues of both oysters (*Crassostrea virginica*) and clams (*Mercenaria mercenaria*) increased with exposure to both higher levels of virus and with exposure for longer periods of time.

The environmental conditions in which shellfish live impact on the risk of their accumulating viruses that are human pathogens. The natural habitats of shellfish like rock oysters and cockles are estuarine areas where the risk of exposure to contaminants from land run-off is greater than on the open coast or in deeper waters. The risk of shellfish contamination arising from resuspension of sediment-bound virus is also greater in estuarine areas. In a study of the prevalence of enterovirus and hepatitis A virus in bivalve molluses from Galicia, Spain, Romalde et al. (2002) observed that the numbers of samples positive for enteroviruses were higher in cockles, in-faunal clams and wild mussels on the shore than in raft-cultured mussels in deeper water in the same zones.

Shallow estuarine habitats, with easy access from the land, have facilitated the development of oyster aquaculture on inter-tidal farms. Although all bivalve shellfish species grown in water contaminated with viral pathogens have the potential to cause illness, epidemiological data suggest that oysters appear to present the greatest risk. Two factors that may contribute to this risk are the environment in which oysters are generally farmed, and the common practice of consuming oysters raw, with no thermal process applied to destroy pathogens prior to consumption.

### 2.3 Shellfish Food Safety Programmes

#### 2.3.1 History of Shellfish Food Safety Programmes

Written records do not indicate clearly when people first became aware that edible shellfish could transmit communicable diseases, but illnesses are ascribed to Romans who gorged themselves on oysters sent from Britain for their feasts (Hackney & Pierson, 1994). In 1603 written records show oysters were incriminated when King Henry IV of France became ill with an intestinal disorder. By 1816 the medical profession had become alerted and a French physician, Pasquier, produced a book entitled, *The Oyster from the Medical Point of View*. He observed that workmen had laid down 60,000 oysters to be stored temporarily in a moat receiving sewage from the French garrison. These oysters, once consumed, caused typhoid fever (Reille, 1907). Harvesting and storing oysters in water was a common practice in France. However, Pasquier was at a loss to understand how the oysters caused the illness as this was well before Pasteur advanced the germ theory of disease transmission in the 1860s.

Eventually scientists began to understand the combined effects of bivalve filter feeding and environmental pollution on shellfish food safety, and today raw molluscan shellfish receive the second highest hazard rating of all foods (International Commission on Microbiological Specifications for Food, [www.icmsf.org](http://www.icmsf.org)). Therefore, most developed countries have some form of food safety legislation which regulates the sale of bivalve species.
The first formal laws were developed in the United States of America (USA) and in some of the countries which now make up the European Union (EU). Today the USA and EU shellfish food safety laws are also often used as the minimum standards to enable the entry of shellfish into other countries. The Codex Alimentarius Commission, established by FAO and WHO in 1963 develops harmonised international food standards, guidelines and codes of practice to protect the health of the consumers and ensure fair practices in the food trade. Therefore Codex have some very generic guidelines on the safe growing, harvesting and processing of shellfish. Australia and New Zealand have developed mandatory food safety laws that define the conditions around the growing, harvesting, processing and sale of bivalve molluscs.

The following sections summarize the history and attributes of the shellfish programmes in the USA, EU, Australia and New Zealand and the guidelines provided by the Codex Alimentarius Commission.

2.3.2 Role of Codex Alimentarius Commission in shellfish food safety

The Codex Alimentarius Commission (Codex) is an intergovernmental body with over 170 members, within the framework of the Joint FAO/WHO Food Standards Programme established by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). The general purpose of Codex is to protect the health of consumers, ensure fair practices in the food trade, and promote the co-ordination of all food standards work undertaken by international governmental and non-governmental organizations (WHO, 2007).

One of the tasks of Codex is to develop food standards, guidelines and related texts such as codes of practice based on the best available science assisted by independent international risk assessment bodies or ad-hoc consultation organized by FAO and WHO. These guidelines can then be used by nations that do not have the technical expertise or financial means to develop their own standards.

While being recommendations for voluntary application by members, Codex standards serve in many cases as a basis for national legislation. The reference made to Codex food safety standards in the World Trade Organizations' Agreement on Sanitary and Phytosanitary measures (SPS Agreement) means that Codex has far reaching implications for resolving trade disputes.

Codex has developed the “Code of Practices for Fish and Fishery Products” CAC/RCP 52-2003. Section 7 of this guide outlines the recommended requirements for classifying safe shellfish harvest areas. The list includes growing water and/or molluscan flesh monitoring for the presence of E. coli/faecal coliforms or total coliforms at an appropriate frequency based on the probability and degree of faecal contamination. While the guide recommends the use of E. coli/faecal coliforms or total coliforms as indicators for the presence of faecal contamination it also states that these indicators do not correlate well with the presence of viruses, therefore other controls such as shoreline surveys should always be employed. The guide recognizes that other methods such as bacteriophage and viral detection could also be used as indicators of faecal contamination when validated analytical methods become available in the future.

Codex has formed a number of Technical Committees empowered to address relevant topics, including for example, the Codex Committee on Food Hygiene. Because of the general increase in viral illness throughout the world, this Committee was tasked to consider mitigation steps for all food products, resulting in the draft “Proposed Draft Guidelines on the Application of General
Principles of Food Hygiene to the Control of Viruses in Food. These guidelines recommend generic food hygiene principles. Annex I entitled “Control of Hepatitis A Virus (HAV) and Norovirus (NoV) in Bivalve Molluscs” states that it is important to:

1) Ensure the seawater quality of growing areas by improving sewage treatment efficiency for virus removal/inactivation and avoid discharging of untreated sewage in the surroundings of the bivalve molluscs growing areas.

2) The sanitary survey of harvesting and/or growing water should include an assessment of possible human faecal contamination sources with *E. coli* and/or faecal coliforms used as indicators for faecal contamination.

3) Monitoring data should be interpreted within the context of the sanitary survey, as viruses may be present in the absence of *E. coli*/*faecal coliforms/total coliforms.

4) When there has been a shellfish-borne outbreak caused by an identified pathogen such as NoV or HAV and the area has been closed, viral testing of the bivalve molluscs or an equivalent approach to ensure safety should be used as part of the process of reopening the affected harvesting area depending on the requirements of the official agency, using either standardized methods or alternative validated methods.

5) Other conditions, including meeting the sanitary survey requirements, should also have been satisfied as a condition of reopening the area. Ideally they should include the identification of sources of pollution/contamination.

2.3.3 USA National Shellfish Sanitation Programme

**History**

In the USA in the late 19th Century, the railways opened up the country, helped populate new cities and facilitated trade including the transfer of marine food products to the inner provinces. In Chicago in 1924 oysters from New York State were served at a civic party of prominent and wealthy citizens. Unfortunately the guests became ill with typhoid fever and there was considerable publicity which resulted in quick and decisive warnings by the health authorities not to eat raw oysters. The sale of oysters plummeted and as a consequence the oyster industry lobbied the US government to introduce a programme that would provide public health assurances for the interstate shipment of oysters and the protection of both sellers and consumers. Therefore the original USA National Shellfish Sanitation Programme (NSSP) was developed because of illness cases associated with commercially sold oysters.

Investigations made from 1914 to 1925 by the states and the US Public Health Service, a period when disease outbreaks attributable to shellfish were more prevalent, indicated that typhoid fever or other enteric diseases would not ordinarily be attributed to shellfish harvested from water in which not more than 50 percent of the 1 cc portions of water examined were positive for total coliforms (an MPN of approximately 70 per 100 ml), provided the areas were not subject to direct contamination with small amounts of fresh sewage which would not be revealed by bacteriological examination (NSSP Manual Public Health Rationale 2009).

Therefore in 1925 the NSSP established the following water quality criteria:
1. The area should be sufficiently removed from major sources of pollution so that the shellfish would not be subjected to faecal contamination in quantities which might be dangerous to the public health.

2. The area should be free from pollution by even small quantities of fresh sewage.

3. Bacteriological examination does not ordinarily show the presence of the *coli-aerogenes* group of bacteria in 1 cc dilution of the growing area water.

Today the NSSP programme is administered by the United States Food and Drug Administration and is operated as a co-operative programme with the shellfish industry and local State authorities. It is known as the Interstate Shellfish Sanitation Conference (ISSC). The ISSC receives scientific input from a number of agencies (for example, the National Oceanic and Atmospheric Administration, Environmental Protection Agency, the National Marine Fisheries Service and FDA scientists (Shumway, 2004)) with the goal of ensuring that bivalve shellfish are only harvested from areas where they are unlikely to have taken up dangerous levels of microbial or chemical contaminates. To achieve this, NSSP uses a combination of science and public policy to protect the oyster consumer. The basic principles of the programme are:

- A public health sanitary survey of the shellfish catchment area
- Water and shellfish samples
- Controlled harvest times
- Labeling of shellfish so that people know the origin of the product

The first three components of the programme are outlined below.

**Sanitary survey**

The use of sanitary surveys originated in the late 19th century as a means to protect drinking water supplies (Fair & Geyer, 1963). Because of its success the drinking water concept was applied to shellfish growing areas. Sanitary surveys involve an examination of the watershed draining into a shellfish harvest area to identify and, where possible, arrange for the elimination or minimization of the actual or potential sources of contamination. The information generated is used to ascertain what waters are safe for the harvest of shellfish for direct human consumption and what waters are unsafe for harvesting under any circumstances.

The NSSP provide guidance documents on how to undertake robust sanitary surveys and how to interpret the findings to determine the appropriate classification on the suitability of a proposed harvest area (NSSP, 2009). Ideally the survey should be conducted by trained technical personnel capable of evaluating the probable impact of sewage, industrial and non-point sources discharges on the shellfish harvest area. Sanitary surveys are generally qualitative using professional judgment based on the information available at the time of the survey.

The NSSP programme states that a full sanitary survey should be done at least every 12 years, with mandated triennial and annual requirements to verify that the situation in the catchment has not changed and the classification status is confirmed. In today’s world of computers and electronic filing systems many agencies keep their 12 yearly survey file updated with information as it comes to hand, therefore keeping the sanitary survey document current.
**Sampling**

The second fundamental step of the classification process is the bacteriological examination of water and shellfish samples to confirm the tentative conclusions of the shoreline survey regarding the risk of contamination. (In addition, shellfish samples are also analyzed for the presence of toxic contaminants such as heavy metals, pesticides etc. to determine whether standards relating to maximum contaminant levels are met). The qualitative assumption underlying the bacteriological analysis is that the more faecal material in the water, the greater the risk of contracting disease. The underlying quantitative relationships have not been validated, but the assumption has been widely accepted in public health programmes (Hackney and Pierson, 1994).

Application of the water quality standards under the NSSP is based on the collection of a specified minimum number of samples at a specified frequency over a 3-year period. When a new growing area is under classification, evaluation across a minimum of 30 sampling events must be undertaken. There are also mandatory requirements with respect to the focus of sampling events: if an area is affected by a specific point source (for example, a wastewater treatment discharge), sampling must aim to ensure that adverse events related to this source are targeted. Growing areas not impacted by point sources may be sampled randomly throughout the year.

When it comes to the microbiological assessment of the water quality, the NSSP allows for the area to be classified using either Total Coliforms or Faecal Coliforms.

For “Approved” areas (those where shellfish can be harvested directly for the market without further treatment) the standards are as follows:

**Total Coliform standard**- the geometric mean of the total coliform Most Probable Number (MPN) of the water sample results for each sampling station shall not exceed 70 MPN per 100 ml; and not more than 10% of the samples shall exceed an MPN of:

a) 230 MPN per 100 ml for a 5-tube, decimal dilution test;
b) 330 MPN per 100 ml for a 3-tube, decimal dilution test; or
c) 140 MPN per 100 ml for the 12-tube, single dilution test.

**Faecal Coliform standard** - the median or geometric mean MPN or Membrane Filtration (MF) (mTEC) of the water sample results shall not exceed 14 per 100 ml of water, and not more than 10 percent of the samples shall exceed an MPN or MF (mTEC) of:

a) 43 MPN per 100 ml for a five tube decimal dilution test;
b) 49 MPN per 100 ml for a three-tube decimal dilution test;
c) 28 MPN per 100 ml for a twelve-tube single dilution test; or
d) 31 CFU per 100 ml for a MF (mTEC) test.

The standards for “Restricted” areas (harvest areas where product must be further treated by an effective process such as relaying or depuration before being placed on the market) are as follows:

**Total Coliform standard** - the total coliform geometric mean MPN of the water sample results for each station shall not exceed 700 per 100 ml and not more than 10% of the samples shall exceed an MPN of:

a) 2,300 MPN per 100 ml for a 5-tube, decimal dilution test; or
b) 3,300 MPN per 100 ml for a 3-tube, decimal dilution test; or
c) 1,386 MPN per 100 ml for a 12-tube, single dilution test.
**Faecal Coliform standard**- the faecal coliform median or geometric mean MPN or MF (mTEC) of the water sample results shall not exceed 88 faecal coliforms per 100 ml of water and the estimated 90th percentile shall not exceed an MPN or MF (mTEC) of:

a) 300 MPN per 100 ml for a three tube decimal dilution test;
b) 173 MPN per 100 ml for a twelve tube single dilution test;
c) 163 CFU per 100 ml for a MF (mTEC) test

In 1946, USA scientists realised the need to standardise laboratory methods to ensure consistency in analysing and interpreting results in different parts of the country. As a result the American Public Health Association published its methods and the McCrady Most Probable Number was adopted as the official analytical method (US Public Health Service, 1950). It was acknowledged by scientists at the time that this method had inherent statistical variability that may bias results. To manage this statistical variability the NSSP allows a 10% deviation from the 14 faecal coliforms. In other words, not more than 10% of the samples shall exceed an MPN of 43 faecal coliforms/100ml provided that the samples are not related to a pollution event. Therefore a qualitative judgment must be made on elevated results.

**Controlled harvest times**
The purpose of regulated harvest times is to ensure that shellfish are only harvested when they are considered safe to eat. As land run-off, emergency sewage overflows and boating activity all impact on microbial safety it is important that times of harvest recognise times of hazard. “Hazard” is defined as the length of time that pathogenic doses of microbes are within the shellfish. Areas can be closed when environmental events cause pollution and this is called “conditional management” (NSSP, 2009). The NSSP conditional management policy requires acceptance of the fact that there are certain predictable times when a harvest area will not meet the established microbiological limits and that at these times the area can be closed for harvest. Such areas are strictly operated on a documented management plan, understood and agreed to by both the shellfish industry and the regulatory authorities. For example there may be defined harvest closures due to high boating activity in an area during the summer.

Usually harvest areas can be reopened when the total or faecal coliforms have returned to the allowable limits. Given the known persistence of viruses in shellfish for periods significantly longer than faecal coliforms, this is based on the tacit assumption of the absence of significant human faecal contamination under the environmental conditions normally encountered in the growing area. However, after another large viral outbreak associated with oysters in the USA the 2001 Interstate Shellfish Sanitation Conference agreed on an NSSP policy to close down harvesting for at least 21 days after the causative pollution source had been remedied in shellfish areas where shellfish had caused viral illness. The rationale was that 21 days would allow the viruses to depurate before the oysters were consumed. However to date there are no scientific studies to validate the estimated length of time that infective NoV remains in shellfish.

**2.3.4 Principles of European Programme**

European societies have traditionally recognised that oysters can cause illness, so for a long time European countries each had their own individual shellfish safety strategies. For example the French industry held their oysters in “claires” (man-made tidal ponds) or “degorgeoirs” (artificial pools) to rid them of any impurities (Furfari, 1981). However, once the European Union was formed there was a need to standardise rules for all shellfish sold on the open market so that there was food safety equivalency between countries. Therefore the European Commission published a
directive EU 91/492 (EU, 1991) which stipulated regulatory microbiological limits for shellfish. This was later replaced by the EU Hygiene Regulation 854/2004 which stipulates the requirements to classify shellfish areas. Europe uses the bacterial indicator *Escherichia coli* (*E. coli*) to predict the presence of microbial pathogens of faecal origin and the regulations stipulate the following limits for live shellfish:

<table>
<thead>
<tr>
<th>CLASS</th>
<th>MICROBIOLOGICAL LIMIT</th>
<th>POST HARVEST TREATMENT REQUIRED</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Live bivalve molluscs from these areas must not exceed 230 MPN <em>E. coli</em> per 100 grams of flesh and intra-valvular liquid.</td>
<td>None</td>
</tr>
<tr>
<td>B</td>
<td>Live bivalve molluscs from these areas must not exceed, in 90% of the samples, 4600 MPN <em>E. coli</em> per 100 grams of flesh and intra-valvular liquid. The remaining 10% of samples must not exceed 46,000 MPN <em>E. coli</em> per 100 grammes.</td>
<td>Purification, relaying or cooking by an approved method.</td>
</tr>
<tr>
<td>C</td>
<td>Live bivalve molluscs from these areas must not exceed 46,000 MPN <em>E. coli</em> per 100 grams.</td>
<td>Relaying or cooking by an approved method.</td>
</tr>
</tbody>
</table>

Table 2.1: Microbial limits for the classification of EU shellfish harvest areas (Source: CEFAS Guide to Good Practice, 2010).

Commercial shellfish harvesting is prohibited in areas where *E. coli* in shellfish samples exceed 46,000 MPN/100g.

There are also associated requirements in Regulation (EU) 853/2004, which lays down specific requirements for food products of animal origin, including the need for shellfish to be labelled to ensure traceability back to the harvest area, and cross references to Regulation 2073/2005 which gives the microbiological standard for products.

The European Commission did not originally require sanitary surveys for harvest area classification, simply using the *E. coli* limits in Table 2.1 to determine food safety. However, EU Regulation 854/2004 requires the following steps to classify all new shellfish harvest areas:

a) An inventory must be made of all animal and human sources of contamination likely to be a source of contamination for the production area.

b) Examine the quantities of organic pollutants which are released during the different periods of the year, according to seasonal variations of both human and animal populations in the catchment area, rainfall readings, waste water treatment, etc.

c) Determine the characteristics of the circulation of the pollutants by virtue of current patterns, bathymetry and the tidal cycle in the production area.

In reality Parts a-c constitute the requirements of a Sanitary Survey.

In 2006, an EU working group first published a guide “Microbiological Monitoring of Bivalve Mollusc Harvest Areas, Guide to Good Practice: Technical Application”, which has been updated
and is now at Version 4, August 2010. This guide recommends the use of sanitary surveys for all shellfish harvest areas, not just new areas, including the need to semi-quantitatively risk assess the pollution sources identified. While EU Regulation 854/2004 states sanitary surveys are only a requirement for newly classified areas, the EU Good Practice Guide recommends that EU Member States introduce a work programme by the 1st January 2011 to complete sanitary surveys by the 1st January 2015 at the latest. Since then a specific guide, the “Community Guide to Principles of Good Practice for the Microbiological Monitoring of Bivalve Molluscan Shellfish Harvesting with Regards to Regulation 854/2004” has been written to assist the Competent Authorities in implementing effective programmes.

Neither EU Regulation 853/2004 nor 854/2004 are prescriptive on the frequency or design of sampling programmes to verify compliance with the E. coli limits but the Good Practice Guide gives clear information on sampling programme design and how to analyze sampling results. It is recommended that areas have regular (monthly) sampling for at least three years with an assessment of the microbiological results for this period before sampling frequency is reduced.

### 2.3.5 Australian Shellfish Quality Assurance Programme

Australia is made up of six autonomous States and two territories. A national guideline “The Australian Shellfish Quality Assurance Program (ASQAP) Operations Manual” has been developed and is maintained by the Australian Shellfish Quality Assurance Advisory Committee (ASQAAC) as a reference document for Federal and State government agencies involved in the implementation of the ASQAP for bivalve molluscs commercially harvested from Australian waters. The purpose of the ASQAP Operations Manual is to provide staff at government agencies with the procedures and guidelines to be used when applying Federal and State legislation governing the control of shellfish growing areas and the harvesting, processing and distribution of shellfish. This operations manual provides the basis for establishing a shellfish quality assurance program and it does not limit any of the individual states in establishing any other requirements deemed necessary to ensure the food safety of bivalve molluscs (ASQAAC, 2009).

Adherence to the ASQAP is not mandatory: Federal and state food safety regulation in Australia is implemented based on the Australia New Zealand Food Standards Code. The Code has been developed by Food Standards Australia New Zealand (FSANZ), a bi-national statutory authority that works in partnership with the Australian federal government, state and territory governments and the New Zealand government. Within Chapter 4 of the Australia New Zealand Food Standards Code, Standard 4.2.1 Primary Production and Processing Standard for Seafood requires food safety management systems for the production and processing of raw oysters and other bivalves. Under this standard a seafood business must comply with the conditions of the ASQAP Manual specified in the Schedule to this Standard, or alternatively, with conditions recognised by the State, Territory or Commonwealth government agency or agencies having the legal authority to implement and enforce this Division of the Code (FSANZ, 2005). New South Wales, the state from which the case studies undertaken in this project are drawn, does implement ASQAP.

The process of classifying shellfish harvest areas in Australia is fundamentally based on the USA NSSP programme, with the use of sanitary surveys, sampling, and management protocols for harvesting outside of contamination events. ASQAP requires that faecal or total coliform levels in water samples be used to classify safe harvest areas, but also suggests that E. coli levels in shellfish be used as an indicator of food safety risk. The acceptable limits for water and shellfish samples are
based on those used by the USA and the EU (14 faecal coliforms/100ml, 70 total coliforms/100ml or 230 \(E. coli/100g\) with the 10% variance to allow for the MPN statistical variability).

### 2.3.6 New South Wales Shellfish Quality Assurance Programme

The New South Wales Shellfish Quality Assurance Programme is regulated under the NSW Food Regulations 2010 which requires all oysters and mussels to be harvested in accordance with the NSW Shellfish Program documented in the *NSW Shellfish Industry Manual*. This programme has adopted the Australian Shellfish Quality Assurance Program (ASQAP) as a minimum standard, but there have been some adaptations, for example, all growing areas must be sampled to reopen after a pollution event (www.foodauthority.nsw.gov.au).

The New South Wales programme uses faecal coliforms in water and \(E. coli\) in shellfish to monitor the microbiological food safety risks.

A handbook “The New South Wales Shellfish Program Coordinator’s Workbook” has been developed to assist with the interpretation and implementation of the New South Wales programme (The New South Wales Shellfish Program Coordinator’s Workbook, Ninth Edition – September 2009, NSW Food Authority).

### 2.3.7 New Zealand Shellfish Quality Assurance Programme

Like the USA and Europe, New Zealand also had pollution issues in the 1800s as cities became established in the newly growing colony. There were at least three recorded typhoid outbreaks associated with eating oysters in the years 1901, 1902 and 1914. These events were all associated with the harvesting of oysters collected or stored in flax baskets near sewage outfalls in Auckland and Dunedin (MacLean, 1964). However, the Public Health Act 1900 marked a turning point as it gave municipal authorities the ability to deal with unsanitary conditions so that city and harbour pollution conditions improved.

Following these early 1900 illness outbreaks there was little evidence of illness associated with shellfish until the 1990s. However, in the late 1970s the growing aquaculture industry identified that they needed a shellfish quality assurance programme to facilitate exports to the USA. The Government requested assistance from the USA who sent Food and Drug Administration officers to assist with the implementation of a programme based on the NSSP, resulting in the 1980 Memorandum of Understanding with the USA which enabled market access.

By 1991 New Zealand was exporting shellfish to many countries around the world so the export industry decided it wanted its own shellfish quality assurance standards rather than relying solely on the USA National Shellfish Sanitation Programme. It was felt that these would reflect the industry’s maturity, and integrate the special features of New Zealand’s environment and aquacultural practices. Consequently in 1991 the *Industry Agreed Implementation Standard: Shellfish Quality Assurance Circular 005.1* was published to manage the food safety risks associated with the harvest of bivalve molluscan shellfish. On June 1st 2006 IAIS 005.1 was replaced by the *Animal Products Bivalve Molluscan Regulated Control Scheme*. This mandatory legislation is made pursuant to the Animal Products Act 1999 and applies to all shellfish for sale.
In 2011 the Government restructured the government departments, so the Animal Products Bivalve Regulated Control Scheme is now administered by the Ministry of Primary Industries (MPI). Often the necessary intelligence associated with the sanitary survey and environmental sampling programmes is gathered by District Health Board professionals or independent contractors. While District Health Board staff have warrants under the Public Health Act 1956 providing them with wide ranging powers to investigate potential public health risks impacting shellfish sanitation, the warrants for MPI staff are more limited with regard to property access, and independent consultants usually have no legal access to properties for environmental investigations. Therefore MPI staff and independent consultants rely on others to provide some specific environmental status information.

In 2011, New Zealand exported shellfish to 78 countries, with the major markets being large well-developed first world countries (Personal communication AQNZ, 2012). Therefore to ensure that their shellfish sanitation programme is internationally recognised, New Zealand must maintain the principles used by the USA and the EU and use faecal coliforms in water and *E. coli* in shellfish as indicators of microbial food safety. Additional criteria to those required by the NSSP have been added by NZ Food Safety Authority and these include:

- a. Minimum 28 day closure event after a viral illness outbreak.
- b. Minimum 28 day closures after a human sewage event impacting a harvest area.
- c. Risk Management requirements e.g. samples from at least five sampling sites in a growing area must be found negative for viruses before the area can be reopened after a virus illness event in which the growing area was implicated.
- d. Annual shoreline surveys to assess pollution sources rather than triennial survey as required by the USFDA
- e. Sorting shed requirements – the need to register sheds where any shellfish are kept in dry storage overnight for farming purposes.

Points a – d above were implemented to try to manage the food safety risks associated with viral pathogens.

### 2.4 Use of Indicators in Shellfish Programmes

#### 2.4.1 Introduction

As outline in Section 2.3, all the major international shellfish sanitation programmes use sentinel indicators to determine the likely food safety risks of harvested shellfish. The basic concepts of the United States NSSP have not changed since they were laid down in 1924 and the European Union has also chosen to use a sentinel microbial indicator to predict food safety risk. New Zealand and Australia have also followed this model with small adaptations.

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2 As New Zealand is required to implement all the requirements of the NSSP, in 2001 it became mandatory to implement the 21 day closure of harvest areas after an outbreak of viral food poisoning. However, the New Zealand Food Safety Authority took an even more conservative public health approach and enacted a policy that where there was evidence of human sewage polluting a commercial harvest area that area would be closed for at least 28 days (Section 78, Animal Products, 2006). The rationale for this was some scientific findings by ESR Ltd, which indicated that viruses were still present in shellfish samples after 28 days.
While all three programme types use sentinel indicators to predict risk there is actually very little underpinning science to validate their use. There are no direct indicators to determine the presence of microbial pathogens in shellfish; the programmes use primary, secondary and tertiary indicators singly or in combination to predict safe harvesting (see Figure 2.1).

Figure 2.1: Relationship between indicators used in current shellfish programmes and the risk of illness arising from shellfish consumption. The order of process in deriving standards used in the management of shellfish programmes is also shown (blue arrow). (Source: Hay & Kiermeier, 2011).

2.4.2 Microbial indicators

Water and/or shellfish sampling are also critical to all the international programmes. When it comes to monitoring the microbial risk it would be laborious, time consuming and expensive to test for all the individual species of pathogens that could be present in the water or shellfish, for example, *Salmonella, Campylobacter, Giardia, Hepatitis A* and noroviruses. Instead, the shellfish sanitation programmes make use of sentinel microbial indicators. Microbial indicator organisms are used in a variety of ways in public health risk assessment frameworks, and within the international shellfish sanitation programmes they are used to assess the presence of pathogens in the marine environment. The food safety goal is to measure harmless commensal bacteria, generally associated with the gastrointestinal tracts of warm blooded animals and shed in faeces in large quantities, as surrogates to reveal faecal contamination and the potential presence of pathogens in the media of concern. Historically *Bacterium coli*, total coliforms, faecal coliforms and *E. coli* have been used as indicator organisms to determine shellfish food safety. In 2009 the USA introduced another indicator, male-specific coliphage, to determine the safe reopening of shellfish harvest area after raw discharge events from wastewater treatment plants.

The most important biological attribute of any indicator organism is a strong quantitative relationship between indicator concentration and the degree of risk to the public. Bonde (1977) suggests that an ideal indicator should meet the following requirements:

- Correlate to public health risk
- Have similar survival characteristics (or greater) to pathogens.
- Similar (or greater) transport behaviour to pathogens.
- Be present in greater numbers than pathogens.
• Be specific to faecal source or identifiable as to source of origin.

However, the faecal coliform and E. coli groups do not satisfy the criteria for a good indicator. The faecal coliform group is not restricted to faecal habitats and may also be associated with vegetative detritus (Bagley & Seidler, 1977). Under certain circumstances faecal coliforms can multiply in the environment - thus causing false concern about pollution levels (Hood, 1983). Of greater public health concern is the weak correlation between faecal coliforms/E. coli and human virus contamination in shellfish. Numerous experimental studies comparing faecal coliforms/E. coli and viruses (including enteric viruses and bacteriophages) with respect to the relative impact of sewage treatment processes, survival in terrestrial and aquatic environments, or accumulation and retention by shellfish have concluded that faecal coliforms/E. coli indicators can underestimate the presence of viruses. These conclusions have been supported by large-scale in situ studies based on shellfish samples analysed for both faecal coliforms/E. coli and human enteric viruses, which show a poor correlation between the two factors. (For example, Romalde et al. (2002) found no relationship between the presence of E. coli or faecal coliforms and enterovirus or hepatitis A virus in 164 shellfish samples collected from the Galician coast in Spain; Lowther (2011) found only a very weak relationship between levels of E. coli and norovirus in 856 oyster samples collected over 18 months from 39 sites in England, Scotland and Wales).

The factors contributing to the sources of variability in the relationship between faecal coliforms/E. coli and enteric viruses can result in both underestimation and overestimation of the risk of viruses by coliform indicators. The greater persistence of viruses than coliforms through sewage treatment, in the environment, and in shellfish can result in an underestimation of the presence of viruses by faecal coliform/E. coli indicators. However, the consistent presence of faecal coliforms/E. coli with human faecal contamination contrasts with the sometimes sporadic or seasonal presence of specific human enteric viruses, which varies with levels of viral illness in the population, and can result in coliform results that overestimate the presence of virus. In the Lowther (2011) study, the impact of this latter factor was illustrated by the stronger correlation between E. coli and norovirus levels in samples taken during the winter months (when clinical laboratory reports indicated elevated levels of norovirus illness) compared to the summer months.

However, while on a sample-by-sample basis faecal coliform/E. coli levels are not reliable predictors of enteric viruses in shellfish, the Lowther (2011) study did find a moderate correlation between within-site geometric mean values for E. coli and NoV in oysters (Spearmans rho=0.453, df=37, p=0.004) i.e. in simple terms, the study showed that there is a tendency for sites that show on average higher levels of E. coli in shellfish to also have higher levels of norovirus in shellfish. As observed in the analysis of the sample-by-sample correlation (see above), this relationship was strengthened (Spearmans rho=0.676, p=0.000) when only the results from winter months (Oct-Mar, when monthly clinical laboratory reports of norovirus infections were greatest in number) were considered, presumably because of the increased coincidence of E. coli and NoV in shellfish when NoV is present in higher numbers in the population. These results suggest that for these sites, within-site analysis of temporally distributed oyster data from monitoring of E. coli levels can provide a general indicator of the risk of norovirus occurrence. We note however that this relationship could be confounded if a major component of the faecal contamination at a site is from non-human sources (e.g. cattle, sheep).

There has been much international work to find an alternative indicator to total and faecal coliforms and E. coli, and for a while the FRNA bacteriophages were viewed as promising candidates (IAWPRC, 1991; Chung et al., 1998; Formiga-Cruz et al., 2003; Lee & Kay, 2006; Vilarano et al., 2004; Younger et al., 2002). However, further work has not shown a good correlation with
pathogens and results to date suggest that they may not be suitable for sites with sewage contamination from low volume sources (e.g. single on-site sewage systems), or from direct sources (such as direct faecal discharge from boat toilets) (e.g. Faatoese et al., 2005). In such instances, bacteriophages may not be detectable. (In their review, the IAWPRC Study Group on Health Related Water Microbiology (1991) commented that bacteriophages are an index of sewage contamination rather than faecal contamination). However, bacteriophages appear to be reliable indicators of sewage contamination in instances of high volume discharge of effluent that has been retained long enough for the multiplication of bacteriophages to occur (such as spills from wastewater treatment plants (European Commission, 2002), hence the 2009 NSSP policy change to allow this indicator to be used in association with sewage spill events.

2.4.3 Environmental indicators used to manage harvest areas

The principles of “Conditional Management” were described earlier (Section 2.3.2, Controlled harvest times). To harvest safe shellfish it is imperative that they are only harvested when the area is clear of pollution. Currently this safety level is normally measured by compliance with the microbial sentinel indicators. Pollution is commonly delivered to these areas in association with rainfall events that wash contamination directly from the land, or with water from flooded rivers, but there can be other events not associated with rainfall that cause a rise in microbial levels, for example, discharges from wastewater treatment plants, seasonal bird roosting or boating activity. Once the impacts of such events are fully understood, harvest areas are often opened and closed using indicators such as rainfall levels, river heights, salinity indices and/or boat numbers. To determine the relationship between the environmental indicators and the mandatory sentinel bacterial indicators, a statistically significant number of events needs to be investigated for each harvest area (usually defined as 15 events) to confirm consistent compliance with the standards.

2.5 Comment on the Science Underpinning the Current Shellfish Sanitation Programmes

To summarize, the international shellfish programmes show three general philosophies on how to predict and prevent the likelihood of microbial illness, namely:

1. The USA Programme, which focuses mainly on the use of the sanitary survey tool and monitoring the overlying waters in which the shellfish are grown.

2. The European programme, which has historically used the level of E. coli in live shellfish in the marketplace, and into which the EU is now slowly introducing the concept of sanitary survey assessments;

3. Combination programmes as used in Australia and New Zealand, where sanitary surveys, and water and shellfish monitoring are all required.

These three international shellfish programmes have been determined using both science and public policy decisions.

Sanitary surveys are generally qualitative, using professional judgment on the information available at the time of the survey. While there are guidelines on how to use semi-quantitative risk analysis
systems to rank pollution sources, the results cannot usually be presented using specific measurable quantitative analysis.

The original 1925 NSSP programme recommended the use of the *coli-aerogenes* group of bacteria as the sentinel indicator for growing waters but the programme has evolved over the years as new information became available. Perry made an extensive bacteriological study of the oyster industry in Maryland between 1925 and 1927 taking samples at various stages of production from the harvest areas to the market (Hackney and Pierson, 1994). One of his significant findings was that stratification of water may cause bacterial quality to vary with depth.

In 1941 another comprehensive study was undertaken of the clams in Raritan Bay, USA to evaluate the existing sanitary conditions with the bacteriological results. The study used human attack rates for typhoid fever, contamination levels in clams and average coliform ratios of 3:1 for clam meat to overlying water quality. Working at this level the scientists made a number of assumptions, for example, a target density of total coliforms was derived based on the dilution of a large point source of domestic sewage with a sufficient volume of water to yield a theoretical final ratio of indicator to typhoid bacteria. The scientists concluded that typhoid fever or other enteric diseases would not ordinarily arise from consumption of shellfish harvested from water in which not more than 50 percent of the 1 cc portions of water examined were positive for total coliforms (an MPN of approximately 70 per 100 ml), provided the areas were not subject to direct contamination with small amounts of fresh sewage which would not be revealed (NSSP Public Health Rationale, 2009). Aside from establishing the 70 total coliform/100mls as the NSSP indicator level this study was also the basis for the water-based NSSP programme (rather than a shellfish-based one). The basic theory was that bivalves (hard clams) grown in water at or below that standard indicator would not concentrate pathogens to densities exceeding a presumed minimum infective dose.

Epidemiological investigations of shellfish-caused disease outbreaks since then have found difficulty in establishing a direct numerical correlation between the bacteriological quality of water and the degree of hazard to health.

The Most Probable Number (MPN) technique used to express the number of bacteria in multiple fermentation tubes was accepted into the shellfish programme in 1946 and is still considered appropriate today (e.g. McBride, 2003). The MPN denotes a range within which the actual number indicating coliform concentration may be expected to lie. For example, for the five tube multiple dilution test, the 95% confidence limits cover approximately 24-324% of the MPN. As applied to an MPN value of 70, the 95% confidence range would be about 17-230 MPN. This methodology is therefore used in regulation with a system to manage the inherent statistical variability (e.g. the NSSP allows a 10% deviation from the 14 faecal coliforms provided that the sample results are not related to a pollution event). Another characteristic of the MPN method in the context of compliance determination is the discontinuous scale of possible reported outcomes, which leaves large gaps between possible outcomes, particularly at higher concentrations. Sampling bias and inherent variability amongst individual samples also generate uncertainty and variation in results (Woodward, 1957), but this is not explicitly managed except by qualitative judgement (for example, in the assessment of outlying results).

The 1946 NSSP manual stipulated that the bacteriological quality of oysters should comply with the following guidelines:

“When an MPN value of 230 or more persists in oyster shellstock sampled at the growing area or in shellstock at the point of shucking it should be interpreted as an"
A literature search and communication with scientists in the European Union and the US Food and Drug Administration has failed to identify the science that was originally used to set the recommended acceptable microbial limits in shellfish flesh (230 faecal coliforms/100 grams). It is likely that they were also based on the infective dosage of *Salmonella typhi* and extrapolated from that information gained during the studies done by Perry (1939) and the Raritan Bay study³.

In 1961 a scientific programme was undertaken in Maryland to assess the sentinel indicators used in the NSSP, with the aim of finding the best indicator to predict the presence of microbial pathogens in seawater (Hackney & Pierson, 1994). This project concluded that faecal coliforms could be used with an acceptable limit of 14 faecal coliforms/100 ml using the Most Probable Number method for reporting results.

Following a number of dilution studies related to sewage discharge events undertaken by the US Food and Drug Administration public health engineering and science group in 2009 they advised the NSSP programme that male-specific coliphage could also be used as an indicator to predict when shellfish harvest areas could be opened after an untreated sewage discharge event. The NSSP programme allows a harvest area to be reopened once the male-specific coliphage levels reduce back to the normal background level or to 50/100 grams of shellfish. There must be at least 7 days closure of the harvest area before these samples can be taken.

In recent years there has been much debate and focus by scientists and policymakers on the equivalency of the EU and the USA programme. Such judgements are often required when free trade arrangements are made between countries and equal levels of food safety protection between countries must be determined. To formally focus on the two programmes there was a joint meeting “Joint Meeting EU CRL/FDA International Workshop” hosted by CEFAS in September, 2008 (CEFAS, 2008). The next joint meeting to further debate public health equivalency will be held at Rhode Island in September, 2012 (Personal communication, Dr W Watkins, USFDA).

While epidemiological reviews indicate that the current programmes have been generally successful in preventing illness from bacterial pathogens it should be noted that as early as 1956 the scientists questioned the adequacy of the microbial indicators (total, faecal and *E. coli*) to manage viral disease. In 1956 the first viral Hepatitis A outbreak associated with oysters was documented (Mason & McLean, 1962). Since then Hepatitis A in shellfish has caused many major outbreaks of disease including in Italy, the USA, China and Australia (Richards, 2002; Richards, unpublished data). In one outbreak in China 292,000 people were infected. In 1996, an outbreak of Hepatitis A occurred in Louisiana and PCR analysis showed the virus was detectable in shellfish for at least 6 weeks following a contamination event (Glass et al., 1996).

³ For example, extrapolation from the value of 70 MPN/100 ml in water using the 1:3 ratio of coliforms in water to clams.
Internationally there have been an increasing number of documented viral outbreaks associated with oyster consumption, especially NoV (EC, 2002; Le Saux et al., 2006; Richards, 2002; Shieh et al., 2000). In many of these outbreaks the sentinel microbial indicators have not been present in high numbers and there is now good evidence that faecal coliform/E. coli indicators are unreliable predictors of the presence of pathogenic viruses (Cole et al., 1986; Lee & Kay, 2006; Henshilwood et al., 1998).

The Food Safety Authority of Ireland were so concerned about the prevalence of viral illness in their country (1647 reported cases of NoV infections in 2009 and a 2010 outbreak linked epidemiologically to oysters) that they asked the European Food Safety Authority (EFSA) for a scientific opinion to consider the latest scientific information and provide an opinion on:

1. The use of real-time PCR as a means of detection and quantification of NoV in oysters.
2. Limits that do not pose an unacceptable risk to consumers for NoV genogroups GI and GII in oysters as determined by PCR.
3. Treatment regimes (post-harvest interventions) that can be relied upon to reduce NoV counts in oysters.

EFSA responded that while NoV is highly infectious the probability of becoming infected increases with the dose but also depends on the characteristics of the organism, the food matrix and the host factors. They found that harvest areas in compliance with the 230 E. coli per 100grams often contained a viral loading. They recommended that risk managers should consider establishing an acceptable limit for NoV in oysters to be harvested and placed on the market, but they pointed out that the most effective public health measure to control human NoV infection from oyster consumption is to produce oysters from areas which are not faecally contaminated (EFSA, 2012).

### 2.6 Epidemiological Trends

To evaluate the success of the current shellfish food safety programmes in preventing microbial illness a review was undertaken of the epidemiological information available for the USA, EU, Australia and New Zealand. While information has been gathered on the reported incidence of disease it is acknowledged that under-reporting of gastrointestinal illness is usual throughout the world. Under-reporting may occur for many reasons, for example, lack of self reporting by patients to a medical practitioner or lack of medical authority reporting to an official state epidemiology authority. It is difficult to know the rate of under-reporting. A Canadian study in 2008 found for every case of gastrointestinal illness a mean of 347 community cases occurred (MacDougall et al., 2008). A New Zealand risk profile assumes that 1 reported case equates to about 1,000 unreported cases (Applied Economics Pty Ltd, 2010).

#### 2.6.1 United States of America

A number of papers have been written on the contemporary illness patterns amongst shellfish consumers in the USA (Hackney & Dicharry, 1988; Hackney & Pierson, 1994; Kohn et al., 1995; Lipp & Rose, 1997; Richards, 2002; Butt et al., 2004, Centre for Science, 2004; USFDA, 2005).

Hackney & Dicharry (1988) state that overall, seafoods have a good safety record, and even shellfish that are usually consumed raw are usually safe for the general public. They conclude that sewage-borne pathogens are by far the greatest hazard. In 2004 Butt et al. found that food-borne
disease caused an estimated 76 million illnesses in the USA each year. Seafood is implicated in 10-19% of these illnesses. A causative agent can be traced in about 44% of seafood-related outbreaks, viruses accounting for around half of these illnesses (Butt et al., 2004). In 2011 Scallan et al. estimated 9.4 million food-borne illness episodes in the USA, of which 58% are caused by NoV. Batz et al. (2011) determined that, measured by Quality Adjusted Life Years, seafood ranked eighth out of 12 food groups (poultry, beef, pork etc) that cause disease burden in the USA.

Lipp & Rose (1997) undertook an analysis of food-borne diseases associated with seafood. They found that during the period 1898 to 1993 ten genera of bacterial pathogens were implicated with seafood. Pathogenic bacteria may be categorized into two groups: enteric bacteria due to faecal contamination, and bacteria which are normal components of the marine and estuarine environment. The most important bacteria associated with faecal contamination of seafood include *Salmonella, Shigella, Campylobacter, Yersinia, Listeria, Clostridium, Staphylococcus* and *Escherichia coli*. However, Lipp & Rose (1997) noted that few of these bacteria continue to pose large scale health threats today. They found that since the 1950s naturally-occurring bacteria have become a more significant cause of shellfish-borne illness. Most of the indigenous marine bacteria belong to the *Vibrio* family, and raw oyster consumption is the most important route for human infection. Their analysis of the last 25 years data showed that in the USA bacterial pathogens associated with faecal contamination represented only 4% of the shellfish associated outbreaks, while naturally occurring pathogens (*Vibrios*) accounted for 20% of shellfish related illnesses and 99% of deaths. However, when it comes to microbial pathogens introduced via pollution, viruses are the most significant cause of oyster associated disease: for example, in New York State 62% of the 196 outbreaks between 1982 and 1991 were caused by viruses. A report produced by the USA Centre for Science in the Public Interest in March 2004 states that noroviruses and *Vibrios* are the most common pathogens associated with oyster consumption (Centre for Science, 2004). Today, viruses continue to be the leading cause of non-bacterial gastroenteritis in USA shellfish consumers and are estimated to cause 40,000 illnesses annually in the USA (Burkhardt, 2011, Richards et al., 2011).

2.6.2 European epidemiological information

To assess the effectiveness of the European shellfish safety policies epidemiological information was obtained from CEFAS for England and Wales for the period 1987-2010 (personal communication R Lee, CEFAS). This information is displayed graphically in Figure 2.2.

While Figure 2.2 shows the information from only two countries it does show that, as in the USA, in the United Kingdom the most frequently identified pathogen types associated with bivalve shellfish consumption are those causing viral gastroenteritis and Hepatitis A. As depicted in Figure 2.2, historically in most cases the aetiological cause of illness was unknown. The graph also broadly illustrates that through time an increasing proportion of the illnesses of unknown aetiology has been able to be attributed to viral sources, presumably because of improved test methods associated with the detection of viral pathogens (such as the development of PCR methods).

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4 We note that shellfish formed one component of "seafood" in this study - seafood also includes fish and crustacea, which may feature a different balance of associated pathogens than shellfish.
Figure 2.2: Illness associated with molluscan shellfish in the UK (Data compiled by HPA Communicable Disease Surveillance Centre).

There is further evidence that viruses in shellfish are a major health problem in the EU as in 2009 Ireland had 1647 reported cases of NoV infections. In January 2010 the Food Safety Authority of Ireland was notified of food poisoning incidents linked epidemiologically to an oyster production area in Ireland, which eventually resulted in 31 reported food poisoning events in England and Ireland with a total of 76 people reported ill, several of whom had norovirus in their stools (EFSA, 2012).

The European situation was confirmed by a number of presentations at the International Molluscan Shellfish Safety Conferences in 2009 and 2011, with public health representatives from the UK, France, Italy (as well as other non-European countries) showing data suggesting that NoV and hepatitis A are now the leading causes of food-borne disease arising from shellfish consumption (Croci et al., 2009; Guillois-Becel et al., 2009; Boxman, 2011).

2.6.3 Australian epidemiology information

Two significant reports provide valuable information on the illnesses associated with seafood consumption in Australia. The first report entitled “Hazards Affecting Australian Seafood” was undertaken Dr John Sumner in May 2011 for SafeFish (Sumner, 2011). This report includes underpinning data on food poisonings for the period 1988-2010 and recalls of seafood products for the period 1999-2011. Table 2.2 summarizes his information on the seafood hazards identified.
<table>
<thead>
<tr>
<th>Hazard</th>
<th>Outbreaks</th>
<th>Cases (deaths)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ciguatera</td>
<td>101</td>
<td>&gt; 597</td>
</tr>
<tr>
<td>Histamine</td>
<td>38</td>
<td>148</td>
</tr>
<tr>
<td>Shellfish Poison</td>
<td>3</td>
<td>117</td>
</tr>
<tr>
<td>Waxy Esters</td>
<td>8</td>
<td>&gt; 98</td>
</tr>
<tr>
<td>Viruses</td>
<td>23</td>
<td>1999 (1)</td>
</tr>
<tr>
<td>Salmonella</td>
<td>5</td>
<td>60</td>
</tr>
<tr>
<td><em>Staph aureus</em></td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td><em>Vibrio spp</em></td>
<td>9</td>
<td>11 (6)</td>
</tr>
<tr>
<td><em>Listeria monocytogenes</em></td>
<td>1</td>
<td>3</td>
</tr>
<tr>
<td>Unknown</td>
<td>20</td>
<td>151</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>209</strong></td>
<td><strong>&gt;3186</strong></td>
</tr>
</tbody>
</table>

Table 2.2: Hazards associated with seafoods implicated in food poisonings in Australia in 1988-2010 (Source: Sumner, 2011)

The data provided in Table 2.2 were not analysed by seafood type, and included all types of seafood. There is likely to be significant variability in hazards between different seafood types. However, Sumner (2011) provided the following narrative on the data with reference to shellfish specifically:

- Viral illness fell significantly and while oysters from NSW waters were responsible for illness during 1988-2001, imported shellfish (predominantly frozen oysters) caused most of the illnesses in 2001-2010.

- The reduction in oyster-associated illness reflects the implementation of shellfish quality assurance programs by all states.

- The third most numerous category is ‘Unknown’ which accounted for 20 outbreaks, of which nine were associated with bivalve shellfish (suspect NoV), one with tuna (suspected histamine) and one with Spanish mackerel (suspect ciguatera).

- Although imported bivalves appear to be responsible for some NoV outbreaks it is possible some are of domestic origin.

He noted that the only shellfish product recall occurred in 2006, and was for under-processed canned clams imported from China.

The second epidemiological report with valuable information is a summary prepared by Katrina Knope, OzFoodNet Co-ordinating Epidemiologist. She summarized the outbreaks of NoV, Hepatitis A and unknown aetiology associated with bivalve shellfish for the period 1st January to 31st December 2011. She noted that during this period there were 17 outbreaks (283 persons) of NoV or unknown aetiology associated with bivalve shellfish, but there were no Hepatitis A outbreaks. Seven of the outbreaks were in New South Wales, three in Western Australia, two in Queensland and Northern Territories, and one in Tasmania. Knope’s report suggests that six of the outbreaks were associated with Australian-grown product. Twelve of the seventeen outbreaks were linked to oysters, six attributed to quick-frozen oysters from Japan. Two outbreaks were linked to mussels and one to pipis (surf clams). (The report does not specify what species were associated
with the other two outbreaks). It was considered that the likely sources of contamination in the NoV outbreaks were in the growing area and not associated with post harvest contamination.

### 2.6.4 New Zealand epidemiology information

After the last reported typhoid outbreak in 1914 there were no further reported illnesses associated with commercially harvested oysters until 1994 when a NoV outbreak occurred that was associated with oysters harvested from Waikare Inlet, Bay of Islands (personal communication ESR, 2006). Although New Zealand commonly has significant numbers of wild and domesticated animals in the land catchments adjacent to oyster harvest areas and there is evidence that faecal material enters streams and marine areas after flood events (Nagels et al., 2002), there are no documented human cases of zoonotic disease associated with oyster consumption.

However, an analysis of disease notifications to ESR Ltd shows that between 1995-2010 there were a number of illness outbreaks associated with oysters. Several cases of NoV illness have been associated with imported Korean and Chilean Pacific oysters. In December 2005 there were two outbreaks associated with recreationally harvested shellfish: _Shigella_ cases were associated with Pacific oysters collected by the public from the marina piles at Opua, and a Hepatitis A outbreak was associated with feral Greenshell mussels taken off Black Rocks in the Bay of Islands. Both of these events were thought to be caused by discharges from marine craft. However, the only cases associated with _commercially_ harvested New Zealand Pacific oysters were NoV outbreaks in 1994, 1999, 2000, 2001, 2004, 2008, and 2009 (NZFSA files and District Health Board files).

ESR Ltd is the government agency responsible for monitoring and collating New Zealand’s epidemiological information. Each year they produce a summary report entitled “Annual Summary of Outbreaks” (www.esr.cri.nz). A review of these reports for the period 2001-2010 shows that in every year the most common outbreaks associated with shellfish, in which the aetiological agent was identified, were due to NoV. It should be noted that some of these outbreaks were associated with imported Korean oysters (2007, 2010), which were also implicated in an earlier 2000 outbreak.

### 2.6.5 Summary of the international epidemiological information

The epidemiological information gathered for the USA, EU, Australia and New Zealand shows that viruses are now the leading cause of food-borne outbreaks amongst shellfish consumers. Oysters are the bivalve species most commonly implicated.

The increasing prevalence of reported viral outbreaks, particularly NoV, amongst shellfish consumers has also been reported at a number of scientific fora. Although the papers presented at the 2011 International Molluscan Shellfish Safety Conference convened at Prince Edward Island Canada have yet to be formally published, presentations by Dr Ingeborg Boorman and Dr Gary Richards continued to affirm that human enteric virus contamination of shellfish continues to pose a significant threat of illness world-wide (Boorman, 2011; Richards et al., 2011).
2.7 **International Environmental Policies and Standards**

2.7.1 **Introduction**

A number of policies and standards common to both Australia and New Zealand are relevant to water quality/shellfish quality in commercial shellfish growing areas. These include marine pollution regulations that have wide international acceptance, and policies and standards that are developed and shared between Australia and New Zealand.

2.7.2 **MARPOL Regulations**

New Zealand and Australia have agreed to abide by what are known as the MARPOL regulations (i.e. the International Convention for the Prevention of Pollution from Ships). These regulations define measures to protect the marine environment from pollution, and include the prohibition of discharge of sewage into the sea from ships except when the ship has in operation an approved sewage treatment plant or when the ship is discharging comminuted and disinfected sewage using an approved system at a distance of more than three nautical miles from the nearest land. Sewage that is not comminuted and disinfected to the specified standards has to be discharged at a distance of more than 12 nautical miles from the nearest land (MARPOL Annex IV, see [www.imo.org](http://www.imo.org)).

2.7.3 **Australian and New Zealand Guidelines for Fresh and Marine Water Quality 2000**

The primary objective of the *Australian and New Zealand Guidelines for Fresh and Marine Water Quality* developed by the Australian and New Zealand Environment and Conservation Council (ANZECC) is: "To provide an authoritative guide for setting water quality objectives required to sustain current, or likely future, environmental values [uses] for natural and semi-natural water resources in Australia and New Zealand."

Chapter 9.4 of this document is entitled “Aquaculture and human consumers of aquatic food”. The current document does not provide much material on how best to manage viral contamination (it is currently focused on chemical contaminants). In May 2009, approval was given by Australian and New Zealand Environment Ministers for these guidelines to be revised. The revision of this document provides the opportunity to give better guidance on how to manage environmental pollution, including sewage contamination. Among other things, early reports indicate that the scope of the revision work includes:

- A revision of the section relating to pathogens in aquaculture foods for human consumption, focussing on the suitability of indicators;
- Improving linkages between methods of trigger value derivation for aquatic ecosystems and aquaculture (Ministry for the Environment, 2010).

In 2012 the revision process is yet to be completed.
2.7.4 Australian/New Zealand Standards

Standards are agreed specifications for products, processes, services or performance. Australian/New Zealand standards are developed in partnership by non-governmental standards organisations in each country (i.e. Standards Australia and Standards New Zealand). These organisations operate within a framework of legislation specific to their country, and regulations may specify compliance with standards.

Some standards have been developed to ensure that environmental quality is maintained. These include for example, the Australian Standard/New Zealand Standard for on-site domestic wastewater management (AS/NZS 1547:2000).

2.8 Environmental Legislation in New Zealand

2.8.1 Introduction

The following pieces of environmental legislation are used to manage the risks of marine pollution in New Zealand:

1) Resource Management Act 1991 and associated polices/plans required to be drafted under this legislation (Coastal Policy Statement and Regional Coastal Plans);

2) Resource Management (Marine Pollution) Regulations 1998 and subsequent amendments;

3) Health Act 1956.

In addition to shared policies and standards shared with Australia as discussed in Section 2.7, the following policies are also associated with controlling pollution to the marine environment:

1) Dairying and Clean Streams Accord;

2) State of the Environment Reporting.

2.8.2 Resource Management Act 1991

In New Zealand the key national environmental legislation is the Resource Management Act 1991 (RMA). This Act is administered by central government, regional councils and territorial authorities (local councils). The Act made regional councils responsible for sustainable management of natural and physical resources, including coastal waters.

The Act’s three central functions are to:

1) Manage the environmental effects of activities on air, water and the land;
2) Manage the use of publicly owned or managed natural resources (including the foreshore and seabed);
3) Control the discharge of contaminants to land, air, and water.
The RMA requires regional councils to prepare coastal plans and requires the Ministry of Conservation to produce a New Zealand Coastal Policy to guide local authorities in their day to day management of the coastal environment. The 2010 NZ Coastal Policy Statement is the only national policy statement in place under the Resource Management Act. Aquaculture is specifically addressed in Policy 8 of the NZ Coastal Policy Statement as follows:

“Recognise the significant existing and potential contribution of aquaculture to the social, economic and cultural well-being of people and communities by:
(a) including in regional policy statements and regional coastal plans provision for aquaculture activities in appropriate places in the coastal environment, recognising that relevant considerations may include:
   (i) the need for high water quality for aquaculture activities; and
   (ii) the need for land-based facilities associated with marine farming;
(b) taking account of the social and economic benefits of aquaculture, including any available assessments of national and regional economic benefits; and
(c) ensuring that development in the coastal environment does not make water quality unfit for aquaculture activities in areas approved for that purpose”.

Policy 21, which relates to enhancement of water quality, also specifically mentions aquaculture as follows:

“Where the quality of water in the coastal environment has deteriorated so that it is having a significant adverse effect on ecosystems, natural habitats, or water based recreational activities, or is restricting existing uses, such as aquaculture, shellfish gathering, and cultural activities, give priority to improving that quality by:
(a) identifying such areas of coastal water and water bodies and including them in plans;
(b) including provisions in plans to address improving water quality in the areas identified above;
(c) where practicable, restoring water quality to at least a state that can support such activities and ecosystems and natural habitats;
(d) requiring that stock are excluded from the coastal marine area, adjoining intertidal areas and other water bodies and riparian margins in the coastal environment, within a prescribed time frame; and” etc.

Regional Councils are responsible for drafting and implementing plans for the coastal marine area. The purpose of the Regional Coastal Plan is to assist the Regional Councils, in conjunction with the Minister of Conservation, to promote the sustainable management of resources in the coastal marine area, defined as the area from mean high water springs to the 12 nautical mile (22.2km) limit of New Zealand’s territorial sea.

Section 15 of the RMA provides the legal sanctions for controlling discharges of contaminants into water, or onto or into land. The presumption in Section 15(1) is that a discharge is prohibited unless it is expressly allowed, either by resource consent, a rule in the plan, or by regulation (depending on the type of discharge).

2.8.3 Resource Management (Marine Pollution) Regulations 1998

The Resource Management (Marine Pollution) Regulations 1998 (which include subsequent amendments made in 2002 and 2011) were the direct result of New Zealand’s agreement to abide
by MARPOL. These regulations prohibit the discharge of untreated sewage from a vessel or offshore installation within 500 metres of a marine farm, or in less than 5 m water depth, or within 500 metres of mean high water spring on the shore. There are different restrictions for treated sewage: Grade A treated sewage may be discharged anywhere except within 100 metres of a marine farm. Grade A treated sewage is defined in Schedules 5 and 6 of the regulations as follows: any treatment systems described in the first 5 columns of the table of treatment systems in Annex 5 of the IMO circular dated 31st August 2005 about pollution prevention equipment required by MARPOL 73/78, or any system that meets (among other requirements relating to suspended solids and BOD) a faecal coliform geometric mean of <250/100ml when tested under IMO Resolution MEPC.2(IV)). Grade B treated sewage (defined as sewage that has been treated by one of the sewage treatment systems listed in Schedule 7 of the regulations) may not be discharged within 500 metres of a marine farm or within 500 metres of mean high water spring on the shore. These regulations are insufficient to consistently protect shellfish (particularly those grown inter-tidally) from virus contamination arising from effluent discharges from boats. However, the regulations provide for the inclusion of more restrictive regulations to be included in regional coastal plans, and in practice some regional councils in areas with significant shellfish farming industries have done so – for example, the Northland Regional Council prohibits the discharge of any untreated sewage within specified harbours and estuaries in its region.

2.8.4 Health Act 1956

The Health Act 1956 sets out the requirements for local authorities to improve, promote, and protect public health within their boundaries. The Act requires authorities to deal with any nuisance conditions or adverse effects and to provide adequate facilities, including sewage treatment, in their region. The Act gives powers to Medical Officers of Health to act when there are public health issues, and Section 128 gives Medical Officers of Health and Health Protection Officers powers of entry at all reasonable times to any dwelling, house, building, land, ship or other premises to inspect/execute any works authorised by or pursuant to the Act. This warrant therefore enables these officers to inspect sewerage infrastructure and on-site sewage systems on any property.

The currently proposed Public Health Bill will update New Zealand’s public health legislation and become the primary public health statute, replacing amongst other Acts, the Health Act 1956 (www.health.govt.nz).

2.8.5 Dairying and Clean Streams Accord

In 2003, there was an agreement reached between Fonterra Co-operative Group (which represents over 95% of New Zealand’s dairy farm milk producers), regional councils and Government. The Accord includes five targets aimed at achieving clean, healthy water in streams, rivers, lakes, groundwater, and wetlands in dairying areas. This Accord will hopefully assist in the reduction of faecal coliforms and E. coli reaching marine waters, but will not reduce the risk of human viral illness (human enteric viruses do not infect cattle).

5 Based on assumptions of $10^{11}$ noroviruses in 100 ml faeces/vomit in one toilet flush diluted by 10 on discharge, a semicircular distribution from the boat towards an inter-tidal farm, and a depth at boat of 5m rising smoothly to 1m at the farm, the water impacting at farm would contain approximately 13 viruses/litre.
Regional councils around the country continue to work with land-care groups and farmers to encourage best environmental management practices on rural land in their regions. This work has included programmes that promote revegetation of river and stream banks to enhance water quality, and fencing of stock from water courses.

2.8.6 State of the Environment Reporting

MfE believe that people who make decisions about the environment need accurate and reliable environmental information. To monitor New Zealand’s environment over time MfE use a range of national “indicators” to assess the overall state of the environment in a practical, cost-effective and meaningful way. The core national environmental indicators are designed to monitor energy use, solid waste disposal, air and water quality, wild fish stock management and native plant and animal distribution.

MfE have designed these indicators to provide nationwide information for decision-makers and environmental managers with the aim of highlighting the aspects of New Zealand’s environment that have come under particular pressure and require priority attention.

Under the RMA, Regional Councils are legally required to collect data on:

- Solid waste disposal to landfill;
- Air quality;
- Land cover and land use;
- Soil health and soil erosion;
- Water quality in rivers, lakes and groundwater aquifers;
- Freshwater demand;
- Water quality at coastal swimming spots;
- Land area with native vegetation.

Most Regional Councils produce a formal report on their indicators annually, while MfE is responsible for collating, analyzing and publishing the national State of the Environment report. The last national report was published in 2007.

It should be noted that there are no national indicators that track the quality of the marine environment as it relates to the food safety of shellfish resources. The water quality at coastal swimming spots is monitored nationally using Enterococci bacteria as an indicator, and generally these sites are not spatially relevant to shellfish growing areas. For those sampling sites with spatial relevance to shellfish growing areas, the Enterococci data cannot be directly correlated with results from the E. coli and faecal coliform indicators used in the national shellfish sanitation programme.

2.8.7 Role of the Ministry for the Environment

The Ministry for the Environment (MfE) is responsible for establishing environmental standards and guidelines to help local authorities and regional councils administer their responsibilities under the RMA. MfE also has responsibility to give advice on sustainable management and to provide public education.
Examples of educational material that have been prepared are the two leaflets, “The Story of Your Septic Tank” and “Keep our Bays Beautiful”, both of which provide the general public with information on what they can do to prevent sewage pollution of the environment.

MfE drafted a proposed National Environmental Standard for On-Site Wastewater Disposal Systems (NES). The proposed standard would have authorised regional councils to implement a scheme that required property owners with an on-site system to hold a current warrant of fitness (WOF) for their system. To obtain a WOF, a system would be required to pass an inspection. Inspections would be required every three years. The draft standard also proposed targeting areas that were known to have problems with the performance of on-site systems, or where there was an actual or potential risk to the environment from higher densities of on-site systems. These standards were designed to clarify the required performance standards for on-site sewage systems and strengthen the monitoring of compliance by owners with their existing obligations (e.g. under the Health Act 1956 and council by-laws). Unfortunately this national environmental standard did not proceed following a cost-benefit analysis that occurred with a change of Government.

2.8.8 Role of Regional Councils

Regional councils (as well as unitary authorities, which combine the role of regional council and territorial authority) are responsible for developing regional plans and policy statements under the Resource Management Act. Their powers and responsibilities cover:

- Managing freshwater, groundwater, and coastal water
- Controlling the discharge of contaminants to water
- Managing the foreshore, water column and seabed including implementing controls on aquaculture in coastal waters
- Environmental education
- Harbour navigation and safety, marine pollution and oil spills

As a result each Regional Council prepares their own individual plan which outlines the rules for all discharges to water, air and soil in their geographical area of responsibility.

2.8.9 Role of Territorial Authorities

Territorial authorities are responsible for:

- Infrastructure (including water, sewerage and stormwater);
- Environmental education

Councils have the ability to pass by-laws appropriate for their community. An example of a by-law that directly impacts on water pollution levels is Far North District Council’s 2010 Chapter 28 Control of On-Site Wastewater Disposal Systems. The purpose of this by-law is to ensure that all On-Site Wastewater Disposal Systems in operation or proposed to be installed, repaired or extended on properties in the District are installed, repaired, extended, operated and maintained in a safe and sanitary way with no or minimal adverse effects on the surrounding natural environment and in a manner that is culturally sensitive.
All local authorities must monitor the efficiency and effectiveness of their policies and plans in meeting their many functions, and report on this every five years, although it seems that most Councils actually produce an annual report for their ratepayers.

2.8.10 Role of the Environment Court

The Environment Court provides a judicial system to deal with appeals on decisions made under the RMA. This generates a body of case law. An example highlighting the role of the Environment Court involved a case in which a group of oyster farmers from a growing area in New Zealand were party to an appeal of a decision by Northland Regional Council in issuing a resource consent to a motor camp for the continued disposal of untreated sewage down a disused mine shaft. The Environment Court found in favour of the oyster industry with the Judge deeming that this sewage disposal method was “unsustainable management” and likely to have adverse effects on the oyster farms.

2.8.11 Role of the Parliamentary Commissioner for the Environment

This role was established when the RMA was enacted, with the Parliamentary Commissioner for the Environment having wide-ranging powers to investigate environmental concerns. This role is independent of the government of the day, with the Commissioner reporting not to a Government Minister but to Parliament through the Speaker of the House. As an Officer of Parliament, the Commissioner's job is to hold the Government to account for its environmental policies and actions. The Commissioner is a policy reviewer standing outside the system of environmental management and reporting on it. However, it should be noted that while the Commissioner can investigate and report on any environmental issue there is no legal requirement for the Government to act on any of the report recommendations.

2.8.12 General comment on the New Zealand environmental legislation

There are regulations governing sewage disposal and impacts on water quality in New Zealand. The RMA, which sets out the high level national requirements, makes it an offence for any “contamination” of water unless the discharge is expressly allowed by a national environmental standard or other regulations, a rule in a regional plan, or a resource consent issued by the Regional Council. The RMA then goes on to empower Regional Councils to control the maintenance and enhancement of the quality of water in water bodies and coastal water.

Regional Councils in turn use a system of automatic approvals or specific consent applications to manage any local environmental pollution. Although the RMA establishes the high level outcome, it is up to each Regional Council to design their own plan and specifications with which to meet the intent of the RMA. This means that the local Regional Council plans may differ in the standards they require. Some Regional Councils opt for the principles of Best Practicable Options while other Councils have set specific standards for design, installation and maintenance of sewage disposal systems, for example, Technical Publication No. 58 “On-site Wastewater Systems: Design and Management Manual” (Auckland Regional Council, 2004).

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6 Waitoto Developments Limited vs Northland Regional Council, NZ Environment Court Decision No. A 164/2005
Once any policy, such as the RMA and the Regional Plans, have been decided upon it must be implemented. Historically there were delays in implementing the RMA, for example, a consent for commercial sewage disposal expired in Northland in 2000 and although there was documented evidence of problems at the site, the Regional Council did not even start the process of considering whether a new consent should be issued until 2003, during which time the discharge continued to operate.

After policy is implemented, monitoring and evaluating are also necessary to ensure that the policy is achieving its intended purpose. Such feedback loops are important when policy decisions, such as environmental laws, are made under conditions of uncertainty. In such cases it is important to keep track of how effective the policies are and to make timely, iterative adjustments.

In 2004 the Parliamentary Commissioner noted in his report “Mission Links: Connecting science with Environmental Policy” (PCE, 2004) that New Zealand suffers from poor policy implementation, which confounds sound policy initiatives. He also noted that assessing the changes brought about by an environmental policy (outcome evaluation) is seldom done systematically or done well in New Zealand.

Each development application is considered on its individual environmental impact, and there is much debate as to how effective the RMA process is at assessing and measuring cumulative environmental impacts. The RMA has been criticised as providing too much discretion and being too much in favour of development. Bruce Pardy of Victoria’s University’s Faculty of Law has argued “that significant long-term environmental changes can be caused by the accumulation of small impacts. Compromise allows environmental death from a thousand inconsequential cuts.” (Pawson & Brooking, 2002).

2.9 New South Wales Environmental Policies

2.9.1 Introduction

Following is a summary of the aspects of environmental policy in New South Wales with relevance to the maintenance of water quality in shellfish growing areas. Further details are provided in Appendix I.

The following legislation and policy is relevant to the management of water quality in NSW shellfish growing areas:

- Protection of the Environment Operations Act 1997;
- Environmental Planning and Assessment Act 1979;
- State Environmental Planning Policy No. 62 – Sustainable Aquaculture;
- NSW Oyster Industry Sustainable Aquaculture Strategy, developed under the Fisheries Management Act 1994;
- NSW Local Government Act 1993;
- NSW Local Government (General) Regulation 2006;
- Marine Pollution Regulation 2006.

The following standards and guidelines assist in the maintenance of environmental quality:
• Australian and New Zealand Guidelines for Fresh and Marine Water Quality 2000 (See Section 2.7.3);
• Australian Standard/New Zealand Standard for on-site domestic wastewater management (AS/NZS 1547:2000) (See Section 2.7.4);
• Environment and Health Protection Guidelines: On-site sewage management for single households (Department of Local Government, 1998).

2.9.2 Protection of the Environmental Operations Act 1997

The Protection of the Environment Operations Act 1997 (POEO Act) is a key piece of environmental legislation in New South Wales, and is administered by the Environmental Protection Authority. The POEO Act enables the Government to set out explicit “Protection of the Environment Policies” (PEPs). PEPs are instruments for setting environmental standards, goals, protocols and guidelines. They provide both the framework for Government decisions that affect the environment, and are the means of adopting Australia-wide environment protection measures set by the National Environment Protection Council. The Act integrates environment protection licensing relating to air pollution, water pollution, noise pollution and waste management.

The EPA licences scheduled activities (e.g. WWTP). (In general, Local councils can regulate non-scheduled activities through notice and enforcement powers in their local government area). Licences are usually issued with conditions. Examples of conditions that can be attached to a licence are provided in the Act, and include requirements to monitor, to provide certification of compliance with a licence, to undertaken and comply with a mandatory environmental audit programme and pollution studies, reduction programmes and financial assurances. The EPA must review a licence once every 5 years, but a licence remains in force until suspended, revoked or surrendered.

Under the Act there is a duty to notify relevant authorities of defined pollution incidents and failure to do this is an offence. We note that all licence-holders for wastewater treatment plants are now required to report incidents of pollution to waterways that might impact on oyster growing areas to the NSW Food Authority as a condition of their licences. In practice, information collected by NSW Food Authority suggests that the level of compliance with this varies between councils in the state (Baker, 2013).

2.9.3 Environmental Planning Instruments

Environmental Planning and Assessment Act 1979 No. 203

The Environmental Planning and Assessment Act 1979 is administered by the NSW Department of Planning.

Under the Environmental Planning and Assessment Act 1979 No. 203 section 37 the Governor may make environmental planning instruments for the purposes for environmental planning by the State. Such an instrument is called a State Environmental Planning Policy (SEPP).

Under section 53 of the same Act, the Minister may make environmental planning instruments for the purpose of environmental planning in each local government area, and in such other areas of the
State (including the coastal waters of the State) as the Minister determines. Any such instrument may be called a Local Environmental Plan (LEP).

**State Environmental Planning Policy No. 62 – Sustainable Aquaculture**

The aims and objectives of the *State Environmental Planning Policy No. 62 – Sustainable Aquaculture* (SEPP 62), which commenced on 1st October 2000, include:

a) to encourage sustainable aquaculture in the State, namely, aquaculture development which uses, conserves and enhances the community’s resources so that the total quality of life now and in the future can be preserved and enhanced, and

b) to make aquaculture a permissible use in certain areas for which a comprehensive and integrated regional aquaculture strategy has been developed (being a strategy that incorporates the relevant Aquaculture Industry Development Plan under the Fisheries Management Act 1994 and the assessment regime for integrated aquaculture development), and

c) to set out the minimum site location and operational requirements for permissible aquaculture development (the “minimum performance criteria”), and

d) to establish a graduated environmental assessment regime for aquaculture development based on the applicable level of environmental risk associated with site and operational factors...

SEPP 62 specifically provides for consideration of effects of proposed development on oyster aquaculture and applies to all development and all land. Consultation with the Director-General of Primary Industries is required in cases where the consent authority considers that because of its nature and location the development may have an adverse effect on oyster aquaculture development or a priority oyster aquaculture area. Consent may be refused if development adversely affects oyster aquaculture.

### 2.9.4 NSW Oyster Industry Sustainable Aquaculture Strategy

Under the Fisheries Management Act 1994 a sustainable aquaculture strategy for the NSW oyster industry was developed in 2006 (NSW Government, 2006). Under the aims and objectives of SEPP 62 this has the effect of making oyster farming a permissible use in those areas specified in the strategy.

Amongst other issues, the NSW Oyster Industry Sustainable Aquaculture Strategy (OISAS):

- Identifies the key water quality parameters necessary for sustainable oyster aquaculture and establishes a mechanism to maintain and where possible improve the environmental conditions required for sustainable oyster production; and,

- Ensures that the water quality requirements for oyster growing are considered in the State’s land and water management and strategic planning framework.

Amongst the planning and approval issues addressed in the strategy, the issue of the impact of other resource use on oyster farming is considered, including with respect to making Local Environmental Plans that may affect oyster aquaculture, and the determination of development applications that may affect oyster aquaculture.
2.9.5 NSW Local Government Legislation

Amongst other issues, the NSW Local Government Act 1998 and NSW Local Government (General) Regulation 2005 provide policy relating to activities that are not scheduled in the Protection of the Environment Operations Act 1997, and which are managed by Councils.

The NSW Local Government Act 1993 specifies what activities require the approval of Council. Amongst others these include:

- To install, construct or alter a waste treatment device or human waste storage facility or a drain connected to any such device or facility; and
- To operate a system of sewage management (the definition of which encompasses on-site sewage systems).

The NSW Local Government (General) Regulation 2005 amongst other things provides for regulation of activities associated with on-site sewage systems, including the matters to be taken into consideration in determining an application for approval to install, construct or alter a system, the performance standards for the operation of an on-site sewage system, and requirements associated with gaining approval to operate such a system.

2.9.6 Marine Pollution Act 2012 and Marine Pollution Regulations 2006

Australia has agreed to abide by MARPOL (see Section 2.7.2), and this is implemented at state level in NSW under the Marine Pollution Act 2012 No.5. This Act includes the prohibition of discharge of sewage into the sea from ships except when the ship has in operation an approved sewage treatment plant or when the ship is discharging comminuted and disinfected sewage using an approved system at a distance of more than three nautical miles from the nearest land. Sewage that is not comminuted or disinfected has to be discharged at a distance of more than 12 nautical miles from the nearest land. Amongst other issues the Marine Pollution Regulations 2006 regulate the discharge of sewage into the marine environment from vessels, including recreational vessels, which are not covered under the Act. In brief, no discharge of untreated sewage is permitted into any navigable waters or onto the bank or bed of any navigable waters. No discharge of treated sewage is permitted within 500 m of any area where aquaculture occurs. Any treatment system fitted to a vessel must be a certified system, and must be fitted according to the manufacturer’s instructions, maintained in good condition, and operated within the maximum treatment capacity specified by the manufacturer. Schedule 4 of the regulations specifies the standard for treated sewage from vessels, which, along with maximum suspended sediment and BOD levels, includes a maximum geometric mean of the faecal coliform count of the samples of effluent taken during a test period of 250 faecal coliforms/100 ml M.P.N. (most probable number) as determined by a multiple tube fermentation analysis or an equivalent analytical procedure. Specified classes of commercial vessels must have holding tanks, and the holding tank requirements are specified in Schedules 5 & 6 of the regulations.

2.9.7 NSW Standards and Guidelines

The NSW Department of Local Government (DLG) has developed guidelines relating to the management of on-site sewage systems (“Environment and Health Protection Guidelines: On-Site Sewage Management for Single Households”) (DLG, 1998). These guidelines were developed to
help local councils assess, regulate and manage the selection, design, installation, operation and maintenance of single household on-site sewage management systems. They provide advice on planning, site evaluation, system selection, systems operation and maintenance, and ongoing system management.

We note that these guidelines specifically address the risk of viral contamination of waterways by human sewage by providing for the calculation of set-back distances of on-site sewage systems from watercourses and coastal waters based on a formula proposed in a paper by Beavers & Gardener (1993).

2.9.8 General comment on NSW environmental policy

The combined impact of the SEPP 62 (enabled under the Environmental Planning and Assessment Act 1979) and the NSW Oyster Industry Sustainable Aquaculture Strategy 2006 (developed under the Fisheries Management Act 1994) provides for explicit consideration of the impact of individual development applications on oyster farming areas through the requirement for Councils to consult with the Department of Primary Industries (DPI) in cases where there could be significant impacts. The NSW Food Authority, which falls under the umbrella of the DPI, should be part of this consultation process, since NSW Food Authority personnel have specific knowledge of water quality issues in shellfish growing areas. Data presented by Baker (2013) suggests that some Councils are less diligent than others in seeking input from the NSW Food Authority.

The pressure for increasing urbanization of coastal regions can result in the degradation of water quality arising from the cumulative impact of many small developments that in themselves may appear to have no significant impact. Under the Oyster Industry Sustainable Aquaculture Strategy there is a similar consideration of the impact on oyster aquaculture in the development of Local Environment Plans. This potentially provides an instrument for the management of cumulative impacts of small changes arising from individual development projects.

The inclusion by the EPA of a clause in the Licence Conditions of each WWTP to the effect that the Food Authority must be notified immediately of any sewage spills that could impact on shellfish harvest areas provides a high incentive for Councils to reliably communicate such events in a timely manner.

While the NSW Food Authority is not directly responsible for environmental policy in shellfish growing areas, the cross-departmental cooperation promoted by the NSW State Government is reflected in the environmental policies currently in place, and provides a potential framework for protection of water quality in oyster-growing areas. We note that the protection provided to oyster growing areas is not replicated for other shellfish harvested in NSW.

2.10 Conclusion

Bivalve shellfish (especially oysters) are a high risk food due to their physical attributes, in particular their filter feeding and associated propensity to concentrate and retain human enteric viruses, the environment where they commonly grow, and because they are often eaten raw.
Because of this food safety risk many countries have implemented mandatory food safety programmes to classify safe harvest areas. These programmes can be broken down into three different types, namely:

1. The USA Programme which focuses mainly on the use of the sanitary survey tool and monitoring the overlying waters that the shellfish are grown in.
2. The European programme that has historically used the level of *E. coli* in live shellfish. The EU is now slowly introducing the concept of sanitary survey assessments.
3. Combination programmes as used in Australia and New Zealand where sanitary surveys, water and shellfish monitoring are all required.

None of the programmes currently include monitoring for specific human pathogens. Instead, direct indicators are used to determine the presence of microbial pathogens in shellfish; the programmes use a combination of primary, secondary and tertiary indicators to predict safe harvesting.

The current microbial sentinel indicators for routine shellfish area management are Total coliforms, faecal coliforms and *E. coli*. None of these indicators satisfy the accepted criteria for good indicators which are:

- Correlate to public health risk
- Have similar survival characteristics (or greater) to pathogens.
- Similar (or greater) transport behaviour to pathogens.
- Be present in greater numbers than pathogens.
- Be specific to faecal source or identifiable as to source of origin.

The non-quantitative judgements used during for sanitary surveys that mean the shellfish programmes are not an “exact science”.

A review of the epidemiological data from the USA, EU, Australia and New Zealand shows that generally the shellfish programmes are preventing illness from bacterial pathogens, but not viral illness. Hepatitis A and NoV outbreaks continue to be a problem in many countries that actively implement a shellfish management programme. Although likely to be influenced by improvement in reporting and analytical methods, there is a worldwide increasing prevalence of reported NoV outbreaks, including outbreaks associated with shellfish. Such outbreaks have been experienced in Australia and New Zealand in recent years.

Both New South Wales and New Zealand have legislation that manages the environmental impacts of activities relating to human sewage treatment and disposal, but in neither case do the regulatory authorities responsible for shellfish safety have direct responsibility or authority with respect to these issues. The environmental policy framework in New South Wales potentially provides more specific protection of water quality in oyster growing areas than that in New Zealand through the formalising of cross-departmental linkages, and through the greater protection provided to shellfish farms through the marine pollution regulations.
SECTION 3 CASE STUDY METHODOLOGY

3.1 Introduction

A case study may be defined as an “intensive study of a single unit for the purpose of understanding a larger class of (similar) units” (Gerring, 2004). Qualitative case study analysis provides tools for researchers to study complex phenomena within their contexts, and is used in research in a wide range of fields (e.g. health science research, social science, business and organisational research). There have been a number of events in both New Zealand and New South Wales in which reported NoV illnesses have occurred as a result of the consumption of oysters contaminated with NoV before they were harvested. The circumstances surrounding each of these illness outbreaks were investigated in detail by the managers of shellfish quality assurance programmes in an attempt to determine the source of NoV contamination in the shellfish so that recurrence of such contamination could be prevented in the future. Whether or not the source of contamination was able to be definitively identified, these investigations generally resulted in an improved understanding of the potential sources of virus contamination in the growing area. Management of the risk of viral contamination of shellfish, particularly oysters, faces a number of challenging issues and unfortunately sometimes hindsight in preventing virus contamination of oysters continues to be clearer than foresight. This project is founded on the premise that analysis of previous events could assist in improving the management of the risk of virus contamination of shellfish in the future. Case study analysis has been undertaken with a view to elucidating the factors that result in failure to prevent NoV contamination of oysters in growing areas and resultant NoV outbreaks in consumers.

3.2 Methodology

The broad framework for case study-based research used in this project was adapted from methodologies set out in Eisenhardt (1989), Kohn (1997) and Baxter & Jack (2008).

3.2.1 Definition of research question and a priori constructs

A priori definition of propositions (preliminary hypotheses), issues or variables can lead to a conceptual framework that guides the research (Eisenhardt, 1989; Baxter & Jack, 2008). The research question for this aspect of the project was defined as: What key factors result in failure to prevent norovirus contamination of oysters in growing areas and resultant norovirus illness outbreaks in consumers?

Based on the findings of McCoubrey (2007), who observed that changing environmental pressures in New Zealand oyster growing waters had resulted in their exposure to increased risk of contamination from human sources that had not been addressed by environmental policy, at the outset of the project two points of control were identified as potentially representing fundamental issues in the management of shellfish quality at harvest. These were:

i) The Shellfish Quality Assurance Programme that ensures that shellfish that are harvested for consumption are safe to eat; and
ii) The legislative/regulatory environment that influences the quality of water in shellfish growing areas.

Consideration of these two control points provided the skeleton for a conceptual framework to structure the data collection and case study analysis.

### 3.2.2 Case definition and selection

In clarifying his definition of case studies, Gerring (2004) provided the following definitions: A “population” is comprised of a “sample” (studied cases) as well as unstudied cases. A sample is comprised of several “units” and each unit is observed at discrete points in time, comprising “cases”. In this study, a “unit” was defined as an individual oyster growing area, and a “case” as a norovirus illness event linked to a growing area.

Based on the research question, in this project the population was identified as all NoV illness events linked to the consumption of oysters that have been contaminated with NoV in their growing areas. There are internationally accepted criteria for establishing the presence of a link between NoV illness and shellfish consumption, as outlined in Box 3.1 below. In the identification of the population of cases in this project, we did not apply these strict criteria, but instead selected the cases to be studied from a population of NoV illness events in which this link had been either established or assumed. However, where possible in the case analysis, epidemiological data were analysed against these criteria to elucidate the situation in each case.

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**Box 3.1 Internationally accepted criteria for establishing a link between observed NoV illness and shellfish consumption**

In order for a NoV illness to be linked to shellfish consumption, both the NSSP manual and the New Zealand BMRCS requires initially that there be at least two cases not from the same household, and then that an epidemiological association can be found.

To meet the case definition for NoV, the case should show a positive test of vomit or faecal samples where there is gastroenteritis of approximately 36 hours duration with an incubation period of 24-48 hours after ingestion.

The criteria for confirmation of the food responsible for the illness are:

- i) p-value for food of <0.05, OR
- ii) isolation of agent from food in agreement with laboratory criteria for confirming etiologic agent.

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The aim of the research was to identify the common and divergent factors that fail to prevent such events across different sites. For this reason a multi-case study using cross-sectional analysis based on a sample of events from two countries (New Zealand and New South Wales, Australia) was considered appropriate. In order to maintain relevance to current conditions, the sample was temporally bounded to events since 1990, and bounded in scope to shellfish growing areas with an
operative Shellfish Quality Assurance Programme (SQAP) at the time of the illness outbreak. (Note that this latter condition restricted the temporal range of cases from NSW, since the SQAP was not introduced to NSW oyster growing areas until late 1990s-early 2000s). The sample size was limited by the relatively low number of events. Therefore the number of units (growing areas) in the study was defined as any growing area that was willing to participate in the study and had experienced a NoV event from 1990 onwards. Within this a diversity of regulatory agencies (Food Authorities, Councils) was achieved. Amongst the units (growing areas) within the sample, some units were subject to more than one NoV event. Each NoV event was treated as one case.

Based on this selection process, eight case studies were selected. The inclusion as a case study of the large outbreak of hepatitis A in 1997 in which 444 people became ill after the consumption of oysters harvested from the Wallis Lakes growing area in New South Wales was considered because Hepatitis A is an enteric virus transmitted like NoV through the oral-faecal route, but this growing area did not have a Shellfish Quality Assurance Programme at the time, and therefore did not meet the case study selection criteria.

The selected case studies represented 89% of the total number of reported enteric virus outbreaks associated with the consumption of shellfish harvested from commercial growing areas with a Shellfish Quality Assurance Programme in NSW or New Zealand within the specified time frame. As all the reported enteric virus outbreaks that matched the selection criteria were attributed to NoV, the case studies considered only norovirus outbreaks.

<table>
<thead>
<tr>
<th>Unit</th>
<th>Case</th>
</tr>
</thead>
<tbody>
<tr>
<td>Growing Area (GA) 1</td>
<td>1</td>
</tr>
<tr>
<td>Growing Area (GA) 2</td>
<td>1</td>
</tr>
<tr>
<td>Growing Area (GA) 2</td>
<td>2</td>
</tr>
<tr>
<td>Growing Area (GA) 3</td>
<td>1</td>
</tr>
<tr>
<td>Growing Area (GA) 3</td>
<td>2</td>
</tr>
<tr>
<td>Growing Area (GA) 3</td>
<td>3</td>
</tr>
<tr>
<td>Growing Area (GA) 4</td>
<td>1</td>
</tr>
<tr>
<td>Growing Area (GA) 5</td>
<td>1</td>
</tr>
</tbody>
</table>

Table 3.1: List of units and associated case studies undertaken in this project. Each unit number represents an oyster Growing Area, and each case is comprised of a norovirus outbreak that was linked to the consumption of oysters from the Growing Area. Each case study is identified by the combined Growing Area/Case numbers.

One of the conditions of the provision of information for these case studies was that all participants should remain anonymous. In order to preserve anonymity, units have been identified by
sequentially assigned growing area numbers, and case studies within each unit have been numbered sequentially through time, as shown in Table 3.1. Specific oyster farms/leases discussed within each case study have been assigned numbers. Other growing areas and farms discussed in association with the case studies have been assigned identification alphabetically (e.g. Growing Area (GA) A, Farm A etc.) within each case. The agencies responsible for the regulatory management and implementation of the shellfish quality assurance programmes vary across cases. These agencies are collectively referred to as the “Food Authority” throughout the case studies. Similarly, local, district and regional councils and consenting authorities are collectively referred to as “Councils”.

3.2.3 Data collection methods

Three researchers were involved in data collection. Multiple data collection methods were used. The primary sources of information were reports written about each growing area and case, including Growing Area Sanitary Survey reports, Growing Area Annual Review reports, epidemiological reports of illness outbreaks, and reports of growing area investigations following illness outbreaks. These were supplemented by Council reports provided to the Food Authorities at the time of growing area investigations, and copies of correspondence and monitoring data provide to us by the Food Authorities. Additional information was provided to us by Food Authorities, Councils and oyster farmers either verbally or by email on request.

In order to provide a systematic process of data collection and subsequent analysis, a guiding framework comprised of potential control points was developed, as illustrated in Figures 3.1-3.3. Figures 3.1 and 3.2 relate to potential control points associated with the Shellfish Quality Assurance Programme (SQAP), and the control points in Figure 3.3 illustrate those outside the control of the SQAP. Figure 3.3 provides an example relating to one potential contamination source, i.e. on-site sewage systems. Similar data collection/analysis processes were followed for all types of contamination sources where information was available.

The charts in Figures 3.1-3.3 outline a series of variables for investigation in the data collection process. Where the investigation process ends in an arrow leading to a “Potential issue” box, factors potentially contributing to the failure at that point were researched in greater depth in each case where possible. We note that these diagrams are illustrative of a general thinking process rather than an exhaustive description of all possible areas of consideration.

The advantages of multiple researchers were captured by assigning data collection for cases to each researcher, and then having each case reviewed by the researchers who not been involved in its data collection (Eisenhardt, 1989).

Across the case studies, we found that the depth of investigation directed toward identifying the source of NoV contamination associated with an illness outbreak varied widely. In addition, the temporal spread of the cases spanned a time of significant development of technology associated with both virus detection and microbial source tracking. It might therefore be expected that the quality of information used by the Food Authorities in determining the implicated sources of NoV in the growing area would vary across cases, resulting in a variation in the reliability of these reported conclusions. Except in instances where relevant information has been subsequently reported, re-evaluation of these conclusions has been considered outside the scope of this study, and our analysis of management issues has been undertaken based on reported conclusions.
Figure 3.1: Illustration of the variables associated with Shellfish Quality Assurance Programme – Sanitary Survey

Potential issue?

Was (potential) source of contamination noted in Sanitary Survey?

No

Yes

Was contamination a result of a malfunction/accidental spill?

No

Yes

Are there protocols in place to assess the level of risk from the type of pollution source?

No

Yes

Potential issue?

Are there management protocols for assessment of risk from such an event?

No

Yes

Was the SQAP notified of the contamination event immediately it occurred?

No

Yes

Are there protocols established for notification of contamination events like this?

No

Yes

Are the local authority or any other agency/public aware of the event?

No

Yes

Potential issue?

Were they followed?

No

Yes

Are they based on current science with respect to viral contamination?

No

Yes

Were required actions followed by farmers?

No

Yes

Were they followed?
Figure 3.2: Variables associated with Shellfish Quality Assurance Programme – Monitoring

- Were implicated shellfish harvested in compliance with harvest criteria?
  - Yes: Proceed
  - No: Proceed

- Is there a programme of regular water/shellfish monitoring required to confirm GA classification/harvest criteria?
  - Yes: Proceed
  - No: Proceed

- Had this monitoring been undertaken in accordance with the programme?
  - Yes: Proceed
  - No: Proceed

- Were results of monitoring in compliance with programme requirements?
  - Yes: Proceed
  - No: Proceed

- Did monitoring data show any indication of deteriorating water quality/intermittent high results?
  - Yes: Proceed
  - No: Proceed

- Did further investigation after the illness event show evidence of elevated bacterial indicators?
  - Yes: Proceed
  - No: Proceed

- Was contamination as a result of a spill event?
  - Yes: Refer to Figure 3.1
  - No: Proceed

- Was this action based on current science with respect to viral contamination?
  - Yes: Proceed
  - No: Proceed

- Was any management action taken as a result of this?
  - Yes: Proceed
  - No: Proceed
Figure 3.3: An illustration of the kinds of variables associated with maintenance of water quality in growing areas using discharge from on-site sewage systems as an example.
3.2.4 Data analysis

Data analysis consisted of two phases: analysis of within-case data; and cross-case analysis.

Within-case analysis: Within-case analysis consisted of detailed case study descriptions for each site, followed by an analysis using the framework illustrated in Figures 3.1-3.3 as a starting point.

Cross-case analysis: Cross-case analysis by examining cases in groups was undertaken to determine whether there were some fundamental issues common to different units. Differences between cases were also explored. In addition to analysis across all cases for some variables, cross-case analysis included:

- analysis of cases grouped based on common causes of NoV contamination (e.g. boat effluent, on-site sewage systems etc);
- analysis within one unit where there were several cases within one unit (i.e. several NoV illness events associated with one growing area);
- analysis across units where there were several cases within one unit.

Other groupings were analysed as themes or issues emerged. Data analysis and data collection were interlinked iterative processes: any data gaps highlighted in the data analysis process were filled by further data collection where possible, and themes or issues that emerged were tested within and across all cases.
SECTION 4    CASE STUDY: GROWING AREA 1

4.1 Description of Growing Area and its Catchment

Growing Area 1 (GA 1) lies in a 7.9 km long inlet formed from a drowned valley, with four sub-estuarine areas where rivers enter the inlet close to its head. The head of the inlet lies to the west, running to the mouth at the east. The inlet itself covers approximately 9 km$^2$, of which a little over 2.5 km$^2$ (28%) is inter-tidal. The upper half of the inlet is shallow, generally less than 2 m deep at low tide, and has extensive mudflat areas. The lower half is very different in character, having no extensive mudflats, a rockier shoreline, and a channel which rapidly deepens to about 16-18 m at the inlet entrance. There are three blocks of oyster farms in the inlet: one in a deep bay close to the inlet mouth, and the other two in southern and northern bays about mid-way in the inlet. The oyster farm implicated in the NoV event (Farm 1) lies adjacent to another farm (Farm 2) in the southern farm block, which is separated from the northern shore of the inlet by a distance of about 2 km. The northern farm block includes Farms 3 and 4.

The total area of catchment for the inlet is approximately 200 km$^2$. The catchment has a basement rock of greywacke that is overlain in some areas by basaltic volcanic flows. The Sanitary Survey report notes that the surface soils of the inlet tend to reflect the underlying geology. The report identifies that the soils associated with the basaltic flows are bouldery loam, and the greywacke appears to be associated with clay soils.\(^7\) Approximately half the catchment of the inlet is in grazing grassland, with 25% in forest or scrub and 18% utilized for horticulture (mainly citrus, avocado and kiwifruit orchards).

Three significant rivers enter the inlet at its head. Town A (population approximately 5,800) lies at the head of the inlet at the mouth of one river, and there is also a small town upstream on one of the other rivers. Most of the coastal area towards the mouth of the inlet has been developed as rural lifestyle blocks, with a few small residential areas, many used as holiday homes. Much of the catchment away from the coastal margin is in horticulture (citrus, avocado etc), but this activity has been in decline with the increasing urban and lifestyle development. Some agricultural activity (dairy, sheep and cattle) occurs further upstream in the catchment and microbial source tracking suggests that faecal contamination in the upper catchment is predominantly from ruminant sources. There is a small amount of light industrial activity associated with both towns, but little heavy industry in the catchment. The region is a popular boating area during summer, and there is a marina in a northern bay close to the inlet mouth, and several areas where permanent moorings are located.

A proportion of the urban area in Town A is serviced by a reticulated sewerage scheme (separate from stormwater) (746 premises), but the balance of properties has on-site sewage systems. Tertiary treated effluent (treatment includes UV disinfection) from the Town A WWTP, and secondary treated effluent (treated by anaerobic ponding, followed by primary and secondary oxidation ponds) from the WWTP for another town outside the inlet catchment is discharged into a wetland within the catchment. The wetlands drain into freshwater lakes, and it is speculated that some input from these lakes could enter groundwater that is discharged through coastal springs.

\(^7\) Although a soil map is provided in the Sanitary Survey report it is not accompanied by a key, and labels inserted onto the map do not provide detail of soil types in the immediate catchment of farm blocks.
The Growing Area in the inlet is subdivided into two sectors based on water quality, which varies from the head of the inlet to the mouth. The immediate catchment of the growing area implicated in the NoV event (Farm 1 in Sector C), which lies on the southern shore in the middle of the inlet, is geologically diverse: the western side of the bay has an underlying greywacke rock, but the eastern side of the bay is basalt. Freshwater springs enter the bay at the coast. The immediate shoreline is predominantly rural lifestyle blocks with few houses. This area is not serviced by a reticulated sewerage system.

### 4.2 Growing Area 1 Shellfish Programme

GA 1 has been a “Conditionally Approved” growing area since 1976. At the time of the NoV event in September 2008, an annual review of the growing area had been completed in January 2008, with the date of the last twelve-year sanitary survey being October 1999. Tables 4.1 and 4.2 below show the results of compliance sampling of water and shellfish respectively, analyzed for the three years to September 2008.

**Table 4.1:** Results of analysis of data from water samples tested for faecal coliforms for purposes of compliance with growing area classification from water sampling sites W (representing Farms 3 & 4) and X & Y (together representing Farms 1 & 2). The results are based on analysis of data from the three preceding years to September 2008.

<table>
<thead>
<tr>
<th>Data Type</th>
<th>Sample Point</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>W</td>
</tr>
<tr>
<td>Number of Samples</td>
<td>24</td>
</tr>
<tr>
<td>Median</td>
<td>1</td>
</tr>
<tr>
<td>% &gt;43 MPN faecal coliforms/100 ml</td>
<td>4.2</td>
</tr>
</tbody>
</table>

**Table 4.2:** Results of analysis of data from oyster samples tested for *E. coli* for purposes of compliance with growing area classification from the shellfish sampling sites W (representing Farms 3 & 4) and Y (representing Farms 1 & 2). The results are based on analysis of data from the three preceding years to September 2008.

<table>
<thead>
<tr>
<th>Data Type</th>
<th>Sample Point W</th>
<th>Sample Point Y</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>24</td>
<td>24</td>
</tr>
<tr>
<td><em>E. coli</em> Median (MPN/100g)</td>
<td>45</td>
<td>45</td>
</tr>
<tr>
<td>% &gt;700 MPN <em>E. coli</em> /100g</td>
<td>4.2</td>
<td>4.2</td>
</tr>
<tr>
<td>% &gt;230 MPN <em>E. coli</em> /100g</td>
<td>25</td>
<td>4.2</td>
</tr>
</tbody>
</table>

In 2008 the harvest criteria applicable to the sector of GA 1 that includes the implicated farm (Farm 1) were:
From 1\textsuperscript{st} May to 31\textsuperscript{st} October:

<table>
<thead>
<tr>
<th>Rainfall in 24 hours</th>
<th>Closure Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-19.9 mm</td>
<td>No restriction</td>
</tr>
<tr>
<td>20-29.9 mm</td>
<td>Closed 6 days</td>
</tr>
<tr>
<td>30-49.9 mm</td>
<td>Closed 7 days</td>
</tr>
<tr>
<td>50-59.9 mm</td>
<td>Closed 9 days</td>
</tr>
<tr>
<td>60-79.9 mm</td>
<td>Closed 10 days</td>
</tr>
<tr>
<td>80-99.9 mm</td>
<td>Closed 12 days</td>
</tr>
<tr>
<td>100+ mm</td>
<td>Closed until opened by the Food Authority</td>
</tr>
</tbody>
</table>

From 1\textsuperscript{st} November to 30\textsuperscript{th} April:

<table>
<thead>
<tr>
<th>Rainfall in 24 hours</th>
<th>Closure Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-24.9 mm</td>
<td>No restriction</td>
</tr>
<tr>
<td>25-34.9 mm</td>
<td>Closed 3 days</td>
</tr>
<tr>
<td>35-44.9 mm</td>
<td>Closed 4 days</td>
</tr>
<tr>
<td>45-54.9 mm</td>
<td>Closed 5 days</td>
</tr>
<tr>
<td>55-59.9 mm</td>
<td>Closed 6 days</td>
</tr>
<tr>
<td>60-79.9 mm</td>
<td>Closed 7 days</td>
</tr>
<tr>
<td>80-99.9 mm</td>
<td>Closed 9 days</td>
</tr>
<tr>
<td>100+ mm</td>
<td>Closed until opened by the Food Authority</td>
</tr>
</tbody>
</table>

Areas were also closed to harvest based on compounded rainfall.

\textbf{Compounded Rainfall}

A compounded rainfall is an event where two or more rainfall events above the minimum 24-hour criteria level of closure take place within 4 days. The closure times are calculated as follows: Add the closure rainfall levels and any intervening levels together. Consult the current 24-hour closure criteria and apply the new closure period as from the first day of closure.

\textbf{4.3 Epidemiology of Norovirus Event}

Oysters harvested off Farm 1 in Growing Area 1 on 21/9/2008 were processed at Company Z in two batches:

- Batch X was processed on the night shift in the early hours of the morning on 23/9/2008
- Batch Y was processed in the day shift on 24/9/2008.

Each batch was implicated in a NoV illness event. The lot of oysters harvested from Farm 1 in Growing Area 1 on 21/9/2008 were processed into the following products: 760 x 200g pottles of fresh oyster meat, and 735 cartons of frozen product. (Some were obviously sold as fresh half-shell oysters directly from the factory). Most of the fresh product was consumed before the illness cases were reported, but no further illnesses were reported.

The company confirmed that no processing or harvesting staff were ill at the time at which the implicated batch had been harvested.
**Illness relating to Batch X:**

1. Pottles of raw oysters from Batch X were purchased directly from Company Z’s factory on 23/9/08 and consumed on the same day. Three people that ate the oysters together became sick with vomiting, diarrhoea and headaches following incubation periods:
   - Case 1: 30 hours
   - Case 2: 4 hours then +/- 44 hours
   - Case 3: 27 hours
   The illness was reported to the health authorities on 26/9/08, and was interpreted as person-to-person spread. No faecal samples were provided. However, leftover oysters were collected from the consumers and frozen. These were later tested for NoV using real-time RT-PCR, and were found to be positive for NoV genogroup II.

2. Pottles of raw oysters from Batch X were purchased from Supermarket D in City B and consumed on 30/9/08. Two people in the same household became ill with vomiting and diarrhoea on the afternoon and night of the following day. Faecal samples were supplied by both people, and tested for NoV. Both faecal samples were positive for NoV genogroup II. No leftovers were available from the consumers, and all stock in the supermarket was dumped, so no samples of product were available for testing.

**Illness relating to Batch Y:**

1. Raw, half-shell oysters from Batch Y were purchased from the Company Z’s factory on 24/9/08. Five people became ill with reported symptoms of vomiting, diarrhoea, headaches, fatigue and elevated temperature after 24-36 hours incubation. No faecal samples were provided. Leftover samples were collected from the consumer. These tested positive for NoV genogroup II.

Table 4.3 provides a summary of the observations made in relation to the evidence required within the regulatory definition of a food-borne illness outbreak associated with the consumption of shellfish (see Box 3.1 in Section 3.2.2 for this definition). We note that Case Group 3 was not officially reported to the health authorities for investigation as the cases did not authorise Company Z to pass on their contact details to the Food Authority.

---

8 Method references: Shellfish processing: Jothikumar et al., 2005 and Greening & Hewitt, 2008; Norovirus real-time RT-PCR: Kageyama et al., 2003.
Table 4.3: Summary of the evidence of a norovirus outbreak with respect to the regulatory definition of a food-borne illness outbreak.

<table>
<thead>
<tr>
<th>Case Name</th>
<th>Symptom</th>
<th>Results of Clinical Samples</th>
<th>Food History/Attack Rates</th>
<th>Results of Leftover Oyster Samples</th>
<th>Details of Oyster Source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case Group 1</td>
<td>Yes</td>
<td>None taken</td>
<td>?</td>
<td>Positive for NoV GII</td>
<td>Company Z Batch X, harvested Farm A 21/9/2008</td>
</tr>
<tr>
<td>Case Group 2</td>
<td>Yes</td>
<td>Faecal samples taken from 2 cases, both positive for NoV GII</td>
<td>?</td>
<td>None available from consumer</td>
<td>Company Z Batch X, harvested Farm A 21/9/2008</td>
</tr>
<tr>
<td>Case Group 3</td>
<td>Yes</td>
<td>None taken</td>
<td>?</td>
<td>Positive for NoV GII</td>
<td>Company Z Batch Y, harvested Farm A 21/9/2008</td>
</tr>
</tbody>
</table>

Norovirus testing from implicated area:

Samples of oysters from the implicated farm (Farm 1) and the adjacent farm (Farm 2) in the same bay were tested for NoV using TaqMan-based one-step reverse transcription-PCR assays (method references Jothikumar et al., 2005; Greening & Hewitt, 2008; Kageyama et al., 2003) as part of the initial investigation by Company Z. Both samples were positive for NoV GII and negative for NoV GI. Very low levels of NoV GII were also found in a concurrent sample taken from Farm 3 on the northern side of the inlet (approximately 2 kilometres away), but no illnesses were associated with oysters on this farm.

4.4 Environmental Conditions Prior to Norovirus Event

The implicated oysters were harvested at a time when the growing area criteria for harvesting were met. This followed a period during which the area had been closed, initially as a result of a sewage spill, and later as a result of rainfall, as outlined below:

The Food Authority was notified of a sewage spill of approximately 97 m$^3$ over 8.5 hours from the Town A sewerage reticulation system on 6th August 2008 (46 days before the harvest of the oysters implicated in the NoV event). This entered a stream that flows into the head of the inlet. Although this was some distance from the growing area, a 28-day emergency closure that included Sector C of the Growing Area was immediately instigated. The daily rainfall from this date until the date of harvest of the implicated oysters (21/9/2008) is shown in Figure 4.1. Based on the harvest criteria
at the time, the growing area would have been closed to harvest from 6th August to 5th September (first from the emergency closure, then followed by a rainfall closure), open till 7th September, and then closed again until 17th September, which was 4 days before the harvest of the implicated oysters.

Samples of water and oysters were taken on 1st September (i.e. 28 days after the date of the sewage spill in Town A) and tested for faecal coliforms and E. coli respectively. This sampling was repeated on 24th September (i.e. 3 days after the implicated batch was harvested). The results of these tests, along with the results of other samples taken when the area was open for harvest in the same 12-month period, are presented in Table 4.4.

![Daily Rainfall from 6/08/2008-21/09/2008](image)

**Figure 4.1:** Daily rainfall at Growing Area 1 between the time of a sewage spill on 6th August 2008 and the date of harvest of the batch of oysters implicated in the norovirus event (21st September 2008).

Figure 4.1 shows there was little rainfall in the 13 days immediately prior to the harvest of oysters implicated in the NoV event, but significant rainfall occurred in the weeks before that.

We note that there was a consistent history of slightly elevated levels of E. coli in oyster samples taken when the growing area was open for harvest in the 12 months prior to the NoV event, and that the E. coli level in one sample (13/5/08) was significantly elevated (2,400 MPN/100g) (see Table 4.4).
Table 4.4: Results of sampling for faecal coliforms/E. coli in water and shellfish respectively from the sites closest to the farm from which the oysters implicated in the norovirus event were harvested on 21/9/2008. Except for the sample on 1/9/2008 that was taken 28 days after the sewage spill at Town A, sampling was undertaken when the growing area met the rainfall criteria for harvesting.

<table>
<thead>
<tr>
<th>Date</th>
<th>Water Site 1 FC/100ml</th>
<th>Water Site 2 FC/100ml</th>
<th>Oyster Site 1 E. coli/100g</th>
</tr>
</thead>
<tbody>
<tr>
<td>21/10/2007</td>
<td>&lt;2</td>
<td>4.5</td>
<td>210</td>
</tr>
<tr>
<td>6/11/2007</td>
<td>&lt;2</td>
<td>&lt;2</td>
<td>45</td>
</tr>
<tr>
<td>28/11/2007</td>
<td>&lt;2</td>
<td>&lt;2</td>
<td>&lt;18</td>
</tr>
<tr>
<td>24/01/2008</td>
<td>&lt;2</td>
<td>&lt;2</td>
<td>20</td>
</tr>
<tr>
<td>13/05/2008</td>
<td>&lt;2</td>
<td>&lt;2</td>
<td>2400</td>
</tr>
<tr>
<td>9/7/2008</td>
<td>&lt;2</td>
<td>&lt;2</td>
<td>130</td>
</tr>
<tr>
<td>1/9/2008</td>
<td>7.8</td>
<td>31</td>
<td>130</td>
</tr>
<tr>
<td>24/9/2008</td>
<td>&lt;2</td>
<td>&lt;2</td>
<td>45</td>
</tr>
</tbody>
</table>

4.5 Investigation and Actions Taken

No action was taken by the Food Authority following the first report of illness on 26/9/2008 because illness was initially attributed to person-to-person spread (at the time no other cases had been reported). When the second case was reported to Company Z on 30/9/2008, the company decided to detain products from the same farm, growing area and production date. After receiving report of the cases on 3/10/08 from the retailer, Company Z notified the Food Authority and a voluntary closure to harvesting from the farms in Sector C was instigated. Following the confirmation of NoV in leftover product and faecal samples on 9th October, Sector C was formally closed under the emergency provisions of the regulations.

A notice to withdraw all products relating to the implicated batches was issued by the Food Authority on 9th October 2008. Retailers advised that all fresh products had been sold or disposed of (use-by dates were 3/10 and 4/10). No product had been exported and no frozen product had been despatched by Company Z. The remaining product (all frozen) was placed under detention by the Food Authority pending the results of product testing for NoV.

It was found that all oysters harvested from farms other than Farm 1 in the GA 1 had been consumed without any reports of illness. Thus an email to industry from the Food Authority on 15th October 2008 stated that only the two farms on the southern side of Sector C (Farms 1 and 2) were to remain closed to harvest. The industry kept in place a voluntary closure to harvest at the farms in the northern part of Sector C (Farms 3 and 4).

Following consideration of a low level of NoV detected in an oyster sample taken from Farm 3 in the northern part of Sector C, this farm, but not Farm 4, was officially closed to harvest by the Food Authority on 29th October. There had been no reports of illness arising from oysters harvested from either farm in that area (however we note that none of the reports from the Food Authority provide an analysis of the numbers of oysters harvested and consumed from farms other than Farm 1, the implicated farm).
A shoreline inspection of the immediate catchment of Farms 1 and 2 was undertaken by the staff of Company Z on 14/10/08, and freshwater samples of a stream entering the bay were taken, along with a seawater sample from adjacent to the stream entry. These samples contained *E. coli* levels below and at the level of detection respectively. Staff from the Food Authority completed a shoreline inspection of the same area on 16/10/08. The conditions at the time were fine and the ground was dry. The assessment by the Food Authority of the risk of viral contamination from on-site sewage systems did not follow a formal documented procedure (although we note that such a procedure was followed in the more recent full sanitary survey in 2011). The growing area investigation report states that they found no evidence of any obvious malfunction of on-site sewage systems at properties along the shore, although they did identify some properties for further investigation of on-site systems by Council officers. Discussion with local householders identified that the ground had been saturated over the months of July and August, and the Food Authority concluded that exfiltration or runoff from disposal fields could not be discounted as the source of NoV contamination. Subsequent visual inspections of on-site systems carried out in the area by Council Environmental Health Officers under by-law provisions were also undertaken under dry conditions. Although requested by the oyster farmers, no dye testing of on-site sewage systems was undertaken. An internal email from one staff member within the Food Authority (who had investigated one of the illness events but is not normally involved in the management of the shellfish programme) argued against dye testing on the grounds that (summarised from an email):

- This was an isolated event.
- The number of reported cases was low compared to the number of oysters that had been harvested, and contamination could have occurred elsewhere.
- Residents have a right to privacy, and a preliminary visual inspection had detected nothing.
- Testing after this event might set a precedent for dye testing all properties around a farm after every incident.
- Uncertainty about how to interpret negative results (e.g. environmental conditions might have changed).
- Logistical issues, such as who would undertake the dye testing and the long period of time (days) that the site would need to be monitored to detect the dye.

The view of the writer of the email was upheld by senior public health personnel in the Food Authority from a public health perspective, and no dye testing was instigated by the management of the shellfish programme in the organisation. No malfunction was reported as having been detected by visual inspection of on-site sewage systems in the immediate catchment of Farms 1 and 2. Similarly, visits to the catchment of Farm 3 provided no evidence of malfunctioning on-site sewage systems.

In the course of this case study we questioned the Council Environmental Health Officer about the decision not to undertake dye testing in the immediate catchment of Farms 1 and 2. He recalled that during a visit to one of the properties at the time, it was observed that the disposal field of the on-site sewage system appeared to be discharging into groundwater that emerged at the surface a short distance away. He noted that this malfunction was fixed by the property-owner before the growing area was opened for harvest.

The sanitary survey by the Food Authority did not identify any other potential sources of contamination. No spills from the Town A sewerage reticulation system had been reported by the Council since the event on the 6th August. Due to the elapsed time between this spill and the harvest date of the implicated oysters, it was considered unlikely that this spill was the source of
NoV contamination associated with the reported illnesses. However, it was suggested that the low positive NoV result from Farm 3 in the north of Sector C (from where there were no associated illness reports) could have been linked to the retention of residual viral material in the shellfish, which would have been detected in the analysis for NoV markers by PCR.

The risk of sewage discharge from boats was considered to be very low, particularly as casual observation by the oyster farmers and Council suggested only low numbers of boats visit the area during the mid-winter months.

The possibility of contamination of groundwater entering Farm 1 from wetlands that receive treated effluent from the two local wastewater treatment plants was mentioned, as the fractured basaltic rock could provide pathways for the transport of groundwater. However there was no direct evidence of this as a potential virus source, and the regional Council strongly advised that they considered this to be a very low risk. This view from Council does not appear to have been backed by any studies of the movement of groundwater in the area.

Testing for faecal coliforms in water and *E. coli* in oyster samples from Farm 3 on 20/10/08 when the growing area met the rainfall criteria for harvest showed <2 faecal coliforms/100m in the water and 20 *E. coli*/100g in the oysters. Water and oyster samples taken on 10/12/08 when the growing area met the rainfall criteria for harvest showed results of <2 faecal coliforms/100ml and 230 *E. coli*/100g respectively.

As a result of the investigation, it was concluded that (quoted from the Summary Report prepared by the Food Authority on 10/12/08): “The ground conditions in the catchment of the affected leases were heavily saturated with the high possibility of waterlogged septic tanks contaminating run-off and discharging into marine waters” and recommended “Ground conditions have now dried out in the affected catchments. However a tighter criteria, based on ground saturation levels and rainfall is being prepared for inclusion within the Management Plan for this growing area”.

### 4.6 Reopening

Because the NoV illness event did not strictly meet the regulatory definition of a food-borne outbreak linked to shellfish consumption, and because Farm 3 in the northern Sector C had been closed only on the discovery of a low level of NoV in an oyster sample from the farm and was not linked to any illness reports, there was some debate about the requirements for reopening the farms to harvest again. Because of the additional information that supported the implication of Farm 1 in the NoV illness event, the regional Food Authority officer decided that reopening procedures for Farms 1 and 2 should match the requirements for reopening the area after an illness outbreak. Consequently, the area was required to be closed to harvest for a minimum of 28 days after the contamination ceased, and in addition to reviewing the growing area classification and determining that the harvest criteria were still appropriate, it was also necessary to determine that the event which had caused the contamination no longer existed and that the pathogen was no longer present in the oysters from the growing area. This required five samples of oysters from the Farm 1/Farm 2 block to be tested for NoV, with samples to be taken from 4 corners of the block and one sample from the centre of the block. These samples were taken on 7th January 2009. No NoV was detected in any of the samples, and consequently the area was reopened for harvest on 14/1/2009 on the understanding that new harvest criteria that included soil saturation would be developed and implemented before the winter months.
The same reopening requirements were applied to Farm 3 with the exception of an exemption for the requirement to test five oyster samples for NoV at the end of the contaminant reduction period. In this case, only one sample was tested for NoV on 7/1/2009. No noroviruses were detected in the sample, and farm was reopened to harvest on 14/1/2009 on the understanding that new harvest criteria that include soil saturation would be developed and implemented before the winter months. (Interestingly, this latter requirement is unrelated to the presumed source of NoV contamination at this location, but presumably relates to earlier concerns about the link between soil saturation and elevated faecal coliform results – see discussion in Section 4.8).

The proposed additional harvest criteria based on soil saturation were as follows (quoted from GA 1 Annual Review 2007-08 report):

“The following procedure should be adopted:

1. From 1st May until 10 September of any year, the following protocols may require to be instigated.
2. A determination is made that soils of the catchments are saturated. This will be done following consultation with the delivery centre after checks of rainfall data and agreement by observers and [FA] staff in the field. A general rule will be at a total monthly rainfall above 100mm spread throughout the month.
3. The Special Saturation Criteria will be imposed until further notice.
4. Those areas likely to be at risk from flooded septic tanks and human effluent contaminating run-off are listed above [list includes Farm 1, Farm 2 and Farm 3] and will be required to impose a viral closure (28 days) from the particular event.
5. All areas not thought likely to be at risk from human effluent will require to adopt a 14 days closure for bacterial clearance. This will be taken from the last agreed “event”.
6. All closed areas to be retested for bacterial compliance prior to re-opening.
7. As a general rule, saturation will be at its worst whilst ground temperatures are low. From the beginning of September it is usual to assume that ground conditions will dry out quicker and the areas may return to normal criteria.

Until it has been agreed that the ground conditions are saturated, the normal existing rainfall criteria will apply.”

The rationale for excluding Farm 4, which lies adjacent to Farm 3, from these criteria is unclear.

4.7 Performance of the Growing Area Since Reopening

There have been no enteric illness outbreaks linked to oysters in Growing Area 1 since the areas were reopened in January 2009 following the earlier illness event in September 2008. We note the harvest criteria relating to soil saturation were excluded without comment from the Annual Review report for the 2008-09 year and subsequent years. Information received verbally from the Food Authority indicates that it was difficult to implement because of the difficulty in measuring the level of soil saturation, and was consequently not well-received by the industry. The Food Authority also commented that the compounded rainfall criteria would contribute to management based on soil saturation.

Due to shortcomings in the rainfall-only based harvest criteria in consistently managing the risk of elevated E. coli in oyster samples, new harvest criteria incorporating elements of rainfall, tidal
range and soil saturation have now been adopted. These criteria (the rainfall-tidal index) were developed based on data from a very intensive sampling programme undertaken in the inlet over 12 months in 2009 by Company Z.

In the 2010-11 Annual Review, it was determined that Farms 1 and 2 no longer meet the required standard for export of shellfish to the EU. A microbial source tracking project is currently being undertaken to identify potential sources of faecal contamination in the catchment.

4.8 Case Analysis

The source of NoV contamination in the oyster growing area was not reported as being definitively identified in this illness event. As there was no apparent source of human faecal contamination in the immediate catchment, the detection of a low level of NoV in oysters at Farm 3 without any associated reported illness was attributed to the residual impact of a sewage spill >46 days earlier. The management of the reopening of this farm reflected a perceived lower risk in comparison with Farms 1 and 2 due to the absence of any reported illness associated with Farm 3 oysters. None of the reports of the event discuss whether any oysters had been harvested and consumed from Farm 3 (or for that matter, Farms 2 or 4) in the time period between the reopening of the area from rainfall closure on 17th September 2008 until the voluntary closure after the reports of illness associated with Farm 1. This might have been useful in the characterisation of the risk.

Norovirus detected in oyster samples from Farms 1 and 2 was attributed to more recent human faecal contamination because of the illness event associated with oysters harvested from Farm 1. A potential source of more recent human faecal contamination at Farm 1 was suggested, i.e. run-off from the disposal fields of on-site sewage systems under saturated soil conditions. None of the documents or reports viewed in this case study provide any detail of the number, location or type of on-site sewage systems on the shore of the immediate catchment of the farms in GA 1, or details of processes of their individual visual inspections, or their inspection outcomes. Regulations forbid the entry of effluent from on-site sewage systems into waterways, and these regulations can be enforced by the local Council. Saturated soil conditions are not uncommon during winter months in the region of GA 1, particularly as this can be exacerbated by clay soils. This should be taken into account in the design of on-site sewage systems to ensure that the required standard of performance is consistently met.

Partly because of perceived logistical difficulties (e.g. observation time, ground conditions), the Food Authority chose not to investigate this potential contamination source in the depth required to either confirm or eliminate it from contention at Farm 1 (e.g. no dye studies were undertaken). With a greater knowledge (e.g. of dye tracking techniques) and technical expertise, the perceived technical barriers could have been overcome. The unwillingness to inconvenience householders in a situation in which the illness event did not strictly meet the regulatory definition of a NoV outbreak linked to the consumption of oysters from that growing area also appears to have influenced the decision not to proceed with dye testing. As a consequence, rather than being able to remedy all sources of contamination, the management measures required to prevent the recurrence of a similar illness outbreak were limited to trying to predict the conditions under which future contamination events might occur in order to instigate appropriate harvest controls. Despite continuing problems with occasional high E. coli levels in oyster samples (which have resulted in the failure of Farms 1 and 2 to meet EU standards), to this date no dye testing of on-site sewage systems close to the shore in the immediate catchment has been undertaken.
A review of reports from the years before the NoV illness event shows that on-site systems were noted as potential pollution sources in previous sanitary surveys: “Increased land development for housing in the vicinity of the inlets is expected to continue. The standard of effluent and its disposal from community waste disposal plants and on-site septic tanks will be a critical factor in the water quality within these harbours. The [Council] by-law for on-site sewage disposal systems should assist”\(^9\) [quote from 2005-06 Annual Review report]. This statement was reiterated in subsequent annual reviews.

Soil saturation had previously been noted as needing to be recognised as an Adverse Pollution Condition (APC). The Annual Review report 2005-06 for GA 1 noted that “A new APC condition of saturated soil conditions has been recognised during the review period and will need to be evaluated and incorporated into criteria before the next winter period. It is clear from this report that an improvement in sampling results will be required should this area continue as a “Conditionally Approved” area”. The following year (Annual Review Report 2006-07) it was proposed by industry that the height of one of the rivers entering the catchment be investigated as a measure of soil saturation, but in this report saturated soil condition was still not listed as an Adverse Pollution Condition under which sampling was required to confirm harvest criteria (although undoubtedly some of the conditions under which adverse sampling occurred included times of soil saturation). Data from the investigation of river height as an indicator of soil saturation had not been presented or reviewed prior to the NoV illness event in September 2008, although soil saturation was listed as an APC.

The oysters implicated in the illness outbreak were harvested from a “Conditionally Approved” area at a time at which the criteria for harvesting were met. The Annual Review report states that water and oyster samples taken on the day that the implicated oysters were harvested returned results that were compliant with the shellfish programme\(^10\). This illustrates that compliance with the SQAP requirements did not prevent the NoV outbreak.

On-site sewage systems had been identified as potential pollution sources in the sanitary survey, and their design and performance noted as being critical factors in water quality. Increasing numbers of on-site sewage systems with increasing land development in the growing area catchment was also signalled in the Annual Review reports, but no quantification of the rapidity of this change was provided.

“Soil saturation” had been identified as a condition under which elevated levels of faecal coliform contamination occur unpredicted by the rainfall criteria used to open and close areas for harvest. Despite signalling the intention that this factor should be included as an Adverse Pollution Condition, this was not specifically implemented for another two years. As a result of failure to implement this, the sample results used to monitor the compliance of the growing area with its classification as “Conditionally Approved” may not have fully reflected the risk represented by “soil saturation” as data are analysed for compliance based on a 3-year dataset. The intention to include “soil saturation” as a factor in the harvest criteria of the growing area had not been explicitly implemented at the time when the NoV event occurred.

\(^9\) The by-law mentioned encompassed a requirement that each on-site sewage system be pumped out at a minimum frequency of every 3 years. At this time any defects noted by the pump-out operator were required to be reported to the Council. This by-law has since been amended to reduce the pump-out frequency to a minimum of every 5 years.
\(^10\) It is possible that in the Annual Report there is some confusion about the date of this sampling – the implicated oysters were harvested on 21/9/08, but elsewhere in the Annual Report sample results for a series of water and shellfish samples taken on 24/9/08 are reported (copied in Table 4.4 earlier in this report).
Discussion with personnel from the Food Authority indicates that although soil saturation was recognised as apparently influencing water quality within the growing area, there were difficulties in utilising it as a factor within harvest criteria. The Food Authority and industry members identified lack of knowledge about how to measure soil saturation as the primary barrier, but no expert advice was sought on this issue. The consequent absence of a dataset that defined a measurable relationship between soil saturation and water quality was also a barrier to implementation in its use in harvest criteria. The Annual Review reports suggest that the responsibility for gathering data to demonstrate this relationship appears to have been placed on industry. No jointly developed strategy for this investigation appears to have been documented.

One of the issues of potential concern that we observed in this case study is the lack of documented information provided to the Food Authority by local and regional Councils with respect to the risk of potential pollution sources (possibly related to the lack of requirement for them to volunteer this information). This was evident not only with respect to the performance of on-site sewage systems, but also in relation to the possible risk presented by the wetlands into which treated effluent from the WWTPs is discharged. Assurances by Council that these wetlands could not impact on water quality were not backed by presentation of any evidence relating to water flow, and the acceptance of this position by the Food Authority precluded further investigation. It is noted that the range and effectiveness of tools now available for microbial source tracking have improved very significantly in the years since this NoV event in 2008, now presenting opportunities for more in-depth sanitary surveys of catchments.

In conclusion, the following issues were potentially relevant in the failure to prevent a NoV illness event arising from the consumption of oysters harvested from Farm 1:

- **The harvest criteria did not protect consumers from the presence of an infective level of NoV in harvested oysters.** The harvest criteria are founded on the relationship between environmental indicators and *E. coli* bacteria in shellfish. It has been acknowledged for many years that bacterial indicators are not reliable indicators of the presence of viral pathogens.

- **The design/installation of on-site sewage systems was not adequate to prevent pollution of waterways under conditions of soil saturation.** The absence of a full investigation and documentation of the performance of on-site systems after the NoV event resulted in the absence of evidence that could have ensured that this issue was remedied for the future.

- **The Food Authority recognised that there appeared to be elevated risk of faecal contamination of the growing waters under saturated soil conditions, but did not fully implement their own recommendations made in earlier annual reviews regarding the confirmation of the growing area classification and harvest criteria.** There were significant technical barriers to such implementation which could have been elucidated and might have been able to be resolved by employing appropriate expertise.

- **The risk of an increase in human contamination of the growing area as a component of the faecal contamination signalled by the bacterial indicator results under saturated ground conditions was not taken into account in the management of the growing area prior to the NoV event.”**
SECTION 5  CASE STUDIES: GROWING AREA 2

5.1  Description of Growing Area and its Catchment

Growing Area 2 (GA 2) encompasses one inter-tidal oyster farm, which is located approximately 400-500 metres offshore. It is situated in a tidal estuary to the east of the River XX, which drains the wider catchment. The estuary has extensive sandy, shelly mudflats. Inland from the marine farm towards the shoreline are shell banks and mangroves. The marine farm is not readily accessible to the public as the bay in which it is situated is surrounded by privately owned farmland.

The oyster farm is surrounded by a catchment that is largely used for low intensity agriculture, with rural lifestyle blocks being the predominant land use. The immediate catchment of the oyster farm is drained by one small stream. River XX flows through the wider catchment which includes pastoral land and a small town. The river mouth enters the sea about 1 kilometre away from the oyster farm.

The closest town, with a population of 2,500 persons, is approximately 10 km from the marine farm. This town and all other houses in the catchment are serviced by on-site sewage systems.

There is a boat mooring area approximately five kilometres upstream from the mouth of the river. Marine pollution regulations prohibit the discharge of any sewage from boats in the river and this mooring area is operated on a Management Plan that does not allow people to stay overnight on their boats. The marine area around the oyster farm is not used for regular recreational boating due to the shallow water depth and because there are other more attractive marine destinations nearby.

The water movement in the area around the oyster farm appears to be predominantly influenced by tides and the River XX. At low tides, channels through the mud flats are evident. Local knowledge suggests that the River XX causes a clockwise eddy within the Bay – the River can have an effect on the Bay during tidal outflows. Areas of mangroves lie within the River mouth.

5.2  Classification Status

GA 2 was first classified in 1987 based on the United States National Shellfish Sanitation Programme requirements of the time. Since then the Sanitary Survey has been formally updated every 12 years, with annual shoreline surveys confirming that the catchment features have not changed. The next 12 yearly Sanitary Survey report is due in December 2012.

The area has been classified “Conditionally Approved” since 1987. The rationale for this classification is the potential for pollution of the shellfish after rainfall events.

The potential and actual pollution sources listed in the Sanitary Survey are described as:

i) Septic tank discharges

ii) Stormwater, sediments and agricultural runoff from farmland and catchment areas. Land run-off is thought to be of potential impact on the marine farm only after rainfall events.
iii) Discharges from the River XX from the larger catchment area.

The area operates on a Management Plan that uses rainfall criteria to open and close the oyster farm.

5.3 Annual Updates

5.3.1 Background

Growing Area 2 was first opened in 1987 and since opening it has operated in compliance with all the regulatory requirements of the shellfish programme. The specifications require that monthly seawater and shellfish samples are undertaken when the farm is open for harvesting. The sample results must be reviewed annually and a shoreline survey undertaken to confirm the classification status.

This harvest area has maintained its “Conditionally Approved” classification. All the sampling, shoreline survey and administration reporting steps have been undertaken in full compliance with regulatory requirements since it was first classified in 1987.

5.3.2 Continued investigations into the impact of River XX on GA 2

In 2003 the Council installed a river level recorder which enabled information to be gathered on River XX. An investigative sampling programme was then activated to learn more about the relationship between the river level and water quality at the oyster farm. Sampling was undertaken at sites at the oyster farm and in the river during 2003. These samples showed a possible relationship between the river level and water quality at the oyster farm: specifically, elevated faecal bacterial indicators were observed in water and oyster samples when the river was running above 3.5 metres in combination with a north to north-easterly wind.

It was then decided to continue monitoring at the farm in 2004 during events in which the River height exceeded 3.5-4.0 metres. However, this proposed plan did not proceed as it was not possible to establish an effective alert communication system on the river height. The shellfish farmer decided to investigate the use of salinity buoys and a neural network model. The development of the latter required monitoring many environmental parameters such as tide, flow rates, and salinity to ultimately devise a harvesting equation.

Some sampling around elevated river events did occur in 2004 and 2005. On analyzing these results it was found that 97% of these events occurred when the oyster farm was officially closed for harvest in compliance with the rainfall criteria of the day.

5.3.3 Routine compliance sampling in the shellfish growing area

The growing area is sampled on a monthly basis using the Adverse Pollution sampling at three water sites and at one shellfish flesh site. The sample sites are located within the growing area and positioned to be representative of the worst contamination conditions on the farm. In 2002-2003, the regulations allowed for the use of faecal coliforms or *E. coli* for shellfish samples. The
allowable limit was 300 faecal coliforms/100 g or 230 \textit{E. coli}/100 g. From June 2004 all shellfish samples were analysed for \textit{E. coli}.

The area has historically been in compliance with the microbiological requirements for water and shellfish. Tables 5.1 and 5.2 show the historical results as presented in the 2002-2007 annual reports.

<table>
<thead>
<tr>
<th>Year</th>
<th>Analysis Applied to Faecal Coliform Data</th>
<th>Sample Site</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Site A</td>
<td>Site B</td>
</tr>
<tr>
<td>2002</td>
<td>Median (MPN/100 ml) 1.8</td>
<td>36</td>
</tr>
<tr>
<td></td>
<td>% &gt; 43 MPN/100 ml 0</td>
<td>0</td>
</tr>
<tr>
<td>2003</td>
<td>Median (MPN/100 ml) 1.8</td>
<td>37</td>
</tr>
<tr>
<td></td>
<td>% &gt; 43 MPN/100 ml 3</td>
<td>3</td>
</tr>
<tr>
<td>2004</td>
<td>Median 1.8</td>
<td>27</td>
</tr>
<tr>
<td></td>
<td>% &gt; 43 / 100 ml 0</td>
<td>0</td>
</tr>
<tr>
<td>2005</td>
<td>Median (MPN/100 ml) 1.8</td>
<td>31</td>
</tr>
<tr>
<td></td>
<td>% &gt; 43 / 100 ml 3</td>
<td>0</td>
</tr>
<tr>
<td>2006</td>
<td>Median (MPN/100 ml) 1.8</td>
<td>31</td>
</tr>
<tr>
<td></td>
<td>% &gt; 43 / 100 ml 3</td>
<td>0</td>
</tr>
<tr>
<td>2007</td>
<td>Median (MPN/100 ml) 1.8</td>
<td>32</td>
</tr>
<tr>
<td></td>
<td>% &gt; 43 / 100 ml 0</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 5.1: Results of analysis of water sample data for compliance with growing area classification as “Conditionally Approved” from 2002-2007. Each set of results is based on analysis of data from the three preceding years.

All 12 oyster flesh samples taken during 2002 were well below 300 MPN faecal coliforms/100 g. In the previous three years there had only been one elevated result (490 MPN faecal coliforms/100 g on 30\textsuperscript{th} May 2001) taken during a rainfall event. It was recommended that further rainfall events be targeted to ensure shellfish cleansing.

In 2003 three of the samples were above the allowable faecal coliform limit of 300 MPN/100 g, ranging from 330 to 24,000 MPN/100 g.

These elevated samples were all retrospectively investigated and it was determined there was a relationship between the elevated results and rainfall events. As a result there was a change to the harvest criteria, with a sampling programme designed to further investigate how shellfish accumulate and depurate bacterial indicators of faecal contamination throughout a rainfall event. Therefore new rainfall criteria became operative on the 1\textsuperscript{st} June 2004 (see Table 5.3). These criteria were in place at the time of the 2004 NoV outbreak.
<table>
<thead>
<tr>
<th>Year</th>
<th>Analysis</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>2002**</td>
<td>n</td>
<td>36</td>
</tr>
<tr>
<td></td>
<td>Median (MPN/100 g)</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>% &gt; 700 MPN/100 g</td>
<td>Nil</td>
</tr>
<tr>
<td></td>
<td>n greater than 300 MPN/100 g</td>
<td>1</td>
</tr>
<tr>
<td>2003</td>
<td>n</td>
<td>35</td>
</tr>
<tr>
<td></td>
<td>Median (MPN/100 g)</td>
<td>25</td>
</tr>
<tr>
<td></td>
<td>% &gt; 700 MPN/100 g</td>
<td>5.7</td>
</tr>
<tr>
<td></td>
<td>n greater than 300 MPN/100 g</td>
<td>3</td>
</tr>
<tr>
<td>2004</td>
<td>n</td>
<td>27</td>
</tr>
<tr>
<td></td>
<td>Median (MPN/100 g)</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>% &gt; 700 MPN/100 g</td>
<td>Nil</td>
</tr>
<tr>
<td></td>
<td>n greater than 230 MPN/100 g</td>
<td>1</td>
</tr>
<tr>
<td>2005</td>
<td>n</td>
<td>29</td>
</tr>
<tr>
<td></td>
<td>Median (MPN/100 g)</td>
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<td>% &gt; 700 MPN/100 g</td>
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</tr>
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<td>n greater than 230 MPN/100 g</td>
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<tr>
<td>2006</td>
<td>n</td>
<td>39</td>
</tr>
<tr>
<td></td>
<td>Median (MPN/100 g)</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>% &gt; 700 MPN/100 g</td>
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</tr>
<tr>
<td></td>
<td>n greater than 230 MPN/100 g</td>
<td>3</td>
</tr>
<tr>
<td>2007</td>
<td>n</td>
<td>32</td>
</tr>
<tr>
<td></td>
<td>Median (MPN/100 g)</td>
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</tr>
<tr>
<td></td>
<td>% &gt; 700 MPN/100 g</td>
<td>Nil</td>
</tr>
<tr>
<td></td>
<td>n greater than 230 MPN/100 g</td>
<td>Nil</td>
</tr>
</tbody>
</table>

Table 5.2: Results of analysis of shellfish sample data for compliance with growing area classification as “Conditionally Approved” from 2002-2007. Each set of results is based on analysis of data from the three preceding years.

<table>
<thead>
<tr>
<th>Rainfall (mm)</th>
<th>Rainfall Period (hours)</th>
<th>Closure Period (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 – 19.9</td>
<td>24</td>
<td>No restrictions</td>
</tr>
<tr>
<td>20 – 29.9</td>
<td>24</td>
<td>5</td>
</tr>
<tr>
<td>≥ 30</td>
<td>24</td>
<td>6</td>
</tr>
<tr>
<td>≥ 60</td>
<td>48 (2 days)</td>
<td>5</td>
</tr>
<tr>
<td>≥ 85</td>
<td>72 (3 days)</td>
<td>7</td>
</tr>
<tr>
<td>≥ 85</td>
<td>96 (4 days)</td>
<td>7</td>
</tr>
</tbody>
</table>

Table 5.3: Rainfall harvesting criteria that were implemented in Growing Area 2 on 1st June 2004
5.4 2004 Norovirus Outbreak

5.4.1 Epidemiological information

Four separate outbreaks, with a total 17 individuals becoming ill, were reported in July 2004. The implicated food consisted of raw oysters on the half shell harvested on the 30\textsuperscript{th} June 2004 and 1\textsuperscript{st} July 2004 from the same growing area.

The reported symptoms included diarrhoea, vomiting, fever, stomach cramps, nausea, headache and lethargy. The median time for onset of symptoms was 36 hours and the duration 38 hours. These symptoms fit the case definition for illness caused by NoV.

Faecal specimens from cases in all three outbreaks were collected and found to be positive for NoV. Samples from the left over oysters were also positive for NoV, as were oysters sampled from the farm on 12\textsuperscript{th} July, and from harvest batches on 29\textsuperscript{th} and 30\textsuperscript{th} June, 2004.

Genotyping showed that the NoV strains isolated from the oyster sample taken from the farm (12/7/04) were indistinguishable from those found in faecal samples provided by cases (all of genotype GII/4), establishing a probable virological linkage between the illness events and the implicated oysters.

5.4.2 Event timeline

Table 5.4 on the following page provides a timeline of events and investigation steps.
<table>
<thead>
<tr>
<th>Date 2004</th>
<th>Action related to outbreak</th>
</tr>
</thead>
<tbody>
<tr>
<td>30&lt;sup&gt;th&lt;/sup&gt; June-1&lt;sup&gt;st&lt;/sup&gt; July</td>
<td>Oysters later implicated in outbreak were harvested.</td>
</tr>
<tr>
<td>6&lt;sup&gt;th&lt;/sup&gt; July</td>
<td>District Health Board notified of first outbreak implicating oysters harvested on 30&lt;sup&gt;th&lt;/sup&gt; June.</td>
</tr>
<tr>
<td>8&lt;sup&gt;th&lt;/sup&gt; July</td>
<td>District Health Board notified of second and third outbreaks.</td>
</tr>
<tr>
<td>8-15&lt;sup&gt;th&lt;/sup&gt; July</td>
<td>Further cases were reported from other establishments implicating oysters.</td>
</tr>
<tr>
<td>12&lt;sup&gt;th&lt;/sup&gt; July</td>
<td>Health Officer inspected growing area and took oyster samples from farm.</td>
</tr>
<tr>
<td>15&lt;sup&gt;th&lt;/sup&gt; July</td>
<td>Oyster samples taken from growing area. The results, which were reported on 27/7, were negative for NoV.</td>
</tr>
<tr>
<td>19&lt;sup&gt;th&lt;/sup&gt; July</td>
<td>Two more cases notified from District Health Board in another area.</td>
</tr>
<tr>
<td></td>
<td>Oyster farm voluntarily closed.</td>
</tr>
<tr>
<td>27&lt;sup&gt;th&lt;/sup&gt; July</td>
<td>On receiving the low positive NoV results from oysters sampled on the 12&lt;sup&gt;th&lt;/sup&gt; July, the Food Authority officially closed the area (which had been voluntarily closed since the 19&lt;sup&gt;th&lt;/sup&gt; July).</td>
</tr>
<tr>
<td>28&lt;sup&gt;th&lt;/sup&gt; July</td>
<td>Further inspection visit to growing area by Food Authority using boat.</td>
</tr>
<tr>
<td>30&lt;sup&gt;th&lt;/sup&gt; July-4&lt;sup&gt;th&lt;/sup&gt; August</td>
<td>Septic tank inspections of identified at-risk properties in catchment undertaken with the Council.</td>
</tr>
<tr>
<td>19&lt;sup&gt;th&lt;/sup&gt; September</td>
<td>Farm reopened after septic tank problems remediated.</td>
</tr>
</tbody>
</table>

Table 5.4: Timeline showing the sequence of events through the norovirus outbreak and subsequent investigation.

### 5.4.3 Harvest status of the farm

The farm was officially “Open” for harvest on the 30<sup>th</sup> June. There was a rainfall event (51.8mm) over the 16-18<sup>th</sup> June, which closed the marine farm to harvest from 19<sup>th</sup>-25<sup>th</sup> June 2004.

On the 19<sup>th</sup> June the River XX levels were recorded as being 3.556 – 3.778 metres from 0046 hours to 0501 hours.

There was also a 14.6 mm rainfall event on the 27<sup>th</sup> June 2004, but this was not sufficient to close the area to harvest.
5.4.4 Sample results prior to the illness event

All the routine microbiological samples taken during the period 13\textsuperscript{th} April 2003 until the 25\textsuperscript{th} June 2004 are displayed in Table 5.5.

<table>
<thead>
<tr>
<th>Sample Date</th>
<th>Faecal Coliforms MPN/100 ml Site A</th>
<th>Faecal Coliforms MPN/100 ml Site B</th>
<th>Faecal Coliforms MPN/100 ml Site C</th>
<th>Faecal Coliforms MPN/100g - Oysters</th>
</tr>
</thead>
<tbody>
<tr>
<td>April 3, 2003</td>
<td>1.8</td>
<td>1.8</td>
<td>1.8</td>
<td>20</td>
</tr>
<tr>
<td>April 29, 2003</td>
<td>1.8</td>
<td>1.8</td>
<td>1.8</td>
<td>330</td>
</tr>
<tr>
<td>July 24, 2003</td>
<td>1.8</td>
<td>1.8</td>
<td>1.8</td>
<td>18</td>
</tr>
<tr>
<td>August 27, 2003</td>
<td>7.8</td>
<td>4.5</td>
<td>4.0</td>
<td>20</td>
</tr>
<tr>
<td>September 24, 2003</td>
<td>14</td>
<td>9.3</td>
<td>6.8</td>
<td>490</td>
</tr>
<tr>
<td>October 22, 2003</td>
<td>3</td>
<td>3.6</td>
<td>3</td>
<td>30</td>
</tr>
<tr>
<td>November 27, 2003</td>
<td>22</td>
<td>7.8</td>
<td>22</td>
<td>68</td>
</tr>
<tr>
<td>January 5, 2004</td>
<td>2</td>
<td>1.8</td>
<td>1.8</td>
<td>18</td>
</tr>
<tr>
<td>April 28\textsuperscript{th} 2004</td>
<td>1.8</td>
<td>1.8</td>
<td>1.8</td>
<td>18</td>
</tr>
<tr>
<td>25\textsuperscript{th} June 2004</td>
<td>&lt;1.8</td>
<td>2</td>
<td>17</td>
<td>230</td>
</tr>
</tbody>
</table>

Table 5.5: Results of testing routine seawater and oyster samples taken from farm for the period April 2003 – June 2004. All samples were taken at times when the rainfall criteria for harvest were met.

In June 2004 the growing area switched to the use of \textit{E. coli} as the microbial indicator for shellfish due to the concerns about vegetative pollution (mangroves in the area) causing elevated faecal coliform results.

Occasional shellfish results exceeded faecal coliform levels of 300 MPN/100g (e.g. 29\textsuperscript{th} April and 24\textsuperscript{th} September 2003) but did not impact on compliance with the required standard to maintain the growing area’s classification of “Conditionally Approved”, which is measured over 15 samples.

As discussed earlier the elevated oyster flesh results of the 29\textsuperscript{th} April 2003 and 24\textsuperscript{th} September 2003 resulted in a change in rainfall criteria that added another day of closure to harvest after 20 -29.9 mm rainfall events.

5.4.5 Post-harvest conditions

The oyster processing premises were inspected on the 19\textsuperscript{th} July 2004. No food hygiene issues likely to have caused the product to become contaminated with NoV were identified in the processing plant.
Staff at the processing plant and on the oyster harvesting vessels were interviewed. There was no known illness and while there was a suitable toilet container on board the harvesting vessel, there had been no need to use this.

The oyster processing company also undertakes batch testing of all harvests as part of their own quality assurance programme to ensure that the product meets the market requirement of <230 E. coli per 100 grams. The June and July batch sample results for the implicated growing area are shown in Table 5.6. Following notification of the illness outbreak, library samples of harvest batches for 28th June – 1st July 2004 were also tested for NoV. The results of the NoV testing are also shown in Table 5.6.

<table>
<thead>
<tr>
<th>Harvest Date 2004</th>
<th>E. coli (MPN/100g)</th>
<th>Norovirus (Positive or Negative)</th>
</tr>
</thead>
<tbody>
<tr>
<td>25th June</td>
<td>78</td>
<td></td>
</tr>
<tr>
<td>26th June</td>
<td>&lt;18</td>
<td></td>
</tr>
<tr>
<td>27th June</td>
<td>No harvest</td>
<td></td>
</tr>
<tr>
<td>28th June</td>
<td>20</td>
<td>Negative</td>
</tr>
<tr>
<td>29th June</td>
<td>20</td>
<td>Positive</td>
</tr>
<tr>
<td>30th June</td>
<td>&lt;18</td>
<td>Positive</td>
</tr>
<tr>
<td>1st July</td>
<td>20</td>
<td>Negative</td>
</tr>
<tr>
<td>2nd July</td>
<td>&lt;18</td>
<td></td>
</tr>
<tr>
<td>3rd July</td>
<td>No harvest</td>
<td></td>
</tr>
<tr>
<td>4th July</td>
<td>No harvest</td>
<td></td>
</tr>
<tr>
<td>5th July</td>
<td>20</td>
<td></td>
</tr>
</tbody>
</table>

Table 5.6: Results of processed oyster samples from growing area

5.4.6 Field investigations related to the outbreak

1) **Boating Activity**: The closest mooring area is approximately 2 km up the River XX. There is also a Cruising and Boating Club about 5 km from the River mouth. As it was winter time at the time of the illness outbreak there was very little boating activity in the area. The area of the oyster farm is not a high use area for recreational boating activity at any time of the year. However, illegal sewage discharge from boats could not be discounted.
2) **Septic tanks:** All septic tanks that were on the foreshore of the marine farm bay and any of river properties up to the Boating Club situated 5kms upstream from the River mouth were inspected. (At the time it was considered this was the probable area of the catchment with the potential to influence viral contamination levels at the farm). The District Health Board and the Council undertook the inspections on the 30th July and the 4th August using visual criteria and dye testing. A total of 12 septic tanks were inspected.

Of the 12 septic tanks inspected, only 2 were found to have any problems, as described below:

i) **On-site sewage system at the oyster processing premises** - the system, which serviced a factory of about 50 staff, consisted of a two-stage septic tank system called a Turbo 2000 Deluxe. The waste water is gravity-fed into a primary sewage tank where the waste undergoes settlement and digestion during a retention period of approximately 24 hours. The settled waste then flows into the Turbojet Unit. This unit is comprised of two distinct chambers – a submerged contact aeration tank and humus tank. There is recycling of effluent in the system. Effluent is finally irrigated through irrigation lines placed throughout a 455 m² effluent disposal garden. The effluent disposal field was behind and adjacent to the processing factory and approximately 30 metres from the coast.

The on-site sewage system received an annual inspection by the service agent for the system. This was undertaken on the 15th June, 2004 and the inspection sheet/service check list noted that the system performance was acceptable.

However, during the Council inspection of the 4th August the Inspector found what he considered to be organic growth associated “break out” of effluent from the flaxed garden area. This effluent stream was possibly due to continued rainfall over the previous days and the inability of the finally treated effluent to be absorbed by the garden mulch. Rhodamine dye was placed in the holding tank on the 4th August and it was observed around the plant irrigation area in the following days.

After discussions with the owner of the oyster processing plant and their septic tank agent it was decided to increase the land application and irrigation area.

The on-site sewage system is situated approximately one kilometre from the oyster farm.

ii) **Gardener’s cottage in Bay (approximately 3 km from the oyster farm)** – the septic tank at the time of the inspection visit was full and overflowing but it did not appear to be flowing into any watercourses. It was recommended that the septic tank be pumped out, however it was considered unlikely that this discharge would have caused the NoV contamination at the oyster farm.

5.4.7 **Food Authority conclusions from 2004 outbreak investigations**

A site inspection and review of classification of the oyster growing area was conducted by the Food Authority as part of the 2004 outbreak investigation. This inspection found no clear cause for the NoV contamination. However, a number of ongoing potential risk factors were noted, including on-site sewage system discharges, run-off from farmland (especially after heavy rainfall), discharges from the River XX and discharges from passing boats.
After remediation work was completed on the two on-site sewage systems identified as malfunctioning, the area was reopened again as the review concluded that the potential pollution sources were considered predictable and manageable, sufficient to retain the “Conditionally Approved” classification.

5.4.8 Actions as a result of the outbreak investigation

The following recommendations were made as a result of the outbreak report. All recommendations were implemented.

1) The larger land application/irrigation system area should be installed at the oyster processing premises for the on-site sewage system. (This was carried out immediately).

2) The septic tank at the old gardener’s cottage should be pumped out and an assessment made of the tank itself to ensure it complies with the Council bylaws.

3) The effect of high flows from River XX should be undertaken using the following parameters.
   a. Sample during an event when River XX height exceeds 3.5-4.0 metres at the gauge. Oyster samples to be taken on the next four days at the marine farm after such an event [and tested for E. coli]. Note that these samples should only be taken if the oyster farm is “Open” under the rainfall criteria.
   b. All environmental conditions must be recorded at the time of sampling e.g. wind, tide and river height.

4) When harvesting at the oyster farm is occurring the harvester shall keep records of any boats in the area within 100 metres, 101-500 metres, and greater than 500 metres. These records should be made available to the Inspector on request.

5) Continued ongoing sampling on the day of opening after a closure due to 20-29.9mm rainfall and a closure due to ≥30mm rainfall is important. This sampling is to establish whether the closure periods continue to be sufficient.

5.4.9 Case analysis – 2004 outbreak

Based on E. coli/faecal coliform testing, the growing area was reported to be in compliance with its classification as “Conditionally Approved” at the time when the outbreak occurred, and the oysters implicated in the NoV outbreak were harvested in compliance with the growing area harvest criteria. The results of batch testing of oysters for E. coli on five occasions from 25th - 30th June 2004 by the processor were not significantly elevated, and provided no indication of the risk of significant levels of NoV contamination. E. coli indicators in harvested product were thus not effective in the management of the risk of NoV contamination in this case, nor did the monitoring for compliance with the growing area classification using faecal coliform/E. coli indicators reliably predict the risk of virus contamination.
We note however that in the previous year the routine testing of samples from the growing area for faecal coliforms/\textit{E. coli} in compliance monitoring had detected some unexpectedly high faecal coliform levels (one exceedingly high) at times when the area was open for harvest. As a result, one harvest criterion had been changed by extending the closure time after 20-29.9 mm rainfall by one day. This suggests the possibility that there had been a change in water quality in the growing area over time. It is the role of the shoreline survey to characterise the nature of the potential contamination in a growing area. Neither the investigation surrounding the elevated faecal coliform levels, nor the annual review had resulted in the detection of the two malfunctioning on-site sewage systems. This raises one of two questions: either the investigation of pollution sources undertaken in association with non-compliance and annual reviews were not undertaken in sufficient depth (assuming that the pollution sources were present at the time when these investigations were undertaken), or the shoreline survey component of the shellfish programme is not effective in detecting rapid changes in the risk of viral contamination in a growing area.

Discharges from on-site sewage systems in the growing area catchment were noted in the Sanitary Survey report as potential pollution sources in the growing area catchment. The symptoms of malfunction in the effluent disposal field of the on-site sewage system at the oyster processing plant (i.e. the presence of slime in the field, suggesting discharge to the surface) suggest that such malfunction was not a very recent or isolated occurrence. This had not been detected by the service agent for the system, who had inspected the system approximately two weeks before the illness outbreak, nor the system operator (the oyster processing company). Under the wet conditions when rainwater was pooling on the ground, this may have been difficult to detect by visual inspection, especially by an untrained eye. The unexpectedly high levels of faecal coliforms in oyster samples taken to determine compliance with classification, which had resulted in a review of the harvest criteria, did not act as a trigger for an in-depth shoreline investigation by the Food Authority - intensive shoreline surveys are not normally undertaken under such circumstances.

The recommended remedy for the malfunction in the on-site sewage system at the oyster processing premises was an increase in the size of the effluent disposal field, suggesting that the initial design of the system, which had been approved by the Council, may not have been appropriate for the effluent volume/site conditions/rainfall conditions, which had not changed since its installation. This leads to questions about the effectiveness of controls that ensure that on-site sewage systems are designed and installed to prevent environmental contamination.
5.5 2008 Norovirus Outbreak

5.5.1 Epidemiological information

Between 11th and 17th July 2008 the local Public Health Service was notified of 11 separate food-borne illness incidents, affecting 68 people who had consumed raw oysters. By the end of July, a further 19 outbreaks had been notified, bringing the number of notified cases to 121. All of these cases were associated with the same oyster processing premises.

The processing premises received oysters from three separate farms within two growing areas (GA 2 and GA B). Both harvest areas were classified as “Conditionally Approved”. One growing area (GA B) is situated off a sizeable island remote from the mainland (two implicated farms) and the other growing area (GA 2, as previously described) at the mouth of River XX.

It took the Food Authority some time to work through which harvest batches and growing areas were implicated in the NoV outbreaks. The processing company uses a coding system to identify the farm from which the oysters are harvested and the harvest date. This information was useful in determining the source of the NoV. However, in several cases the restaurants had no knowledge of which oyster batches had been served to their customers. In these cases the processor’s sale records were used to identify the batches that had been supplied from the processor batches and therefore potentially served to the consumers.

The dates implicated in the outbreak extended from the 23rd June - 11th July 2008.

Faecal samples for microbiological and virological analysis were obtained from cases that were still symptomatic at the time of interview.

The epidemiological investigation concentrated on the two largest outbreaks of food-borne illness. Both involved private functions at which raw oysters were served. The first was a boat launch on 6th July 2008, and the second was a bird-shooting fundraiser on 12th July 2008. Investigations into both functions were conducted as retrospective cohort studies to determine which foods or beverages were associated with illness. For both functions, a case was defined as any person who consumed food or drink and subsequently experienced diarrhoea or vomiting within 72 hours. Data were entered into and analysed in Microsoft EXCEL.

The epidemiological investigations into the boat launch and the fundraiser had response rates of 100% and 67% respectively. The overall attack rate was higher at the boat launch (36%) than at the fundraiser (22.5%), with the majority of cases reporting symptoms of nausea, vomiting, stomach cramps and diarrhoea. Mean incubation periods were 36 and 30 hours respectively, and the mean duration of illness was approximately 53 hours for both outbreaks. For both functions, raw oysters were the only foods significantly associated with illness, with relative risks of 21.9 (95% CI 1.4-343.7) and 44.3 (95% CI 6.2-315.2) for the boat launch and the fundraiser outbreaks respectively.

Sixteen faecal samples from symptomatic cases were tested for NoV by real-time reverse transcriptase polymerase chain reaction (RT-PCR). Of these, 15 (94%) were positive for a recombinant strain of NoV genogroup II (GII.c-GII.12) not previously described in the literature. One faecal sample was negative for NoV.

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Twenty-three oyster samples were also sent for virological analysis, 14 (61%) of which were positive for NoV genogroup II\textsuperscript{11}. Further typing revealed that at least one of these samples (a “fresh” oyster sample taken from the farm) was positive for GII.c-GII.12, indistinguishable from the strains identified in the faecal samples. (See Table 5.9 later for further detail of tested samples).

### 5.5.2 Event timeline

A timeline for the 2008 NoV event is shown in Table 5.7.

<table>
<thead>
<tr>
<th>Date 2008</th>
<th>Action related to outbreak</th>
</tr>
</thead>
<tbody>
<tr>
<td>6\textsuperscript{th} July</td>
<td>Oysters harvested on 2\textsuperscript{nd} July were consumed at first outbreak.</td>
</tr>
<tr>
<td>11\textsuperscript{th} July</td>
<td>First notification received by District Health Board.</td>
</tr>
<tr>
<td>11-17\textsuperscript{th} July</td>
<td>Other notifications received.</td>
</tr>
<tr>
<td>17\textsuperscript{th} July</td>
<td>Farms in the two growing areas supplying the processor were closed.</td>
</tr>
<tr>
<td>18\textsuperscript{th} July</td>
<td>First shoreline survey of GA B and GA 2. Collection of oyster samples from GA B and GA 2, and wild oysters from River XX. Processing premises inspected.</td>
</tr>
<tr>
<td>31\textsuperscript{st} July</td>
<td>Second shoreline survey with Council.</td>
</tr>
<tr>
<td>4\textsuperscript{th} August</td>
<td>Another shoreline survey of GA B to assess pollution potential.</td>
</tr>
<tr>
<td>5\textsuperscript{th} August</td>
<td>GA B was reopened after shoreline survey and review of oyster results for NoV testing.</td>
</tr>
<tr>
<td>18\textsuperscript{th} September</td>
<td>Shoreline survey to ensure all potential sources were fixed in GA 2.</td>
</tr>
<tr>
<td>3\textsuperscript{rd} October</td>
<td>Virus samples were taken from GA 2 to reopen the growing area.</td>
</tr>
<tr>
<td>13\textsuperscript{th} October</td>
<td>GA 2 officially reopened for harvest.</td>
</tr>
</tbody>
</table>

Table 5.7: Timeline showing the sequence of events through the norovirus outbreak in 2008 and subsequent investigations.

### 5.5.3 Identification of implicated Growing Area

At the initial stages of the outbreak investigations, both growing areas (three farms) that supplied the processor were potentially implicated as the source of the NoV contamination.

\textsuperscript{11} Method references: Shellfish processing: Jothikumar et al., 2005 and Greening & Hewitt, 2008; Norovirus real-time RT-PCR: Kageyama et al., 2003.
Assessments of GA B and GA 2 were undertaken. This included shoreline surveys and sampling oysters for NoV analysis.

The survey involved performing a site inspection of properties lining GA B, as well as looking for boat and other pollution sources. Two properties were identified as having the potential to discharge untreated effluent into GA B. The first property, located approximately 250 m west of the growing area, appeared to have a pipe discharging wastewater from the laundry straight into the river. However, the on-site sewage system did not appear to be connected to this pipe, nor did it show any signs of failing at the time of inspection.

The second property, located approximately 1,500 m south-east of GA B did appear to have a failing on-site sewage system that was discharging runoff into the catchment area. However, this property did not appear to be inhabited, and ammonia (used to detect the presence of sewage) was not detected in water coming from the septic tank. The lack of evidence that the property was inhabited, together with its distance from both farms A and B at GA B led to the investigation team concluding that, although this second property was a potential pollution source, it was highly unlikely to have caused the contamination observed in a NoV-positive sample of processed oysters harvested from GA B on 4/07/08.

The conclusion from the environmental investigation of GA B was that these farms could not be implicated as the source of contamination for the NoV outbreak, particularly because there was a lack of epidemiological evidence linking product sourced exclusively from GA B. In addition, the potential contamination sources identified during the first site survey of GA 2 were thought to be much more likely causes of the NoV outbreak.

The following sections will now focus on the investigations at GA 2 and the oyster processing premises, which were considered to be the likely source of the NoV illness outbreak.

5.5.4 Harvest status of the farm at Growing Area 2

Table 5.8 shows the Growing Area 2 harvest criteria based on rainfall that was current at the time of the NoV event in 2008.

<table>
<thead>
<tr>
<th>Rainfall (mm)</th>
<th>Rainfall Period (hours)</th>
<th>Closure Period (days)</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 – 19.9</td>
<td>24</td>
<td>No restriction</td>
</tr>
<tr>
<td>20 – 29.9</td>
<td>24</td>
<td>5</td>
</tr>
<tr>
<td>≥ 30</td>
<td>24</td>
<td>6</td>
</tr>
<tr>
<td>≥ 60</td>
<td>48 (2 days)</td>
<td>5</td>
</tr>
<tr>
<td>≥ 85</td>
<td>72 (3 days)</td>
<td>7</td>
</tr>
<tr>
<td>≥ 85</td>
<td>96 (4 days)</td>
<td>7</td>
</tr>
</tbody>
</table>

Table 5.8: Rainfall harvesting criteria for Growing Area 2 as at June 2008

The farm was “Open” for harvest at the time of the harvest of the implicated oysters.

A combined total of 431mm of rainfall fell in the harvest area catchment for the months of June and July, and this is likely to have saturated on-site sewage system disposal fields at the processing factory and in the growing area catchment. This heavy rainfall, in combination with high river
flows (the river level reached 3 metres in height), occurred one week prior to the first sample of processed oysters in which NoV was detected, which was taken from oysters harvested on the 29th June 2008.

5.5.5 Sample results prior to the illness event

Table 5.9 shows the results for routine seawater and oyster samples taken from GA 2 for the period June 2006-July 2008 as required by the SQAP. These results show that the farm was performing within the microbiological limits for seawater and oyster flesh in the months preceding the 2008 NoV outbreak.

<table>
<thead>
<tr>
<th>Sample Date</th>
<th>Results from Water Samples</th>
<th>Results from Oyster Samples</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Faecal Coliforms (MPN/100 ml) Site No. 1</td>
<td>Faecal Coliforms (MPN/100 ml) Site No. 2</td>
</tr>
<tr>
<td>26th June 2006</td>
<td>1.8</td>
<td>1.8</td>
</tr>
<tr>
<td>17th July 2006</td>
<td>1.8</td>
<td>1.8</td>
</tr>
<tr>
<td>25th Sept 2006</td>
<td>1.8</td>
<td>1.8</td>
</tr>
<tr>
<td>18th Oct 2006</td>
<td>1.8</td>
<td>1.8</td>
</tr>
<tr>
<td>6th Dec 2006</td>
<td>1.8</td>
<td>1.8</td>
</tr>
<tr>
<td>18th Dec 2006</td>
<td>1.8</td>
<td>1.8</td>
</tr>
<tr>
<td>23rd Jan 2007</td>
<td>1.8</td>
<td>2.0</td>
</tr>
<tr>
<td>23rd April, 2007</td>
<td>1.8</td>
<td>1.8</td>
</tr>
<tr>
<td>9th May, 2007</td>
<td>1.8</td>
<td>1.8</td>
</tr>
<tr>
<td>19th June, 2007</td>
<td>1.8</td>
<td>1.8</td>
</tr>
<tr>
<td>26th July, 2007</td>
<td>1.8</td>
<td>1.8</td>
</tr>
<tr>
<td>15th Aug, 2007</td>
<td>1.8</td>
<td>1.8</td>
</tr>
<tr>
<td>27th Sep, 2007</td>
<td>1.8</td>
<td>1.8</td>
</tr>
<tr>
<td>29th Oct, 2007</td>
<td>1.8</td>
<td>1.8</td>
</tr>
<tr>
<td>8th Feb, 2008</td>
<td>1.8</td>
<td>1.8</td>
</tr>
<tr>
<td>10th Mar, 2008</td>
<td>1.8</td>
<td>1.8</td>
</tr>
<tr>
<td>25th Mar, 2008</td>
<td>1.8</td>
<td>1.8</td>
</tr>
<tr>
<td>7th April, 2008</td>
<td>1.8</td>
<td>2.0</td>
</tr>
<tr>
<td>29th May, 2008</td>
<td>1.8</td>
<td>1.8</td>
</tr>
<tr>
<td>1st July, 2008</td>
<td>1.8</td>
<td>1.8</td>
</tr>
</tbody>
</table>

Table 5.9: Results of routine seawater and oyster samples taken from farm at Growing Area 2 for the period June 2006 - July 2008.

5.5.6 Post-harvest conditions

The oyster processing premises were inspected on the 18th July 2008. No food hygiene issues likely to have caused the product to become contaminated with NoV were identified inside the processing plant.
Staff at the processing plant and on the oyster harvesting vessels were interviewed. There was no known illness and while there was a suitable toilet container on board the harvesting vessel there had been no need to use this.

However, a potential source of contamination was identified at the outside oyster washing area. This source may have contributed to the June/July NoV outbreak. On arrival at the shore base and before entering the processing plant all oysters were first sprayed with water externally to remove extraneous mud and other organic material. The wash water was taken from the estuary potentially contaminated with effluent from the processing plant.\(^\text{12}\)

Investigation revealed that the disposal field for the on-site wastewater treatment system for the factory, which lay at the boundary of the factory area, was failing, resulting in the pooling of effluent at the surface. During a rainfall event there was the potential for this pooled effluent to flow along the concrete and gravel surface into the estuary.

Water pumped from the estuary was used for washing the oysters after harvest and prior to entering the processing factory. This estuary water had no treatment step prior to use.

The oyster processing company undertakes batch testing of processed product from all harvests as part of their own quality assurance programme to ensure that the product meets the market requirement of <230 \(E.\ coli\) per 100 grams. The June and July batch sample results for the implicated growing area are in Table 5.10.

### 5.5.7 Sample results

The Food Authority report on the event states that there were 23 oyster samples taken during the outbreak investigations. These oyster samples were sourced from:

- The processing company’s “library”. The “library” is a store of finished product from each production date.
- Samples of the processor’s product taken from two restaurants.
- Oysters taken directly from the two growing areas initially implicated (GA 2 and GA B) on date 18\(^{\text{th}}\) July 2008
- Wild oysters taken from up River XX on 18\(^{\text{th}}\) July 2008.

Details and the results of NoV testing of these samples are shown in Table 5.10. Sample analysis for NoV was undertaken using real-time RT-PCR (Jothikumar et al., 2005, Greening & Hewitt, 2008; Kageyama et al., 2003)

\(^{12}\) Note that this was not the source of wash water at the time of the previous norovirus contamination event in 2004.
<table>
<thead>
<tr>
<th>Farm</th>
<th>Date Harvested</th>
<th>Source of Sample</th>
<th>Test Result (Norovirus Genogroup Presence/Absence)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Norovirus GI</td>
</tr>
<tr>
<td>GA B Farm A</td>
<td>18/07/08</td>
<td>Processor Library Sample</td>
<td>-</td>
</tr>
<tr>
<td>GA B Farm B</td>
<td>23/06/08</td>
<td>Processor Library Sample</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>20/06/08</td>
<td>Processor Library Sample</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>01/07/08</td>
<td>Processor Library Sample</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>14/07/08</td>
<td>Processor Library Sample</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>30/06/08</td>
<td>Leftover Restaurant #1</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>30/06/08</td>
<td>Processor Library Sample</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>04/07/08</td>
<td>Processor Library Sample</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>26/06/08</td>
<td>Processor Library Sample</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>27/06/08</td>
<td>Processor Library Sample</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>02/07/08</td>
<td>Processor Library Sample</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>04/07/08</td>
<td>Processor Library Sample</td>
<td>-</td>
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<tr>
<td></td>
<td>06/07/08</td>
<td>Processor Library Sample</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>08/07/08</td>
<td>Leftover Restaurant #2</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>08/07/08</td>
<td>Processor Library Sample</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>10/07/08</td>
<td>Processor Library Sample</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>11/07/08</td>
<td>Leftover Restaurant #1</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td>18/07/08</td>
<td>Fresh sample- East Side</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Fresh sample- West Side</td>
<td>-</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sample of feral oysters from adjacent to Cruising Club in River XX.</td>
<td>+</td>
</tr>
</tbody>
</table>

Table 5.10: Summary of results of analysis of oyster samples for norovirus by genogroup. 
Processor Library Sample = sample of processed oysters; Fresh sample = sample of oysters taken directly from the farm; +/- = presence/absence.

5.5.8 Field investigations related to the outbreak

Within this investigation three separate shoreline surveys were undertaken in the catchment area of Growing Area 2.

The first was performed on 18/07/08, and involved taking a boat around the catchment area and up River XX, for the purposes of identifying properties with the potential to discharge sewage into the river, where it could potentially be transported out to the farm.

The second visit, performed on 31/07/08, was a joint effort between the Food Authority and the Council’s Environmental Health Officer and the Wastewater Officer, for the purposes of reviewing all pollution sources accessible by road that may have been missed in the initial survey, and for the
Council to serve abatement notices against any offending properties discharging sewage illegally into the River XX.

The third visit was performed on 18/09/08 by the Food Authority and involved reviewing the identified pollution sources for the purposes of evaluating the remediation works ordered by the Council.

**Boating Activity**

As mentioned in the earlier sections of this report the closest mooring management area to the oyster farm lies in River XX approximately two kilometres from the oyster farm.

A further mooring management area is located at another bay approximately five kilometres east of the oyster farm. This mooring area was considered unlikely to have any impact on the marine farm because of its distance from the farm. On-shore toilet facilities are located at the Cruising Club close to the mooring area.

The 2008 investigation showed that there were 20 swing moorings and 34 pile moorings in the mooring management area in River X. This was the maximum allowed at that location in the regional council management plan.

**Boating and other recreational uses of the area i.e. recreational fishing**

1. Boats going up River XX all pass the oyster farm but travel at least 1 kilometre away from the farm. Other use of boats is considered minimal. Occasional fishing is the only other use in the bay. This is very limited as the water is very shallow, and because of an explosives safety zone in the area.

2. There is no overnight anchoring of boats in River XX or the bay.

3. There are no live-aboards on boats in the vicinity of the growing area.

4. River XX is navigable upstream as far as the local town at high tide and is an important recreational resource, as well as being used for the mooring of boats. The local Cruising and Boating Clubs have moorings on the river and facilities (including toilet facilities) adjacent to the river. There are also a number of private moorings on the river. These are approximately 4-5 kilometres upstream from the river mouth.

**Conclusions on Boating activities**

While sewage discharge from a boat into the growing area may have been a potential source of contamination, the Food Authority concluded that the likelihood of this occurring was very low. The main points of discharge from a boating source that could impact on the oyster farm would include a boat discharging its waste while directly passing the farm, discharge from a boat’s occupants living up River XX, or a faecal accident/vomiting episode from an oyster farm worker into the growing waters.

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13 The basis for this conclusion was not communicated to the researchers but did not explicitly consider transport distance over a tidal cycle.
Boats returning to their mooring in the River XX pass within approximately 1 kilometre the farm, but are prohibited from discharging their untreated sewage within 500m of the oyster farm as per the marine pollution regulations.

The stormy weather with high winds, heavy rainfall, and choppy seas prior and at the time of the NoV event meant that any boating activity in the vicinity of the farm would have been unlikely.

There is the potential for people to live aboard boats up the River XX and illegally discharge their untreated effluent into the river, where it could be transported downstream to impact on the farm. The visual inspection of the River XX by boat on 18/07/08 revealed no signs of habitation in the moored boats. Therefore it is unlikely that moored boats were the source of the contamination event.

The third potential point of discharge from boating activity at the farm, coming from an ill worker vomiting or having a faecal accident into the growing area, is unlikely to have occurred. No workers involved in the harvesting process reported sick with gastrointestinal symptoms prior to the contamination event, nor were any vomiting/faecal accident episodes reported by staff into the growing waters.

**On-Site Sewage Systems**

During the 2004 NoV investigations all septic tanks 5 kilometres from the mouth of the river were inspected (up to and including the Cruising Club). Due to the concern about this second NoV outbreak in 2008, the field investigations were extended to 10 kilometres from the river mouth.

A number of properties with the potential to discharge untreated effluent into the river were observed lining the River XX.

Properties were assessed by visiting each one and conducting a visual inspection of their on-site sewage systems, the discharge point/disposal field, and its performance. The Council Officers looked specifically for the direction of sewage outflow, as well as any indications of failure, such as algal growth or sodden treatment fields.

Following this visit, notices were served to each of the properties identified in the initial sanitary survey as having malfunctioning systems, and these were followed up as to their completion on the third site visit performed on 18/09/08.

**Property Number 1** – This property, situated approximately 5 kilometres from the mouth of River XX and 6 kilometres from the oyster farm, had a long drop toilet approximately 5-10 metres from the river. The toilet effluent appeared to go into a storage pit that had no irrigation field or other piping. During heavy rainfall the Council Officers considered that this pit could overflow, with effluent subsequently flowing downhill into the River XX. A caravan was also located at this site and appeared to have been occupied prior to the site assessment.

**Property Number 2** – Situated about 6 kilometres from the mouth of the River and 7 kilometres from the oyster farm is a boat club, which was found to have a stand-alone flush
toilet that emptied into a steel tank with no treatment field. During heavy rainfall conditions this toilet was assessed as having the potential to overflow and discharge into the adjacent creek that wound its way out into the River XX. At the time of inspection this tank was close to full, and there was green slime surrounding the tank and in the creek, indicating previous sewage discharges.

**Property Number 3** - Situated approximately 5 kilometres from the river mouth and six kilometres from the oyster farm. The Cruising Club house and ground-keeper’s property bordered the river, and it was not clear where their effluent went. This property was re-inspected on 31/07/08 and found to be discharging effluent from its septic tank into the creek area behind the clubhouse.

**Property Number 4** – This property was located at approximately 9 kilometres from the river mouth and 10 kilometres from the oyster farm. A toilet used by the caretaker appeared to have a pipe running from the toilet cubicle straight into the river. Indicative green slime of effluent discharge was seen on the walkway outside the toilet. This toilet discharged untreated effluent into the river when flushed.

**Property Number 5** – The property was located approximately 9 kilometres up from the river mouth and 10 kilometres from the oyster farm. A pipe was traced from the property straight down into the River XX. Further investigation of this site found that the pipe was sourced directly from the septic tank, which received effluent from the tank’s first chamber. The property had no discharge field and it was assumed that all sewage was piped downhill into the river, untreated.

**Property Number 6 – Oyster Processing Premises**
As discussed previously, investigation revealed that the sewage disposal field associated with the oyster processing factory appeared to be failing, possibly due to heavy rainfall and soil saturation. This caused pooling of wastewater potentially contaminated with NoV at the surface. During a rainfall event there was the potential for this pooled wastewater to flow along the concrete and gravel surface into the estuary. Effluent from the disposal field was observed to enter the estuary adjacent to the factory, approximately 1 km from the oyster farm.
As previously discussed, the estuary water was used for spraying the oysters after harvesting and prior to entering the processing factory (this washing process did not include submersion of the oysters). This estuary water had no treatment step prior to use. The failure of the effluent disposal field could thus have presented a risk of virus contamination both at the farm and during post-harvest washing.

**Summary of on-site sewage system issues:**

The 2008 field investigations extended 10 kilometres up the river from the mouth (the 2004 investigations explored 5 kilometres up the river). (The additional area investigated did not include the town, which is further upstream). With the extra five kilometres of exploration of the rural catchment, two new properties (Number 4 and 5) were identified with the potential to pollute the river with effluent. These properties were newly developed and they were not likely to have been present during the investigation following the 2004 NoV outbreak associated with this growing area. Properties 1-3 which were found to have non-compliant on-site sewage systems in the 2008 survey were also investigated following the 2004 event but at that time the disposal systems were deemed to be operating effectively.
Compliance Status under Resource Management Act 1991 and Ancillary Environmental Policies

During the 2008 investigations properties were identified as non-complying with the Regional Plan and the local Council requirements for on-site sewage disposal. Owners of all these properties were issued legal notices by the Council, ordering them to ensure that their systems were designed and maintained effectively.

In all cases the properties were re-inspected by the Council officers and found to have facilities operating in compliance with the Council environmental legislation before the growing area was re-opened for harvest.

5.5.9 Food Authority conclusions from 2008 event

The interconnection of numerous factors had the potential to contribute to the NoV outbreak in July 2008. Heavy rains, in conjunction with sewage discharge into River XX, elevated river flows, and failure of the discharge field at the oyster processing premises, are all key events that could have caused the contamination at the farm. A combined total of 431mm of rainfall fell in the growing area catchment for the months of June and July, and this is likely to have saturated on-site sewage system disposal fields at the factory and in the wider growing area catchment. This heavy rainfall, in combination with high river flows (which reached 3 metres in height 1 week prior to the first positive NoV library sample on the 02/07/08, compared to a background river height of 0.5 metres), would have further impacted on the growing area.

In the three shoreline surveys of the growing area performed following the outbreak event, a number of potential pollution sources were identified as being likely to impact on the quality of oysters in the growing area and cause the NoV event. Through the site surveys of properties lining the River XX, several properties were identified with the potential to discharge raw sewage into the river. With high river heights and elevated river flows during winter there is the strong possibility that higher levels of contamination from the observed sources could be transported down to the farm, causing the NoV outbreak observed.

The failing treatment field at the oyster processing premises was also highlighted as a potential cause of the outbreak. At the time of the NoV outbreak, effluent from the on-site sewage system disposal field was discharging directly into the estuary about one kilometre from the oyster farm. Water from this estuary was used for washing the external surface of the oysters before sending them into the processing premises for shucking and processing. Ongoing management of the performance of the newly installed treatment field will be required to ensure that it does not fail and contaminate the growing area in the future.

5.5.10 Actions as a result of the outbreak investigation

Following the identification of on-site sewage system problems, remedial actions were immediately undertaken. The following is a summary of these actions:

1) Formal notices were issued to property owners and these were followed up on the 18th September, 2008 to ensure full compliance.
2) Property Number 1 – The stand alone toilet was completely removed on 28 August 2008. Upon inspection the site of the long drop toilet and hole had been completely filled in.

3) Property Number 2 – the tank holding the septic tank sewage was pumped out on 1 August and the toilet was bolted off by the property owners with signage displayed. Upon inspection on 18/09/08 access to the toilet was not attainable.

4) Property Number 3 - The septic tank that handles sewage from the caretaker’s property and the clubrooms was pumped dry on 15 August and 15 September, with the Club now pumping out their septic tank on a monthly basis. Receipts were viewed confirming these works. Inspection of the tank on 18/09/08 showed the tank to be ¼ full. A new on-site sewage system was subsequently designed and installed in consultation with the Council.

5) Property Number 4 - within 24 hours of inspection on 4 August the property owners had complied with the abatement notice. Actions taken by the home owner were as follows.
   i) Turned off the water, preventing the discharge of water referred to in the notice.
   ii) Provided a portable toilet facility by the toilet accommodation. Instructed all persons to cease use of the toilet accommodation immediately and use the portable toilet.
   iii) Contacted a consultant engineer to commence an assessment and recommendation for a permanent solution to the drainage problem.

6) Property Number 5 – works were completed on 15 September by the contractor. Actions taken by the home owner were as follows: the septic tank was reviewed by the drain layer and found to be malfunctioning, resulting in the discharge going directly into the river. The drainlayer made adjustments to the design of the on-site sewage system and redirected the effluent to a land disposal field. The Council approved and signed off on these remedial actions.

7) Property Number 6 Oyster Processing Premises - The effluent disposal field was been relocated to a piece of land more distant from the coastal foreshore (approximately 100 metres) and an alternative source of water is now used to wash the external surface of the oysters before they enter the processing plant. Ongoing management of this new discharge field will be needed to ensure it is operating effectively.

The Food Authority report noted: “To prevent future contamination events at the farm an ongoing commitment is required from [contractor to the Food Authority] and the Council to ensure septic tank discharges into the River XX no longer continue. The actions taken to fix these pollution sources by the Council and the respective property owners were effective measures for ensuring the water quality on the farm was suitable for reopening. However, ongoing environmental assessment of the growing area on a regular basis is required to ensure that these properties continue in the containment of their septic systems”.

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5.5.11 Case analysis – 2008 outbreak

The growing area was reported to be in compliance with its classification as “Conditionally Approved” at the time when the outbreak occurred, and oysters implicated in the NoV outbreak were harvested in compliance with the growing area harvest criteria. The results of batch testing of oysters for *E. coli* by the processor on seven occasions from late June – mid-July 2008 indicated extremely low (just at the level of detection) or no faecal contamination of oysters, and provided no indication of the risk of significant levels of NoV contamination. As in the previous NoV event in this growing area, this indicates that the coliform testing of harvested oysters does not provide a reliable indication of the risk of NoV contamination.

Several on-site sewage systems that did not comply with Council regulations were discovered in the intensive shoreline survey following the NoV outbreak. Discharges from on-site sewage systems in the growing area catchment were noted in the Sanitary Survey report as potential pollution sources, and had been implicated in an earlier NoV outbreak linked to the same growing area and processor. However, shoreline surveys associated with annual reviews did not reveal the non-complying on-site sewage systems close to the river in the catchment, or at the oyster processing plant. This is likely to be because the surveys associated with annual reviews do not generally involve intensive investigation of individual on-site sewage systems.

Given that the effluent disposal field at the oyster processing plant was once again found to be discharging effluent to the estuary via surface run-off, it could be concluded that the measures taken to prevent entry of effluent from the on-site sewage system following the NoV illness event in 2004 had not been effective. The upgraded disposal field design and installation had met Council requirements. The discharge had not been detected by the oyster processor, but this may have been difficult to recognise by visual inspection by an untrained eye because of the extremely wet conditions over the winter of 2008.

The oyster processor did not identify the use of the creek water as wash water for the oysters as a potential risk. This should have been identified in their HACCP plan. In addition, Food Authority inspections of the oyster processor failed to observe that the creek water was being used as wash water for the oysters in their inspection of the premises.

5.6 Conclusions from Critique of these two Case Studies

In neither the 2004 nor the 2008 NoV outbreak was the actual cause positively identified. However, in both cases there is a strong suspicion that failing waste disposal systems were the cause of the contamination.

Boat discharges could not be discounted but were considered highly unlikely by the Food Authority due to the time of the year and because boats are not regularly within the vicinity of the oyster farm.

It is of interest that both the 2004 and 2008 events took place at the same time of the year (June/July). In both cases rainfall had been heavy; River XX was in flood and the soils were saturated, possibly causing problems with effluent disposal fields.

In the 2004 outbreak two non-complying on-site sewage systems were identified in the catchment and in the 2008 there were six non-complying on-site sewage systems identified. Most of these
were distant (6-10 km) from the oyster farm, but on the banks of the river that discharges into the bay of the oyster farm.

None of the defective systems had been identified in the annual report, although an intensive shoreline survey is not required for the annual review. The Council were not aware of these properties either due to their rural nature, with the households predominantly situated some distance from the road. The identification of these defective on-site sewage systems highlights the need for management processes that readily identify, confirm and facilitate the rectification of malfunctioning systems that have the potential to impact upon a growing area.

In both the 2004 and 2008 events the Food Authority and oyster farmer secured the full support and assistance of the Council when undertaking the environmental investigations. The oyster farm/processor is a significant and valued industry in the area, and this therefore likely underpinned the Council’s willingness to provide resources for the investigations. It should be noted that in many regions only the Council officers have the legal right to enter properties and undertake intensive site investigations. Therefore, the timely and active response by Councils is paramount in such investigations.

In both the 2004 and 2008 events one of the malfunctioning on-site sewage systems belonged to the oyster processing plant. In each case, the problems were associated with the effluent disposal field, which was found to malfunction under wet soil conditions. We note that visual identification of such malfunction can be difficult under such conditions. Both the on-site sewage system and the effluent disposal field had been designed by an expert and met the legal requirements of the Council. This suggests some problem in the design standards or their implementation.

In addition to the potential for the discharge from the effluent disposal field at the oyster processing premises to contaminate the oyster growing area, a critical food safety defect that was identified during the investigations at the oyster processing premises in 2008 was the use of estuary wash water that did not meet the legal requirements. It is unclear as to why this had not been identified during the routine inspections by the Food Authority. It is possible this was because it was external to the registered processing plant and therefore not considered during the internal premises inspections. As a result of this incident the critical defect was subsequently used as a teaching tool for all NZ Food Officers reminding of the importance that all sources of water used on food products must meet the regulatory requirements.
SECTION 6  CASE STUDIES: GROWING AREA 3

6.1 Description of Growing Area and its Catchment

Growing Area 3 (GA 3), which includes 14 oyster farms, lies within Inlet X in the southern part of a harbour formed from a drowned valley. The inlet is approximately 9.7 km long with numerous embayments on either side, including a sub-estuary (Inlet Y). The large central channel is relatively shallow at the head of the inlet but progressively deepens to over 10 metres at the mouth. Most of the inlet is relatively wide (700-1000 m) with a progressive tapering toward the head in the upper third.

Inlet X runs west-east from mouth to head, and covers an area of approximately 16.9 km$^2$, of which over half is inter-tidal. The mouth of Inlet X adjoins that of an estuary (Estuary Z) to the west which is fed by two rivers (River Z and River A). A small port lies within the confluence of the two estuaries, and the tidal connection with the outer harbour is through a channel to the north.

The immediate catchment of GA 3, including a stream W that enters at the head, has an area of approximately 124 km$^2$. The catchment of Estuary Z is approximately 485 km$^2$.

The soils in the area are a mixture of clay loams and stony clay loams, with an underlying geology of weathered sedimentary rock. The land surrounding Inlet X and the sub-estuary of Inlet Y is predominantly covered in native broadleaf forest, with pockets of agricultural land (cattle and sheep). The catchment of Estuary Z is comprised of forest and farmland (cattle and sheep). Small areas of residential subdivision lie on points at the mouth of the channel from the estuaries leading to the harbour, and elsewhere houses are sparsely distributed. Houses on the western side of the channel mouth have a reticulated sewerage system, which until December 1994 was served by a package wastewater treatment plant at the village. This discharged treated effluent to the estuary at the port. Subsequently this effluent has been directed to a wastewater treatment plant associated with a town on the coast further out in the harbour, from which treated effluent is discharged to a inland wetland in forest in a more distant catchment (approximately 20 km away). All other houses in the immediate catchment of GA 3, including the small residential lots on the eastern point, operate on-site sewage systems. Two small towns are located upstream on the River Z. The closest, approximately 8 km from the mouth of Inlet X, is served by a Wastewater Treatment Plant (WWTP). Until 2002 this WWTP provided treatment in two oxidation ponds and discharged treated effluent into River Z. Subsequently the WWTP has been upgraded to provide UV disinfection and now discharges treated effluent to a wetland draining into the river, and during the summer months, by subsurface irrigation. The town further upstream in River Z has on-site sewage systems.

The port close to the confluence of Inlet X and Estuary Z consists of a wharf and car ferry landing, plus a marina. The port is used seasonally by commercial fishing vessels, and serves as a popular entry and exit point for overseas yachts. Not far from the port there is a quarantine mooring area for yachts and an area of swing moorings where boats are moored permanently. Boating is not a popular activity within Inlet X as the deeper waters of the harbour are more attractive. Toilet facilities connected to the reticulated sewage system are provided at the Port adjacent to the car ferry landing, at the marina and at the quarantine wharf.
Inlet X is well-flushed. During spring tides, approximately 68% of the tidal water within the inlet at high tide drains out with the outgoing tide. During neap tides, the volume discharged is slightly less at approximately 58%. Based on the calculated water volumes at high and low tides, the flushing time of the whole inlet (i.e. the average time a particle remains in the estuary) is estimated as 1.5 tidal cycles for spring tides and 1.7 tidal cycles for neap tides. These flushing times vary between the mouth of the inlet, which has the shortest flushing time, and the head of the inlet, which has the longest flushing time. Tidal excursion distances in the Inlet X are 4.5 km (neap tides) to 5.5 km (spring tides). Studies have shown that water quality in Inlet X is potentially influenced by Estuary Z, due to a lag in the tides in Estuary Z compared to Inlet X: during the early stages of the incoming tide in Inlet X, water that is still draining out from Estuary Z is carried into Inlet X.

6.2 History of Growing Area 3 Shellfish Programme

The first oyster farms were established in Inlet X in 1969, and application for further farms were granted by the Marine Department in 1971. At the time there was some correspondence between the Marine Department and the Health Department about the suitability of water quality for shellfish farming, and some applications for farms in Estuary Z were declined on these grounds.

1977 The first sanitary survey was undertaken. The major potential pollution sources quoted in the survey were the River Z and a small sewage treatment plant associated with the village at the port.

1986 Problems with compliance based on current rainfall criteria. Suggestion that salinity would be a better indicator of water and flesh conditions.

1991 A new farm (Farm 1), the closest to the confluence of the two estuaries, was added to growing area.

1992 USFDA reviewed the area and expressed concern that area may not be classified correctly. They recommended a tightening of the harvest criteria, and also required that a full sanitary survey of the area be undertaken.

The Food Authority undertook the full sanitary survey in accordance with the NSSP requirements at the time. The survey does not clearly state that the area should be classified as “Conditionally Approved”, but by implication suggests that with certain closure conditions it should operate with this classification.

There were several recommendations made for further work, including the need to take flesh samples to assess flesh clearance rates after wet weather. (At that point no studies had been undertaken to show the rate of clearance of faecal coliforms in oysters in Inlet X to background level following rainfall events).

1993 Annual report shows that the area did not comply with the requirements for classification as “Conditionally Approved” due to elevated faecal coliform levels observed in water samples taken during July-October. Harvest criteria changes were made. Seven flesh samples were taken during winter runs. Comment by Food Authority that level of faecal coliforms in flesh was variable and faecal coliform results in water samples did not correlate well with these.
1994 Emergency closure on 30/4/94 due to high faecal coliform levels (970 faecal coliforms/100g) found in oyster samples taken in export market.

Investigations by Food Authority identified that high tides could be linked to elevated faecal coliform levels. Tidal conditions put into management plan. Farm 1 was given separate criteria to ensure compliance with standards.

The Food Authority reported in the 1994 Annual Report: “The criteria as set are meeting the requirements of the NSSP “Conditionally Approved” areas, but the level of safety in the area is less than in other areas in [the region]”...“We have learned a lot about the factors that are impacting this area over the past three years. This has shown that this area is the most difficult water system to manage for oyster farming in the [the region] due to the impact of tide, and the various inputs of faecal coliforms from the [River Z] and the [Inlet X] catchment.”

Subsequently a NoV illness outbreak was linked to oysters harvested from the growing area in November 1994.

1995 Annual report shows water sample results in compliance with requirements for a “Conditionally Approved” classification. One flesh sampling round was undertaken on the 28/6/95. 14

1996 Annual report shows water sample results in compliance with a classification of “Conditionally Approved”. No flesh samples taken.

The growing area was reviewed by management and compliance groups in Food Authority as part of national calibration exercise. The group did not express concern at the “Conditionally Approved” classification.

1997 Annual report shows water in compliance. One flesh sampling round was undertaken on the 17/9/97.

1998 Annual report shows water sample results in compliance with a “Conditionally Approved” classification. One flesh sampling round was undertaken on 23/6/98.

A report on flesh cleansing rates of oysters in [the wider region] was done by Food Authority. Data specifically from GA 3 were not included in this report.

1999 Food Authority’s report confirms “Conditionally Approved” classification is appropriate. Some water sampling sites on the 10% compliance level. Correspondence between the local and regional Food Authority Officers expressing concern. Asked for details on evidence of flesh cleansing. Using modelling, the local Food Authority officer gave information on flesh cleansing and expressed concern with current regulatory requirements in a number of areas. These concerns were passed to the higher management within the Food Authority.

As a result of a NoV outbreak in November/December 1999 that was linked to the consumption of oysters from the growing area, the “Conditionally Approved” classification was again considered and verified by the Food Authority.

Note: compliance with classification criteria were based on water sample results – shellfish sampling was not included in the SQAP at the time.
2000 Annual Report shows water in compliance with NSSP standards. Flesh tests were taken during investigations into spring tides. All results were ≤330 faecal coliforms /100g. In January 2000, NoV was detected in an oyster sample taken from the middle of the growing area. No associated illnesses were reported.

Elevated *E. coli* levels (3,500 *E. coli*/100g) were detected in oysters harvest from Farm 1 as a result of testing in an export market in April 2000, and in oysters tested from another farm close by. Investigation by the Food Authority found an illegal septic tank discharging directly to the vicinity of the growing area.


Re-classification of middle and lower sections of GA 3 as “Restricted” on 8/10/2001. The upper section of the growing area, where no oysters were linked to NoV illness events, remained classified as “Conditionally Approved”. Risk assessment completed by consultant in November 2001.

2002 Classification reviewed after investigation and some remediation of potential sources of viral contamination in growing area. Food Authority decided that “Restricted” classification was still appropriate.

2005 12-yearly Sanitary Survey completed. Classification of growing area remained “Conditionally Approved” for the upper section of the growing area, and “Restricted” for the lower and middle section.

2009 Full Sanitary Survey report completed. Growing Area classification revised to “Conditionally Approved”, with the exception of Farm 1, which remains classified as “Restricted”.

The following sections discuss three NoV illness events that were linked to oysters consumed from GA 3. These events occurred in November/December 1994, December 1999/January 2000, and August 2001.

### 6.3 1994 Norovirus Outbreak

#### 6.3.1 Harvest Criteria Prior to Event

There were several changes in the harvest criteria in GA 3 in the year prior to the NoV illness outbreaks.
The criteria for harvest from July 1993 were as follows:

<table>
<thead>
<tr>
<th>Rainfall Range</th>
<th>Closure Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-14.9 mm</td>
<td>No restriction</td>
</tr>
<tr>
<td>15-19.9 mm</td>
<td>Closed 4 days</td>
</tr>
<tr>
<td>20-29.9 mm</td>
<td>Closed 5 days</td>
</tr>
<tr>
<td>30-44.9 mm</td>
<td>Closed 6 days</td>
</tr>
<tr>
<td>45-59.9 mm</td>
<td>Closed 7 days</td>
</tr>
<tr>
<td>60-79.9 mm</td>
<td>Closed 9 days</td>
</tr>
<tr>
<td>80-99.9 mm</td>
<td>Closed 10 days</td>
</tr>
<tr>
<td>100+ mm</td>
<td>Closed until opened by Food Authority</td>
</tr>
</tbody>
</table>

Closed when large vessels without holding tanks are within the [Channel] or at the [wharf at the port]. Closed until the area has been re-opened by the [Food Authority].

From 1st March 1994 the harvest criteria were expanded to include consideration of soil saturation and boat numbers. The following criteria were added to the existing criteria:

<table>
<thead>
<tr>
<th>Rainfall Range</th>
<th>Closure Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-14.9 mm</td>
<td>No restriction</td>
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<tr>
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<td>Closed 5 days</td>
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</tbody>
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<td>Closed 10 days</td>
</tr>
<tr>
<td>80+ mm</td>
<td>Closed until opened by Food Authority</td>
</tr>
</tbody>
</table>

Closed between 15 October and 31 March if the Food Authority considers the number of occupied yachts/boats anchored in the vicinity of the “Conditionally Approved” area represents a danger to the oysters. This will remain until the yachts/boats leave the area and testing verifies compliance with water/flesh requirements.

On 7th August 1994, additional criteria relating to compounded rainfall were added to the criteria above as follows:

A compounded rainfall event is an event where two rainfalls above the minimum level of closure (in the current criteria for the area) take place within four days. In these cases the criteria will be handled in the following way: Add the closure rainfalls and any intervening figures together. Consult the current 24-hour closure criteria (normal conditions or saturated conditions) and apply the new closure period as from the first day of closure. In the case of a 48-hour closure, the following would apply in Growing Area 3: Once an area is closed, any rainfall within the next two days at above half of the lowest criteria closure figure (i.e. if you close after 20 mm in 48 hours, the figure would be 10 mm, after 30mm the figure would be 15 mm in 24 hours etc) would be treated as below: Add the closure rainfalls and any intervening figures together. Consult the current 24 hour closure criteria (normal conditions of saturated conditions) and apply the new closure period as from the first day of closure.
6.3.2 Epidemiology of norovirus event

A total of 117 people were reported ill after consumption of oysters. Four separate illness events were reported, as summarised below:

**Event 1:**
36 of 95 people attending a Christmas party at a Yacht Club on 3/12/94 became ill with nausea, stomach pains, vomiting, diarrhoea and fever. Median incubation time was 37 hours. Oysters were implicated (RR = 4.3; 95% CI 2.6-7.2). Norovirus was detected in faecal samples by PCR. The oysters that were served were harvested from Growing Area 3 and one other growing area.

**Event 2:**
50/150 people who ate at an hotel on 25th and 26th November 1994 became ill with symptoms of stomach cramps, nausea, diarrhoea after a median incubation time of 33 hours. There was a statistically significant association with the consumption of raw oysters (RR=4.2; 95% CI 1.2-14.3, p<0.001). 10 out of 23 people who ate oysters became ill. No faecal samples were tested for NoV, and no leftover samples of oysters were tested. The oysters were harvested from Growing Area 3 in November 1994 and supplied frozen from a packhouse.

**Event 3**
A number of people became ill after eating a meal at a conference on 21/1/95. 69 people were interviewed and 28 had symptoms that met the case definition for NoV. There was a statistically significant association of illness with the consumption of raw oysters (RR=4.66; 95% CI 2.3-9.3, p<0.001). The attack rate was 76 %. NoV was detected in one faecal sample. The oysters were harvested from Growing Area 3 and supplied frozen to the hotel from a packhouse.

**Event 4**
Three people out of a group of 9 became ill after eating at a restaurant on 28/1/95. The 3 sick people were interviewed. They were the only ones in the group who had eaten oysters. The oysters were harvested from Growing Area 3 in November 1994 and supplied frozen directly from the farm.

Investigations of the food preparation chain in each event revealed no significant problems that could have led to the outbreak. It was concluded that the pattern of illness and the absence of significant bacteriological results in these outbreaks suggested that oysters harvested from Growing Area 3 during a 2-week period in November 1994 were contaminated with noroviruses. There was no commercial NoV testing for shellfish available at the time of the outbreaks, and the results of testing of leftover product were not available until 7-8 months later. These results confirmed the presence of NoV in oysters.

Growing Area 3 was closed to harvesting on 4/2/95 pending investigation. On 23/2/95 the Food Authority ordered a recall of all oysters harvested from Growing Area 3 between 16-24 November 1994. This was the first major regulatory recall of shellfish from local producers for both the local and export markets. Due to the nature of the events and the time delay involved, no fresh product was involved in the recall and some frozen product had already been consumed. The practice of batch-mixing of product on the local market, combined with poor record-keeping, resulted in the destruction of some product that may not have been implicated in the illness events. The Food Authority also noted that the recall process managed by distributors in the local market was inadequate, and that implicated product could have remained on the market. These issues were addressed with the industry in a series of meetings in 1995.
Following investigation in January 1995, the Food Authority determined that there was no evidence of any NoV illness caused by oysters harvested from Growing Area 3 over the period 10th December 1994 to 1st January 1995. Accordingly, on 8th February 1995 the Food Authority reopened the area to harvesting.

6.3.3 Growing Area investigation and remediation

Early in 1995 an investigation was undertaken in Growing Area 3 by the Food Authority to identify the source of viral contamination. No sewage spillages had been reported to the Food Authority by the local or regional councils in the few months before the implicated oysters were harvested, and a shoreline survey revealed no pollution sources that could definitively be held responsible for the oyster contamination. Several potential sources were considered, including the effluent discharge from the package sewage treatment plant at the port, septic tank systems at the residential area at the mouth of the estuary, and discharge of untreated effluent from boats (note that this was prior to the construction of the marina at the port). The latter source appears to have been considered most likely, and is the source most frequently cited as being associated with these outbreaks in subsequent reports by the Food Authority.

The package sewage treatment plant at the port was decommissioned in December 1994, with sewage subsequently being treated at a more distant WWTP that discharges effluent into a wetland in a separate catchment. The Food Authority and oyster farmers continued to lobby the government to introduce regulations to prohibit the discharge of effluent from boats in the vicinity of marine farms, but these regulations were not introduced until 2000.

An interesting sequel to the initial investigation undertaken in 1995 occurred some years later. Following another NoV outbreak associated with the consumption of oysters from Growing Area 3 in 2001, a consultant was engaged by the industry and Councils to conduct a risk assessment of viral contamination in Growing Area 3. In the course of this work, Council records (e.g. incident logs and reports, operating logs, sampling data, correspondence etc.) were examined to provide information about potential sources of virus contamination, and to ascertain whether any of the previous NoV outbreaks might have been able to be predicted. This investigation identified supplementary information about the potential source of contamination in the first NoV event based on monitoring records, Regional Council file notes, and correspondence between the District and Regional Councils. In mid-September 1994, the monthly monitoring undertaken in River Z as part of the consent conditions for the Town Z WWTP detected significantly elevated faecal coliform levels in water samples from upstream and downstream of the WWTP outfall. The Council monitoring officer had noted on the sampling form that the level of Pond 2 at the WWTP was unusually low (i.e. one outlet pipe was “sticking way up out of the water”). This prompted inspection by officers responsible for the operation of the WWTP, who reported that some sewage was still entering the plant, and that they could find no obvious leak. The District Council undertook additional sampling a fortnight later (3/10/94), and faecal coliform levels were still very significantly elevated at both sample points. The Regional Council requested further investigation, and the District Council agreed to more intensive sampling. The results of this sampling obviously prompted more intensive inspection of sewer lines near the river. A letter from the District Council to the Regional Council on 5th December 1994 confirmed that a rupture of a 225 mm steel rising main (carrying raw sewage to the WWTP) had been found near the bank of River Z and that a replacement main had been installed under the river and connected. Given that there was a significant reduction in the volume of effluent reaching the WWTP (evident from the significantly
lowered pond levels), the volume of raw sewage spilt into the river through the broken pipe would have been significant. The location of the discharge was approximately 9 km from the farms in the lower part of GA3. Water from River Z is known to be transported into Growing Area 3 on the low incoming tide. As the mains rupture occurred in the period just prior to when oysters implicated in the NoV illness outbreak were harvested, it is likely that it could have been the source of NoV contamination.

6.3.4 Case analysis

The environmental criteria for harvest of oysters from Growing Area 3 were met at the time when the implicated oysters were harvested on 16th – 30th November 1994. The harvest criteria were based on rainfall levels, and also provided for closures to harvest when large vessels without holding tanks were at the port or the channel leading into it, or by high boat numbers in the vicinity. A closure to harvest instigated by boats had not been implemented. Because no significant sources of viral contamination were identified on the shoreline during the investigation after the outbreak, the Food Authority concluded that discharge from boats was the most likely source. At the time of this outbreak there were no regulations preventing the discharge of sewage from boats in the vicinity of shellfish farms, and this enhanced the risk of contamination.

The harvest criteria would not have prevented the harvest of oysters contaminated with NoV if the rupture in the rising sewer main across River Z were the implicated source. The control on the shellfish programme for risk arising from spillages such as this relies on the communication of the event by the Council to the Food Authority.

The monitoring for faecal coliforms in water samples taken in the growing area over September, October and November 1994 indicated that the area was in compliance with its classification criteria, despite the presence of contamination sufficient to cause an outbreak of NoV illness arising from virus-contaminated oysters in November. This observation is consistent with research showing that the faecal coliforms are not reliable indicators of the risk of virus contamination in shellfish or their growing waters.

The level of dilution from the spillage site in River Z to the growing area could account for the absence of elevated faecal coliform levels observed in GA3. Because there was no investigation undertaken at the time, the amount of effluent discharged through the broken main is unknown, although we note that it was sufficient to very noticeably impact on the level in the pond at the WWTP. There is enough evidence to conclude that the discharge occurred over several weeks. This therefore may have been an instance in which oysters concentrated viruses out of low levels in the water over a long time period. As discussed in Section 2, this manner of exposure ultimately results in a greater proportion of viruses retained within oyster tissues (and thus more resistant to depuration) than a short, higher level exposure (see also Seamer, 2007).

Had the Food Authority known of the discovery of a ruptured sewer main discharging raw sewage into River Z, they would have been able to make more informed decisions about harvest closure times in the growing area. Based on an email from the Regional Council to the consultant in 2001, it appears that the breakdown in communication between the Councils and the Food Authority occurred because the spillage was detected as a result of routine District Council monitoring, and therefore didn’t get recorded in the incident log that triggered notification of spillages to the Food Authority.
It is interesting that the significance of this spill event did not come to light when potential sources of viral contamination in November 1994 were being actively investigated by the Food Authority in February 1995. However, the report from the local Food Authority officer indicates that his enquiry about potential spills, which was not made until February, was limited to the time period during which the contaminated oysters were harvested, and did not include October 1994. The opportunity to identify and remedy issues relating to the communication between Councils and the Food Authority was therefore missed.
6.4 1999 Norovirus Outbreak

6.4.1 Shellfish Programme and Harvest Criteria 1999

Prior to the NoV illness event in 1999, Growing Area 3 was classified as “Conditionally Approved”. The sampling regime to ensure compliance with this classification included monthly water testing for faecal coliforms when the area was open for harvesting. No regular testing of oysters was required, and none was undertaken in Growing Area 3.

The harvest criteria in 1999 were based on rainfall, salinity, tidal and seasonal closures as follows:

**Compounded Rainfall (applicable to all farms in GA 3)**

A compounded rainfall event is an event where two rainfalls above the minimum level of closure (in the current criteria for the area) take place within four days. In these cases the criteria will be handled in the following way: Add the closure rainfalls and any intervening figures together. Consult the current 24-hour closure criteria (normal conditions or saturated conditions) and apply the new closure period as from the first day of closure.

<table>
<thead>
<tr>
<th>Criteria for all farms except Farm 1:</th>
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</tr>
</thead>
<tbody>
<tr>
<td>0-14.9 mm rainfall in 24 hours</td>
<td>No restriction</td>
</tr>
<tr>
<td>15-19.9 mm rainfall in 24 hours</td>
<td>Closed 4 days</td>
</tr>
<tr>
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</tr>
<tr>
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<td>Closed 9 days</td>
</tr>
<tr>
<td>80-99.9 mm rainfall in 24 hours</td>
<td>Closed 10 days</td>
</tr>
<tr>
<td>100 + mm rainfall in 24 hours</td>
<td>Closed until opened by Food Authority</td>
</tr>
</tbody>
</table>

Also closed when large vessels without holding tanks are within the [channel from port to outer harbour mouth], or at [wharf at port], until the area has been re-opened by Food Authority.

**Soil saturation criteria for all farms except Farm 1:**

<table>
<thead>
<tr>
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<tbody>
<tr>
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</tbody>
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<thead>
<tr>
<th>Soil saturation criteria for all farms except Farm 1:</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-19.9 mm rainfall in 48 hours</td>
</tr>
<tr>
<td>20-29.9 mm rainfall in 48 hours</td>
</tr>
<tr>
<td>30-39.9 mm rainfall in 48 hours</td>
</tr>
<tr>
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</table>
**Criteria for Farm 1:**

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<th>Action</th>
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<tbody>
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</tr>
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<td>80+ mm</td>
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</tr>
</tbody>
</table>

Closed for harvesting from 1st December to 31st March. (Harvesting prohibited from 17th December 1999 to 28th March 2000).

Dates prohibited due to increasing tide above 2.7 metres at [M Point] will be notified.

### 6.4.2 Epidemiology of norovirus event

In December 1999/January 2000 there were a series of NoV outbreaks associated with the consumption of fresh and frozen oysters harvested late November-December. Details of the outbreaks are provided in Table 6.1. Three of the outbreaks were epidemiologically confirmed.
<table>
<thead>
<tr>
<th>OUTBREAK NUMBER</th>
<th>DATE OF OUTBREAK</th>
<th>BRIEF DETAILS OF OUTBREAK</th>
<th>IMPLICATED PREMISES</th>
<th>HARVEST DATE</th>
</tr>
</thead>
<tbody>
<tr>
<td>A1</td>
<td>4/12/99</td>
<td>8 cases out of 33 who attended a private BBQ. RR for half shell oysters 3.3, 95% CI 0.83-13.4 p = 0.12 4 cases positive on faecal analysis for NoV.</td>
<td>Private function</td>
<td>29/11/99</td>
</tr>
<tr>
<td>A2</td>
<td>4/12/99</td>
<td>North Shore City Council function. 7 cases out of 50 who attended. Raw half shell oysters RR 24.0, 95% CI 3.37-171; p&lt;0.001. NoV confirmed on faecal analysis.</td>
<td>Function Centre</td>
<td>25/11/99, 29/11/99</td>
</tr>
<tr>
<td>A3</td>
<td>7/12/99</td>
<td>10 cases out of 27 who attended a Christmas function. NoV confirmed on faecal analysis. RR only 1.2, 95% CI 51-2.83 P = 1.0, but response rate poor at 51%. Left over oysters tested from Lease [x] negative for NoV.</td>
<td>Restaurant 1</td>
<td>1/12/99</td>
</tr>
<tr>
<td>A4</td>
<td>10/12/99</td>
<td>6 cases out of a group of 6 who all ate half shell oysters. Faecal test positive for NoV.</td>
<td>Restaurant 2</td>
<td>3/12/99</td>
</tr>
<tr>
<td>A5</td>
<td>17/12/99</td>
<td>27 out of 65, 4 confirmed on faecal analysis. Oysters from Lease [x] negative, but positive from Lease [y]. Attack rate for oysters 80.0%, RR 49.3, 95% CI 2.31 – 10.83, p&lt; 0.00001.</td>
<td>Restaurant 3</td>
<td>8/12/99</td>
</tr>
<tr>
<td>A6</td>
<td>16/12/99</td>
<td>6 cases out of 16 attending Christmas function, half shell oysters consumed. Attack rate for oysters 100%, RR 11.0, 95% CI 1.70-71.28, p = 0.004. Faecal analysis positive for NoV. Oysters from same batch as outbreak A5, positive for NoV.</td>
<td>Restaurant 4</td>
<td>8/12/99</td>
</tr>
<tr>
<td>W7</td>
<td>11/01/00</td>
<td>3 out of 7 implicating half shell oysters. No epi calculations done or samples taken.</td>
<td>Restaurant 5</td>
<td>14/12/99</td>
</tr>
<tr>
<td>W8</td>
<td>15/01/00</td>
<td>2 out of 9 implicating half shell oysters. No epi calculations done or samples taken.</td>
<td>Restaurant 5</td>
<td>14/12/99</td>
</tr>
<tr>
<td>W9</td>
<td>15/01/00</td>
<td>5 cases from a 13 person function. No epi calculations done or samples taken</td>
<td>Restaurant 5</td>
<td>14/12/99</td>
</tr>
<tr>
<td>W10</td>
<td>16/01/00</td>
<td>3 cases from a 7 person function implicating oysters. No epi calculations done or samples taken.</td>
<td>Restaurant 5</td>
<td>14/12/99</td>
</tr>
</tbody>
</table>

**Table 6.1: Summary of norovirus outbreaks associated with the consumption of oysters harvested late November-early December 1999 from Growing Area 3.**

The oysters consumed in the ten events were distributed by 6 different distributors, processed in 5 different premises, and harvested by 4 different farmers from 8 different farms in Growing Area 3. The cases W7-W10 were not investigated using full epidemiological techniques. Due to staff shortages at the District Health Board B, one person from each outbreak was interviewed and the restaurant was visited to assess food-handling conditions.

The sequence of events through the epidemiological investigation was documented in a Food Authority report as follows:
21\textsuperscript{st} December, 1999

- Phone notification to the regional Food Authority officer from two District Health Boards that they had been investigating cases of food poisoning implicating oysters from Growing Area 3.

- Regional Food Authority officer asked local Food Authority to investigate the growing area.

22\textsuperscript{nd} December, 1999

- Received details from District Health Board A on cases investigated to date. At that stage sufficient epidemiological evidence that Outbreak A2 was caused by raw half shell oysters (p-value <0.0001), but not enough to implicate a specific growing area.

- Food Authority advised both District Health Boards of epidemiological proof required to undertake a recall action within a growing area.

- Food Authority management asked local officer for confirmation of growing area classification.

29\textsuperscript{th} December, 1999

- Food Authority confirmed the classification of GA 3.

24\textsuperscript{th} January, 2000

- Advised by District Health Board B of suspected NoV cases, which implicated oysters from the Growing Area 3.

- Further epidemiological information supplied by District Health Board A that the laboratory had confirmed the presence of NoV in oysters consumed in Outbreak Numbers A5 and A6. The oysters from both these outbreaks were sourced from Growing Area 3.

- Regional Food Authority officer reviewed all data, including harvest dates. On assessing the information, the regional officer made the decision to recall all product from Growing Area 3 harvested during the period 25\textsuperscript{th} November – December 15\textsuperscript{th}. These dates were established on harvest dates associated with confirmed illness and then adding an extra 21 days.

28\textsuperscript{th} January, 2000

- After further review of the data by National Manager at Food Authority and the Ministry of Health it was decided to extend the date to a period of 21 days post harvest date associated with last suspected case. Therefore recall dates were extended: 25/11/99 – 4/1/00 inclusive.

- All export packhouses were notified by fax of this recall and detention.
2nd February, 2000

- A complete inventory of all product harvested during the recall period was compiled by Food Authority. All remaining product was identified.

- Food Authority advised overseas agencies of the recall.

16th February, 2000

- Meeting held with industry and interested parties to discuss the event.

22nd March, 2000

- Ministry of Health hosted debrief meeting for health authorities, Food Authority and laboratory personnel involved with outbreaks.

March – September 2000

- On-going appeals by industry over the decision to condemn product. All product was ultimately disposed of under Food Authority supervision.

There were no reports of illness associated with oysters that had been exported.

6.4.3 Growing Area Investigation

Following notification to the local Food Authority officer on 21st December, a field investigation began on the last week of December 1999. The officer reported that there were no known land-based pollution problems in the housing and coastal regions near Farm 1 (which was the farm initially implicated). He also visited most of the properties with houses or where people were camping (it was the height of the holiday season) in the immediate vicinity of the farms later implicated in the outbreaks. It was noted that many of the houses visited had long-drop or bucket toilets, but these were not considered a significant risk by the officer. None of the residents reported having been ill in late November or early January. The local septic tank pump-out operator was interviewed and reported that he had not noticed any problems with septic tanks in the area. Consideration was given to the possibility that boats in the area were a source of contamination. The officer reported: “There were three yachts/boats that were in [Inlet X] at the time. One boat has no marine discharge, and occupants on two others reported no illness. Only one yacht was within 500 m of a marine farm. Two other boats were moored in the area but their occupants were visiting and living at a nearby house. No illness was reported at the house. There were many movements of recreational boats in the [port] area. If the problem was associated with foreign boats clearing customs at [the port], or [local] boats visiting the area then any investigation on the 21st December 1999 would have been pointless as most of these boats would have moved on”.


The local Food Authority officer concluded that a direct discharge of sewage into the sea was the most likely source of viral contamination of shellfish, but that the source was unknown. His report implied that boats visiting the area were the most likely source.

After a review of the event, the regional Food Authority officer made the following recommendations for the routine regulatory management of GA 3:

- Monthly water sample be continued at all water sampling stations. Compliance with the criteria for “Approved” waters shall be maintained.
- Three flesh test sites should be established in the upper, middle and lower Growing Area 3. Oysters from these three sites should be sampled monthly and tested for faecal coliforms, and compliance with the following standard should be maintained:
  - E. coli (or faecal coliform) median MPN in flesh shall not exceed 230/100 g (300/100 g) and not more than 10% of samples shall exceed an MPN of 700/100 g (900/100g). These statistics shall be calculated over a minimum of 15 sampling events for each site.
  - Any faecal coliform level of >230 MPN/100g should be investigated. The farmers in the growing area are encouraged to use available scientific technology (e.g. gene probes, E. coli typing) to gain an understanding of any growing area pollution source.
- Written agreements shall be established in the Management Plan between the Port Authority and the Food Authority to ensure that notification occurs when there are vessels without holding tanks at the port.
- A written summary of the water and flesh results shall be submitted to the regional officer at three-monthly intervals for compliance assessment.

On 1st July 2000 regulations were introduced forbidding the discharge of untreated sewage from boats within 500 m of marine farms and in waters less than 5 m deep.

6.4.4 Case analysis

The oysters implicated in the NoV outbreaks were all harvested at times at which the growing area harvest criteria were met. A Food Authority review of the compliance monitoring data and growing area immediately after the illness outbreaks concluded that the growing area was compliant with its classification as “Conditionally Approved”. These aspects of the shellfish programme thus failed to predict the presence of NoV contamination in the oysters.

One of the issues regarding the management of growing areas implicated in illness events that arose out of the analysis of this series of NoV outbreaks by the Food Authority relates to the level of epidemiological evidence required before action is taken. Early in the investigation (21st December) Growing Area 3 was implicated as the source of oysters that had caused the illness outbreaks. However, because at that stage there were no results available from NoV testing of leftover product, the level of epidemiological evidence required to definitively link the illnesses to oysters from Growing Area 3 was not met, and no action was taken to recall product until a month later when the laboratory results became available. In the meantime the consumption of frozen product remaining in the market resulted in another 4 illness events in the region administered by the District Health Board B a month later.
These latter cases from the region of DHB B implicated oysters from batches harvested later than those that had caused the earlier outbreaks (i.e. 14/12/99 c.f. 18/12/99). When the decision to recall product was made, this risk was managed by extending the period for which product had to be recalled to 21 days after the last suspected case was reported.

The few weeks before Christmas represent the time of peak domestic and export sales in the oyster industry, and a decision to recall product from this time was not taken lightly. However, time delay in receiving confirmatory analytical evidence from the laboratory was a significant issue in the management of this NoV outbreak. The delay arose because at the time the local laboratory did not have a validated method for analysis of NoV in shellfish samples. Oyster samples were sent to the laboratory on 23\textsuperscript{rd} December 1999 and results were not received by the Food Authority until 24\textsuperscript{th} January 2000. During this time the samples were analysed by the local laboratory, and subsequently the results were verified by a laboratory in England. We note that since then technology for analysis of NoV in shellfish samples has advanced significantly, and the laboratory in the region of this case study now has the capability and capacity to analyse these samples in a timely manner.

The source of NoV contamination in the growing area was not definitively identified in the field investigation undertaken following the illness outbreak, but the report from the local Food Authority officer concluded that it was most likely to have been sewage discharged from boats. This potential source had been previously identified in the sanitary survey and annual reports, and an earlier NoV outbreak in 1994 was at the time also attributed to effluent discharged from boats. The management programme for Growing Area 3 included harvest criteria based on the presence of large vessels without holding tanks at the port, but at the time of the NoV outbreak there was no formal agreement requiring the Port Authority to inform the Food Authority when such vessels were in port (although an informal arrangement was in place). Harvest criteria at Farm 1 in the lower inlet also included an additional closure period over the peak holiday period (which includes a popular boating period) from 1\textsuperscript{st} December to 31\textsuperscript{st} March. The peak season for yacht visits to the area runs from the end of October (when the area is the first port of call for boats returning from overseas before the hurricane season in the Pacific) to May. Local boating activity is high over the summer holiday period, and in April/May the number of occupied yachts in the area is relatively high as boats gather at the port before leaving for overseas. The seasonal closure to oyster harvesting did not cover the months in which occupied yachts gather at the port before and after the cruising season in the Pacific. Despite lobbying by the industry and Food Authority, in 1999 there were no regulations preventing the discharge of effluent from boats in the vicinity of marine farms. Assuming the source of NoV contamination in the growing area was effluent from boats, this risk was not adequately managed in the shellfish programme.
6.5. 2001 Norovirus Event

6.5.1 Growing Area Classification and Harvest Criteria 2001

Prior to the NoV illness event in 2001, Growing Area 3 was classified as “Conditionally Approved”, and water sample results complied with this classification. We note that the results of sample analysis indicate that monthly shellfish sampling, a condition of the growing area maintaining its “Conditionally Approved” classification that was recommended by the regional Food Authority officer early in 2001, had not been implemented.

Harvest criteria in 2001 were based on rainfall, salinity, tides and season as follows:

*Compounded Rainfall*

A compounded rainfall event is an event where two rainfalls above the minimum level of closure (in the current criteria for the area) take place within four days. In these cases the criteria will be handled in the following way: Add the closure rainfalls and any intervening figures together. Consult the current 24-hour closure criteria (normal conditions or saturated conditions) and apply the new closure period as from the first day of closure.

**Criteria during 1st May – 31st October for all farms except Farm 1:**

<table>
<thead>
<tr>
<th>Rainfall Range</th>
<th>Closure Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-14.9 mm</td>
<td>No restriction</td>
</tr>
<tr>
<td>15-19.9 mm</td>
<td>Closed 4 days</td>
</tr>
<tr>
<td>20-29.9 mm</td>
<td>Closed 5 days</td>
</tr>
<tr>
<td>30-44.9 mm</td>
<td>Closed 6 days</td>
</tr>
<tr>
<td>45-59.9 mm</td>
<td>Closed 7 days</td>
</tr>
<tr>
<td>60-79.9 mm</td>
<td>Closed 9 days</td>
</tr>
<tr>
<td>80-99.9 mm</td>
<td>Closed 10 days</td>
</tr>
<tr>
<td>100 + mm</td>
<td>Closed until opened by Food Authority</td>
</tr>
</tbody>
</table>

Also closed when large vessels without holding tanks are within the [channel from port to outer harbour mouth], or at [wharf at port], until the area has been re-opened by Food Authority.

**Criteria during 1st November – 30th April for all farms except Farm 1:**

<table>
<thead>
<tr>
<th>Rainfall Range</th>
<th>Closure Period</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-19.9 mm</td>
<td>No restriction</td>
</tr>
<tr>
<td>20-24.9 mm</td>
<td>Closed 3 days</td>
</tr>
<tr>
<td>25-39.9 mm</td>
<td>Closed 4 days</td>
</tr>
<tr>
<td>40-44.9 mm</td>
<td>Closed 6 days</td>
</tr>
<tr>
<td>45-59.9 mm</td>
<td>Closed 7 days</td>
</tr>
<tr>
<td>60-79.9 mm</td>
<td>Closed 9 days</td>
</tr>
<tr>
<td>80-99.9 mm</td>
<td>Closed 10 days</td>
</tr>
<tr>
<td>100 + mm</td>
<td>Closed until opened by Food Authority</td>
</tr>
</tbody>
</table>
Criteria for 1st May – 31st October for Farm 1

<table>
<thead>
<tr>
<th>Rainfall Range</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-14.9 mm</td>
<td>No restriction</td>
</tr>
<tr>
<td>15-19.9 mm</td>
<td>Closed 4 days</td>
</tr>
<tr>
<td>20-29.9 mm</td>
<td>Closed 5 days</td>
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<tr>
<td>30-44.9 mm</td>
<td>Closed 6 days</td>
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<tr>
<td>45-59.9 mm</td>
<td>Closed 7 days</td>
</tr>
<tr>
<td>60-79.9 mm</td>
<td>Closed 9 days</td>
</tr>
<tr>
<td>80-99.9 mm</td>
<td>Closed 10 days</td>
</tr>
<tr>
<td>100+ mm</td>
<td>Closed until opened by Food Authority</td>
</tr>
</tbody>
</table>

Also closed when large vessels without holding tanks are within the [channel from port to outer harbour mouth], or at [wharf at port], until the area has been re-opened by Food Authority.

Criteria during 1st November – 30th November and 1st April to 30th April for Farm 1:

<table>
<thead>
<tr>
<th>Rainfall Range</th>
<th>Duration</th>
</tr>
</thead>
<tbody>
<tr>
<td>0-19.9 mm</td>
<td>No restriction</td>
</tr>
<tr>
<td>20-24.9 mm</td>
<td>Closed 3 days</td>
</tr>
<tr>
<td>25-39.9 mm</td>
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</tr>
<tr>
<td>60-79.9 mm</td>
<td>Closed 9 days</td>
</tr>
<tr>
<td>80-99.9 mm</td>
<td>Closed 10 days</td>
</tr>
<tr>
<td>100+ mm</td>
<td>Closed until opened by Food Authority</td>
</tr>
</tbody>
</table>

Also closed when large vessels without holding tanks are within the [channel from port to outer harbour mouth], or at [wharf at port], until the area has been re-opened by Food Authority.

Closed for harvesting from 1st December to 31st March.

Dates prohibited due to increasing tide above 2.7 metres at [M Point] will be notified.

Salinity Criteria for [For middle-inlet Growing Area 3 farms]:

1. The area will close immediately whenever the mean salinity index value of minus 14 is reached;
2. The area will reopen after 24 hours if the mean salinity value exceeds 23 ppt throughout the closure event;

OR:
2 (a) If during closure event the mean 24 hour salinity value falls below 23 ppt, but always exceeds 16 ppt, then the area will reopen 3 tidal cycles after the 24 hr equals 23 ppt;

OR:
2 (b) If during the closure event the mean 24 hour salinity level falls below 16 ppt then the area will reopen 6 tidal cycles after the mean 24 hour salinity equals 23 ppt.

The tidal criteria for lower Growing Area 3 farms were introduced in June 2000, and the salinity criteria for middle Growing Area 3 farms were introduced in November 2000.

6.5.2 Epidemiology

District Health Board A was alerted to a NoV outbreak potentially linked to oysters from Growing Area 3 when cases of acute gastroenteritis were notified by diners at three restaurants in City A in August 2001. These events were subject to a full epidemiological investigation. Further reports of
illness were received from other venues but for various reasons these were not investigated as rigorously. Details of the epidemiological investigations are provided below.

Restaurant 1:
The illness event was initially reported on 18/8/2001 when 7 out of a group of 12 people who ate in the restaurant became ill with gastroenteritis. Thirty-nine diners from the 18th August were questioned. 26% satisfied the case definition for NoV. Fresh, raw Pacific oysters were determined to be the probable source of illness with an attack rate of 54% and relative risk (RR) of 12.92 (95% CI 1.78-93.94, p=0.0011). Five out of ten faecal samples were positive for NoV. No leftover oysters were available for testing.

Restaurant 2:
Illness was reported when 8 out of 11 members of a group who ate at Restaurant 2 on 19/8/2001 became ill. The illness incubation times and symptoms of 6 of the 8 patrons were consistent with the case definition for NoV. The attack rate for those who had eaten Pacific oysters was 65%, RR = 20.0 (95%CI 2.70-148.14, p=0.0005). No faecal samples were analysed, and no leftover oysters were available for testing.

Restaurant 3:
Illness was reported by a group of 9 who had eaten at Restaurant 3. Seven had become ill. The symptoms of 5 diners were consistent with the case definition for NoV. The attack rate for those who had eaten oysters was 71%, with RR = 1.43 (95% CI 0.33-6.17, p = 1.0). This relative risk was not statistically significant, but the analysis was based on a very small sample and only one person did not eat oysters. One out of two faecal samples analysed was positive for NoV. No leftover oysters were available for testing.

Oysters from these three outbreaks were traced back through 2 distributors and 1 processor (Processor 1) to 3 batches of oysters. Two batches were harvested on 13/8/2001 from different farms in Growing Area 3 (Batches A and B), and one batch (Batch C) was harvested from a farm in another growing area (Growing Area B) on 14/8/2001. Due to mixing of the batches at the restaurant level, it was not possible to determine which batch or batches were responsible for the virus outbreaks. Oysters from the implicated batches at Processor 1 were distributed to 31 other restaurants. Unconfirmed illness was reported in 5 staff members of one restaurant who had apparently consumed oysters, and two unconfirmed cases were reported from one other restaurant. One of these cases did not meet the case definition for NoV illness and the other was not investigated. Oysters from two of the three implicated batches from Processor 1 (Batch A from Growing Area 3 and Batch C from Growing Area B) were obtained from unsold stock held by distributors and tested for NoV. Neither sample tested positive for NoV.

On 24/9/2001, oysters were sampled from the three farms from which Batches A, B and C had been harvested. The results of testing of these samples were negative for NoV. Samples of feral oysters collected on 28/8/2001 from the wharf at the Port, and from the Marina also contained no detectable NoV.

Other potentially related outbreaks:
Later in the course of the investigation a number of other potentially related outbreaks were reported: these included another restaurant outbreak in the city (Restaurant 4), one case from each of two restaurants (Restaurants 5 & 6) in the region of Growing Area 3, several rumoured cases from two functions in a region close to Growing Area 3, and an outbreak in United States relating to exported oysters.
Restaurant 4:
Due to the restaurant proprietor’s lack of cooperation, very little information was gathered about this event. The restaurant received a number of complaints of suspected food poisoning during August 2001 from patrons and staff members. The reported symptoms appeared to be consistent with gastroenteritis caused by NoV, and the only two cases able to be contacted had incubation periods and symptoms consistent with NoV infection. The proprietor believed that the only food they had eaten in common was raw oysters. All oysters were supplied by one processor (Processor 2) although the implicated oysters could have come from any one of six different batches. Three of these batches were harvested from Growing Area 3, one from Growing Area B, and two from another growing area (Growing Area C). No faecal samples were analysed. One sample of leftover oysters was tested for NoV, and no NoV was detected. These oysters were from the same farm (and harvest date) as one of the batches (Batch B) implicated in the outbreak associated with Processor 1 (see above).

Restaurant 5:
A doctor notified the Food Authority that one person had become ill after consuming oysters from a farm (Farm D) in Growing Area 3. A faecal specimen was negative for bacterial pathogens, but was not tested for NoV.

Restaurant 6:
A tourist reported illness to the Food Authority after consuming oysters at Restaurant 6. No details of illness or incubation period were provided. No faecal samples were provided for testing. The oysters consumed were harvested from Farm D in Growing Area 3 on 8/8/2001. A sample of oysters from the same batch was tested for NoV, and the result was positive for NoV. Of all the samples of oysters tested in association with the August 2001 NoV outbreaks, this was the only sample in which NoV was detected.

Two rumoured outbreaks:
The rumoured outbreaks from the two functions in the region of Growing Area 3 were reported by the oyster farmers, who were unable to supply details of the events or the cases. These rumoured outbreaks were apparently associated with oysters harvested from Growing Area B, not Growing Area 3.

US outbreaks:
The US Center for Disease Control and Prevention was notified of an outbreak of diarrhoeal illness associated with raw oysters in Hawaii and San Francisco. Illness onset was between August 5th and September 2nd, and occurred in several groups eating at different establishments on different dates. In all of the groups, only those who ate raw oysters became ill. The cases from San Francisco (4 persons) were all associated with the same restaurant, and the restaurant was unable to identify whether the oysters were from a batch from Growing Area 3 (harvest date 13/8/2001) or from Growing Area B (harvest date 16/8/2001). Faecal samples taken from patients were positive for NoV. (If leftover oysters were tested for NoV, the results were not reported in the Food Authority epidemiological reports). The oysters consumed in the premises in Hawaii were all from a different growing area (Growing Area C), and these cases were subsequently discounted as a NoV outbreak.
<table>
<thead>
<tr>
<th>Case Name</th>
<th>Symptoms Meet Case Definition for Norovirus</th>
<th>Results of Clinical Samples</th>
<th>Food History/Attack Rates</th>
<th>Results of Leftover Oyster Samples</th>
<th>Results of investigative sampling from farm 10 days after harvest of implicated oysters</th>
</tr>
</thead>
<tbody>
<tr>
<td>Restaurant 1</td>
<td>Yes – 10 people</td>
<td>5/10 positive for NoV</td>
<td>Attack rate 54%, RR=12.92 Statistically significant correlation with oyster consumption (p=0.001)</td>
<td>Negative for NoV in the one batch from GA3 tested. (No leftovers from other batch, but sample of oysters from same farm harvested on same date negative for NoV)</td>
<td></td>
</tr>
<tr>
<td>Restaurant 2</td>
<td>Yes – 6 people</td>
<td>-</td>
<td>Attack rate 65% RR= 20.0 Statistically significant correlation with oyster consumption (p=0.0005)</td>
<td>-</td>
<td>Negative for NoV</td>
</tr>
<tr>
<td>Restaurant 3</td>
<td>Yes – 5 people</td>
<td>1/2 positive for NoV</td>
<td>Attack rate 71% RR=1.43 No statistically significant correlation with oyster consumption (p=1.0)</td>
<td>-</td>
<td>Negative for NoV</td>
</tr>
<tr>
<td>Restaurant 4</td>
<td>Yes – 2 people</td>
<td>-</td>
<td>-</td>
<td>Negative for NoV in sample of the one batch from GA3 tested (same farm and harvest date as untested batch from Restaurant 1)</td>
<td>Samples from farms tested were negative for NoV</td>
</tr>
</tbody>
</table>
Table 6.2: Summary of the epidemiological data from the norovirus outbreak in 2001.

The internationally accepted criteria for linking illness to shellfish consumption have been described previously in Box 3.1 in Section 3.2.2 of this report. Based strictly on these criteria and the reported information, there are 5 cases from the Restaurant 1 event that meet the case definition for NoV, and for which NoV is statistically linked to the consumption of oysters. The case definition for NoV is also met for one case from Restaurant 3, but in that event there was no statistically significant link to the consumption of oysters. For all the other cases, insufficient information was collected for NoV illness to be confirmed.

In the instance of one restaurant, an illness outbreak that was not confirmed as NoV presented a statistically significant relationship with the consumption of oysters.

In the one reported illness from another restaurant (Restaurant 6), in which there was insufficient information about the case symptoms and no clinical testing was undertaken, a sample of oysters from the same batch as those consumed tested positive for NoV.

All the confirmed NoV cases were associated with the consumption of oysters processed by one processor, but in no case did leftover oysters (or in one case, oysters harvested from the same farm on the same day, but processed by a different processor) test positive for NoV. Nor did oysters sampled from any of the same farms 10 days after the implicated oysters test positive for NoV. Although it seems clear that the NoV illnesses were associated with the consumption of oysters, the possibility that the NoV contamination could have occurred at the processor level rather than in the growing waters does not appear to have been investigated in detail as part of the epidemiological investigation. However, we note that the norovirus detection methods (using nested PCR) used in oyster samples at the time were less sensitive than those of today and more analytical controls are now used.
### 6.5.3 Growing Area Investigation

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>22nd August 2001</td>
<td>District Health Board received notification of NoV outbreak in diners at a restaurant on 18th August.</td>
</tr>
<tr>
<td>23rd August 2001</td>
<td>Notification of two further outbreaks relating to meals eaten at different restaurants on 19th August.</td>
</tr>
<tr>
<td>24th August 2001</td>
<td>Emergency closure of the two implicated growing areas imposed for 21 days. Food Authority visited both growing areas and took samples of oysters for NoV testing from the implicated farms.</td>
</tr>
<tr>
<td>27th August 2001</td>
<td>Shoreline investigation of both growing areas by Food Authority. No evidence of failure of on-site sewage systems was observed in Growing Area 3. In Growing Area B, on-site systems close to the shoreline near the oyster farms were dye-tested. No evidence of malfunction was observed.</td>
</tr>
<tr>
<td>29th August 2001</td>
<td>Two cases, one from each of two restaurants, were reported in the Growing Area 3 region.</td>
</tr>
<tr>
<td>30th August 2001</td>
<td>Rumours of illness arising from consumption of oysters from Growing Area B at two functions in region of Growing Area 3 were reported.</td>
</tr>
<tr>
<td>10th September 2001</td>
<td>Meeting between Food Authority, Ministry of Health and oyster growers from Growing Areas 3 and B. The meeting agreed to keep Growing Area 3 closed until the sources of contamination had been identified and a Risk Management Plan developed. The oyster farmers and local and regional councils agreed to cooperate in the development of a risk management plan to be undertaken by a consultant.</td>
</tr>
<tr>
<td>13th September 2001</td>
<td>Growing Area B reopened to harvest. Closure of Growing Area 3 to harvest extended for an unspecified time. The implementation of a recall of product from Growing Areas 3 and B for the period 13th – 24th August 2001 was begun.</td>
</tr>
<tr>
<td>4th October 2001</td>
<td>Instruction from Food Authority to packhouses that all detained product (harvested 13th–24th August 2001) from the upper Growing Area 3 could be released. All other detained product from these harvest dates from Growing Area 3 and Growing Area B must either be destroyed, or application made to further process the detained product in such a way that NoV would be inactivated.</td>
</tr>
<tr>
<td>8th October 2001</td>
<td>Reclassification of middle and lower Growing Area 3 to “Restricted” by Food Authority. Upper growing area retained classification of “Conditionally Approved” and reopened to harvest. Relay conditions specific to the “Restricted” section of Growing Area 3 were set: these included a requirement for a relay period of at least 60 days at a location a minimum of 300 metres distant from oysters that are harvested directly for sale. The latter condition severely restricted farm areas available for relay, and resulted in most farmers from Growing Area 3 being unable to relay their oysters.</td>
</tr>
<tr>
<td>November 2001</td>
<td>Risk analysis report completed by consultant.</td>
</tr>
</tbody>
</table>
25th March 2002 – A review of the classification of middle and lower Growing Area 3 following the Risk Analysis report determined that the area should remain classified as “Restricted”. The upper section of Growing Area 3 retained a “Conditionally Approved” classification and was reopened for harvest.

August 2005 – An outbreak of *Shigellosis* linked to the consumption of feral oysters taken from the marina at the port at the mouth of Estuary X. This outbreak produced evidence of continued faecal contamination at the port, with an inference that Growing Area 3 could also be impacted.

December 2005 – A full 12-year sanitary survey was completed. This report identified a number of issues that still required attention in Growing Area 3 including (quoted from report):

- The source for the shigellosis outbreak needs to be determined;
- Sampling data and plume dispersion information collected to show that the growing area is subject to viral loading ≤ 0.04 particles per litre at the growing water boundary;
- Sampling data collected to show that on-site disposal systems are not responsible for introducing viruses to the marine environment;
- The issue of possible discharges from boats particularly those berthed in the quarantine area and permanent live-aboards anchored on swing moorings still requires attention;
- A management plan and testing programme for the [town Z] WWTP is prepared and becomes operative that meets the expectations of [the Food Authority];
- Once all matters relating to pollution from the WWTP, on-site disposal systems and boats have been satisfactorily attended to an agreement on how the [councils] will annually report on the performance of the pollution sources will need to be reached;
- The various responsible authorities will need to formulate a plan for on-going potential hazard identification and develop appropriate response mechanisms;
- The origins of the elevated levels of *E. coli* in the wetland at the [Town Z] WWTP need to be investigated.

2008 – Meetings between Food Authority, oyster farmers, local and regional councils, and fisheries authority to develop a plan to facilitate the reopening of middle and lower sections of Growing Area 3 for direct harvest. Salinity, rainfall and microbiological monitoring were resumed to collect required data for classification review.

Change in relay conditions for Growing Area 3 to match conditions in all other growing areas.

April 2009 – A review of the hydrodynamics of Estuary X and their impact on water quality in Growing Area 3 was completed.

A report detailing the reclassification survey of middle and lower sections of Growing Area 3 was completed. This report recommended the reclassification of all except Farm 1 in the lower growing area to ‘Conditionally Approved”. Farm 1 remains classified as “Restricted”.

The box above shows the timeline of investigation and events associated with the NoV event in 2001 in which GA 3 oysters were implicated.

Following the reported illness outbreak and the emergency closure of the growing area, a meeting was held on 10th September 2001 to discuss the way forward. This meeting was attended by oyster farmers from the growing area, representatives from the Food Authority, Ministry of Health, local and regional councils, scientists from the virus testing laboratory and from University, and consultants invited by the farmers. After outlining the situation, the Food Authority informed the
meeting that the potential sources of contamination in the growing area would need to be predictable and manageable for the area to retain a “Conditionally Approved” classification, and that the role of the Food Authority did not extend to identifying and managing the remediation of potential sources. For this reason, the oyster farmers, and local and regional councils agreed to work together and to fund a consultant to undertake a risk analysis of viral contamination in the growing area, with a view to developing an acceptable risk management plan.

A review of the potential sources of viral contamination was undertaken by the consultant in conjunction with the local and regional councils. This involved a review by the consultant of relevant documents held by the Councils (e.g. incident logs, environmental hotline logs, monitoring reports, pump logs, maintenance reports, consultants/engineering reports, correspondence relating to water quality), followed by some shoreline survey work and discussion with boat operators, business owners and residents in the catchment of the growing area. Analysis of the number of oysters harvested from the upper, middle and lower sections of the growing area in August 2001 in relation to the oysters associated with the reported illnesses suggested that there was a decreasing gradient of risk from the lower to upper growing area. Analysis of environmental and oyster sample data indicated that generally the NoV contamination in oysters was associated with sewage spill events or when salinity levels were low/river levels high following heavy rainfall.

A range of potential sources of viral contamination were identified in the consultant’s risk analysis report, including: on-site sewage systems at properties within the immediate catchment of the growing area; on-site sewage systems at a subdivision at the point at the mouth of the Channel; the sewage reticulation system at the Port; on-site sewage systems at properties at the Port not serviced by the reticulation system; an on-site sewage system at a small industrial estate in River Z estuary; the sewage reticulation system and WWTP at the town A upstream on River Z; on-site sewage systems at town B upstream of town A on River Z (including a sewage treatment system at a meat processing plant); and effluent discharged from boats at the Port, Marina, customs quarantine area and moorings at the confluence of Estuary X and Estuary Z. Each of these potential sources was investigated in more detail by the Councils, and any issues that were identified were remediated or managed as follows:

**On-Site Sewage Systems:**

- **On-site sewage systems in the immediate growing area catchment:** The shoreline of the immediate catchment of the growing area is sparsely populated and dwellings have on-site sewage systems. All systems were inspected by the Environmental Health Officer in March 2002, including systems on properties only accessible by boat. Of the 71 systems inspected, 24 were found to require further investigation or monitoring. No obvious effluent discharge into the sea was noted. Further inspections were undertaken of the 24 properties, and a few observed malfunction or deficiencies were detected and subsequently rectified (e.g. fitting outlet filters). All septic tanks that had not been pumped out within the previous two years were pumped out. The properties were re-inspected by the Environmental Health Officer in 2005 and no defects were detected.

- **On-site sewage systems at the Point:** A subdivision of 136 properties, of which 100 had dwellings built on them, lies on the Point to the east of the channel leading to the mouth of the estuary. In 2001 the vast majority of properties used septic tanks discharging to either deep soakage trenches or soak holes/deep bores. The deep bores generally comprised of holes of about 0.6 m diameter drilled into the clay soils and often into the underlying fractured rock. The fractured rock lies about 2 m below the surface, and boreholes and
trenches were typically 3-4 m deep. An inspection by the Environmental Health Officer in September 2001 showed that 28% of the on-site sewage systems were faulty, and another 7% possibly faulty. A further inspection by wastewater engineering consultants in December 2001 also resulted in the observation of system failure, including multiple instances of effluent flows down the road gutter and into stormwater drains or catchpits. Some of the disposal trenches were located under driveways where they were covered by concrete and/or subject to vehicular traffic. Others were not suitably protected from stormwater entry. The engineers report identified the soil type as Soil Category 5 or 6 (poorly drained or very poorly drained), and not generally considered to be suitable for on-site wastewater disposal using traditional soakage trenches or beds. The slope on many of the properties is steep. The property sizes are small, typically between 800 m$^2$ and 1,200 m$^2$ in size. It was noted that this is substantially lower than the minimum residential lot size of 3,000 m$^2$ required in the local council planning policy for areas zoned for coastal residential development if on-site sewage systems are used, but was compliant with the minimum lot size required for on-site treatment and disposal systems prescribed by the regional council in the Revised Proposed Regional Water and Soil Plan, which did not take into consideration difficult soil conditions. The engineers’ report concluded that it was highly likely that some contamination of the estuary resulted from the failure of on-site systems at the Point. Various options for solving the problem were proposed, with the recommended option being the reticulation of the subdivision to transfer the sewage to the local WWTP for treatment and disposal. Cost was identified as a barrier to implementation of the suggested solutions. In the interim, at a meeting in March 2002, the local council proposed increased monitoring (including monitoring of *E. coli* levels in stormwater on the Point) and inspection of existing systems to reduce the risk of discharge to the sea. Any property which was identified as requiring repair to its soakage field or bores had a 6m test bore undertaken to assess the soil and percolation rates prior to redesign by an engineer. Percolation rates did not support the suggestion that effluent short circuits to the sea through fractured rock. Test results from regularly monitored bores indicated little contamination of groundwater. Consequently in 2003 the Council engaged another engineer to design site-specific solutions on a case-by-case basis. Each property was visited, and where possible, consultation took place with individual property owners. Monitoring officers recorded the type of effluent disposal system on each site, its location and maintenance background to date. The engineer identified several specific problems as follows: a number of septic tanks that had not been cleaned for many years; very few septic tanks had filters on exits to keep solids in the tanks; some properties had problems with stormwater runoff from public roads entering soakage fields and septic tanks; and flooding of soakage areas from some private water storage tank overflows and greywater discharges. In addition, many property owners were unsure of septic tank maintenance issues. Following this, work was undertaken to control stormwater runoff from public roads. The local Residents’ Association organised the pump out of septic tanks, and arranged for the bulk purchase of outlet filters, which were fitted to all 80 septic tanks that required them. All other work required to bring each system up to standard (e.g. diversion of stormwater and/or tank overflow, repairs to covers, new boreholes to an agreed design) was completed. The Council stated that this work resulted in a decrease in *E. coli* levels in subsequent stormwater samples from the Point. A long-term Maintenance Management Plan was established pending the establishment of a District-wide plan supported by by-law, and plans for regular monitoring of stormwater for faecal coliforms were established. A hydrodynamic study of the growing area undertaken in 2009 prior to reclassification of GA 3 indicated that the failure of an individual on-site sewage system at the Point would not result in NoV contamination of oysters in the growing area.
• **On-site sewage systems at the Port:** Some dwellings at the Port and associated bay eastwards are not serviced by the reticulated sewerage system and have on-site sewage systems. All these properties were inspected, and a few systems were identified as requiring upgrade or replacement. This had all been completed by 2005. A hydrodynamic study of the growing area undertaken in 2009 indicated that the risk of any contamination from these on-site sewage systems being transported into the estuary containing the growing area is very low.

• **Sewage system at industrial estate:** The environmental hotline log indicated that the flooding of the sewage system at the industrial estate close to the mouth of a river leading into Estuary Z had been the subject of several complaints from tenants at the site, and this risk was confirmed based on observation during a site visit by consultants during the preparation of the risk analysis report. Subsequent visits by Council officers and the Environmental Health Officer failed to detect any malfunction.

• **Sewage systems at Town B:** Town B is a small town that lies on the bank of a small stream that enters River Z. There is no reticulated sewerage at Town B, and residents are reliant on on-site sewage systems. Investigation revealed that soakage is poor in some areas of Town B, but these areas lie well away from the stream and are unlikely to impact on the water quality in the stream. A meat works on the outskirts of the town also has an on-site sewage treatment system for processing human waste. This consists of an extended aeration plant that discharges to rapid filtration beds to ground. The effluent disposal field is >100 m away from the stream, and even in heavy rainfall is unlikely to result in the discharge of contaminants into the waterway. All on-site systems in Town B were inspected by Council officers following the NoV outbreak – one malfunctioning septic tank was identified and rectified. The results of these investigations, plus the significant distance of the systems from the growing area (up to 16 km) indicated that on-site sewage systems from Town B would not be a significant source of NoV contamination in the growing area.

The investigation following the NoV outbreak prompted the local Council to improve its management of on-site sewage systems. A new by-law was introduced requiring the inspection and pump-out of on-site sewage systems at a minimum frequency of every 3 years, and the local Council set up a database of all on-site systems to support the recording and monitoring of this. Properties close to waterways or the coast in the catchment of shellfish growing areas were included on building hazard maps, therefore requiring the design of on-site sewage systems by a qualified Engineer as part of the Building Consent process. An emergency plan was established to ensure that elevated monitoring results, major system failures and flooding or inundation of on-site systems observed by the Council is reported immediately to the Food Authority.

A Council report from 2005 showed that 5 new homes had been constructed on properties on the Point in the preceding year, all with secondary treatment systems. A high faecal coliform level observed in one of the water samples taken from the Point was investigated and was found to be linked to the use of paunch as fertiliser by a resident.
Sewage Reticulation Systems:

- **Sewage reticulation system at the Port:** Originally a package treatment plant operated at the Port and collected sewage from the Port facilities, the Port public toilets, the boat club at the port, and some houses along the margin of the channel. This plant has since been replaced by a pump station that collects the reticulated section of the port sewage and pumps it to an WWTP outside the growing area catchment. The environmental hotline log reviewed by the consultant in the growing area investigation showed a history of failure of the sewage pump station close to the wharf at the Port, which resulted in spillage of effluent into the sea. Inspection of the reticulation system by Council officers also found minor leaks in sewer pipes in the wharf area, which were subsequently fixed. An associated pump station further from the Port also had reported problems. One pump station was subsequently completely upgraded, and a back-up pump and telemetric alarm system was installed at the other.

- **Town A sewerage reticulation system:** Prior to the NoV outbreak the sewerage reticulation system at Town A was subject to significant infiltration of stormwater related to heavy rainfall. Among other things, this was manifested in the surcharging of manholes in the town, and the discharge of raw sewage mixed with stormwater into the street. One particular manhole lies at a low point in the town, from where discharged effluent flowed directly into a stream that feeds into River Z. In 1997 a comprehensive survey of the system had been undertaken for the local Council by consulting engineers. This survey identified a range of issues that needed to be addressed to remedy the problems, including the need to repair/replace the majority of manholes in the system, and pipelines with fault/leaking joints (approximately 130 faults to be repaired). Despite these repairs having been completed by the time of the investigation after the NoV outbreak, local business owners still reported that the manhole was surcharging in heavy rainfall, and analysis of pump logs undertaken as part of the risk analysis showed significant stormwater infiltration of the sewer following rainfall. A review of Council documents showed an engineer’s report to the Council in 1999 had identified a high degree of infiltration entering the system via laterals in the township, and this had not been rectified. In addition, correspondence between the Council’s consultant engineers indicated that the low gradient on the pipeline from the town to the wastewater treatment plant was also a contributing factor. Following the risk analysis report, the Council undertook a comprehensive investigation of the sewerage system in the town, and identified a significant number of properties at which stormwater drains were directed into the sewerage system. These faults were rectified, and subsequent monitoring records from pump station logs indicated that sewage flows were not significantly impacted by rainfall. This resolved the problem of surcharging from manholes in town and the resultant contamination of the stream.

Wastewater treatment plant:

- **Town A WWTP:** The Town A WWTP was constructed in 1969 and lies adjacent to River Z. Hydrodynamic studies show that water from Estuary Z travels up to the growing area under some tidal/environmental conditions. At the time of the NoV outbreak in 2001, the WWTP consisted of a two-pond system that discharged treated effluent into River Z. An engineers report in 1998 described the system as follows: *Flows from the reticulation system enter a facultative pond (Pond 1) via an inlet pumping main. Treated effluent from Pond 1 flows through to the maturation pond (Pond 2), before discharging into the [River Z].* Following
the renewal of the consent in 1988, the level of Pond 2 was lowered and wetland plants were planted to create a wetland area for further treatment of the effluent before it discharges to the [River Z]. Replanting of the pond has occurred where plants have not taken, however the depth of Pond 2 has restricted plant establishment to the edges of the pond. The risk analysis report completed after the NoV outbreak identified that despite the compliance of effluent with faecal coliform levels specified in the Resource Consent conditions, the low level of treatment provided would result in significant numbers of viruses in the effluent discharged to the river. This was further exacerbated by the high level of stormwater infiltration, which was calculated to reduce the residence time of effluent in the ponds from 89 days during dry conditions to 11 days during rainfall.

A significant upgrade of the WWTP was completed at the end of 2006. Tertiary treatment is now provided, consisting of: screening; treatment in a Bio-Reactor (aeration followed by secondary clarification); filtration via a disc filter, and UV disinfection. Under normal operating conditions the UV dose is 200-250mWs/cm². This plant has been designed to provide a 4-log reduction in virus levels.

Further upgrades were carried out in 2008 to provide additional sensors and associated valves. Risk prevention strategies are now incorporated into all stages of the treatment process, including:
- Fully automatic monitoring of the processes to a centralised system;
- Provision of 16 hours storage of dry weather flow;
- Provision of 19,000 cubic metres of wet weather storage sufficient for a 1 in 50 year flood;
- Stand-by pumps for all critical processes;
- Sensors and diversion mechanisms should UV disinfection fail or be below the required dose to achieve the required outcomes for discharge;
- Ability to divert inadequately treated sewage to holding ponds for subsequent re-treatment and prevent discharge of effluent to wetlands in these situations.

**Discharges from Boats**

The issues associated with the discharge of effluent from boats in the region of this growing area have been discussed previously in Section 6.4.4. An in-depth investigation of the risk presented by boats was undertaken by the local and regional Councils following the NoV outbreak in 2001. Newly highlighted issues included:

- **Zones where discharge from boats was allowed:** On 1st July 2000 Marine Pollution Regulations were introduced forbidding the discharge of untreated sewage from boats within 500 m of marine farms and in waters less than 5 m deep. A distance of 500 m is insufficient to prevent NoV illness arising from contaminated oysters if faeces from a carrier of NoV are discharged from a boat in an inter-tidal oyster farming area (see footnote in Section 2.7.5). The application of the Marine Pollution Regulations left areas where untreated effluent discharges were permitted (i.e. areas that were greater than 500 m from a marine farm and greater than 5 m deep). One such area lay in the channel in the lower section of the growing area, and other in the main channel linking the estuary to the outer harbour. Oyster farmers were concerned that commercial boat operators were taking advantage of these areas where discharge was allowed. Subsequent to the NoV event and following public consultation, the
Council amended their Coastal Plan to remove these areas where untreated boat effluent discharge was permitted.

- **Discharges from boats in the Quarantine area:** Crew on boats arriving from overseas are not allowed to leave the boat until having been cleared by Customs. This may not happen for up to 18 hours, during which time effluent might be discharged if the boat had no holding tank. This problem has subsequently been overcome by designating a special Quarantine berth area at the marina, with associated toilet facilities.

- **Public education and enforcement of “No discharge” zone:** The investigation identified communication and enforcement of “No discharge” zones as a potentially significant issue in preventing contamination of the growing area. The local council, which owns the marina, has ensured that the operators of the marina communicate the “No discharge” rule to every boat entering the marina, and crew using the marina are required to sign a declaration that they will not discharge effluent. Seals are put onto the heads of each boat without holding tanks. The implementation of these measures is audited by the Regional Council twice each year. The Council also introduced a “BayWatch” programme over the peak boating season, which ensures that each boat anchoring in the area is visited and provided with information about the “No discharge” zone. Boats without holding tanks with skippers that refuse to give verbal agreement to abide by the no discharge rule are asked to leave the area.

- **Availability of toilet and pump-out facilities:** The lack of ready availability of toilet and pump-out facilities was identified as an issue in failing to adequately manage the risk of discharge of effluent from boats. Consequently, additional portable toilets are now provided during peak boating seasons, and two pump-out facilities are now available – one at the Port and the other at the Marina.

6.6. **Case Analysis**

Although the epidemiological evidence from this NoV illness event met the definition of a NoV outbreak and there was a statistically significant relationship between the occurrence of illness and consumption of oysters at two restaurants supplied by the same processor, the analytical evidence from oyster testing suggesting the contamination of oysters in the growing area was slight – of 9 oyster samples from leftover oysters or oysters from the same batches or growing area, only one produced a low level positive NoV result. This sample was taken from a farm with which no confirmed cases of NoV were associated, five days before the harvest of oysters implicated in confirmed cases. The subsequent decision by the Food Authority to reclassify the middle and lower sections of the growing area as “Restricted” (plus the imposition of very strict relay conditions) was made in consideration of not just this outbreak, but also the two earlier NoV outbreaks associated with the growing area (1994, 1999), plus evidence from two oyster samples taken in 2000 (January & October) in which low levels of NoV were detected.

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15 We note that the sensitivity of the test method for NoV at the time was lower than the real-time RT-PCR method subsequently introduced in 2006. The reliability of the test method has also increased significantly in recent years with the use of quantified standards and certified reference materials, the incorporation of controls in the test method, and the use of laboratory ring trials to confirm performance.
The in-depth investigation of potential sources of NoV contamination in the growing area catchment that was instigated by the oyster farmers and local and regional Councils brought to light information that might have impacted on the assessment of risk of virus contamination of the growing area had it been known earlier. This highlights the importance of informed synthesis of in-depth and detailed information from Councils in the completion of sanitary surveys and annual review reports. The investigation also provided previously unobserved links between evidence of NoV contamination of oysters and sewage spillages (for example, with respect to the 1994 NoV outbreak, and the detection of NoV in an oyster sample taken on 17/1/2000). At least one of these spillages (1999) had not been reported to the Food Authority, and in the other instance, if the Food Authority had been aware of the spillage, no link had been made with the observed NoV reported in the oyster sample. Provided that there is an effective communication of spillages from the Councils to the Food Authority, neither of these events would have resulted in unpredictable NoV illness.

All the oysters assumed to be implicated in the 2001 NoV outbreak had been harvested when the rainfall/salinity harvest criteria were met, and the compliance monitoring data were consistent with the classification of the growing area as “Conditionally Approved”.

The source(s) of NoV contamination associated with this NoV outbreak were not definitively identified. However, the investigation that followed the outbreak identified several potential sources that could be regarded as having presented a high risk of virus contamination in the growing area. The presence of these potential sources arose as a result of a number of issues:

- **On-Site Sewage Systems**: Some on-site sewage systems were inappropriately designed for the environmental conditions. There was no requirement by Council for design of on-site systems in areas close to shellfish growing areas or associated watercourses to be undertaken by a suitably qualified engineer and approved by Council. In one subdivision, the regional Council policies regarding section size did not provide adequate protection against contamination of waterways at sites with difficult soil conditions. Malfunction of on-site sewage systems occurred as a result of lack of maintenance (or in some cases, modification of systems) by home owners/occupiers. There was no system by Council to regularly ensure that on-site systems were adequately maintained.

- **Sewage Reticulation Systems**: Problems associated with sewage reticulation systems arose from both poor design (e.g. absence of back-up pumps, lack of alarms, direction of stormwater from houses into sewage lines) and inadequate maintenance by the Council. Several instances of the occurrence of NoV contamination in earlier times were able to be linked to failure of the Council to notify the Food Authority of a spillage.

- **Wastewater Treatment Plant**: The WWTP was designed to provide only a low level of wastewater treatment and did not provide an adequate reduction in virus numbers to protect shellfish quality in the growing area. The design issues were exacerbated by the problems associated with the sewerage reticulation system, which resulted in reduced effluent treatment time, and on occasion, direct discharge of effluent by overtopping of the bunding on the ponds.

- **Discharges from Boats**: The regulatory requirements regarding the discharge of effluent from boats were inadequate to protect the growing area from viral contamination, and the advantage taken by commercial boat operators of small areas where discharge was allowed presented a risk to the quality of shellfish in the growing area. The absence of pump-out and adequate toilet facilities associated with the marina and quarantine area made it difficult
for boat owners to comply with “No discharge” regulations, and compliance was not enforced in any way. The harvest criteria for the growing area did not prevent harvest at all times of high boat numbers at the Port and Marina e.g. May and November (however, we note that this outbreak did not occur at a time of high boat numbers).

Subsequent to the NoV outbreak, the regional Council amended the Regional Coastal Plan to remove the areas near the growing area where boat effluent discharge was permitted. However, these rules are difficult to monitor and enforce, as the Council must have proof of discharge in order to further a prosecution. It has been suggested that this should be amended to require boat owners planning to stay overnight in a “no discharge” zone to have a vessel with a holding tank or approved portable toilet.

### 6.7 Comment on Cases within Growing Area 3

The increasingly stringent and complex harvest criteria through time in GA3 up to the NoV outbreak in 2001 reflect the struggle to manage deteriorating water quality at the lower part of the growing area. These revisions of the harvest criteria allowed the growing area to remain in compliance with its classification based on the *E. coli* /faecal coliform monitoring, but there was some concern within the Food Authority that the quality of shellfish in the growing area might not be manageable and predictable. The third NoV outbreak arising from oysters harvested from GA 3 was seen as a confirmation of this.

Correspondence indicates that along with the oyster industry, the Food Authorities at local and regional level had actively advocated for improvement of environmental policies and infrastructure (for example, regulation of discharges from boats, improvements to sewerage and wastewater treatment systems) over the years. However, with the exception of the introduction of marine pollution regulations (which at the time of the third NoV outbreak still provided inadequate protection to the shellfish farms in GA 3), little improvement in the management of potential contamination sources by Councils occurred until after the third NoV outbreak, when the economic impact of the reclassification of the growing area prompted a coordinated response. This illustrates the need for environmental policies that prevent the degradation of water quality in shellfish growing areas.

The ensuing investigation of potential sources of viral contamination with the full cooperation of the Councils uncovered multiple issues that were considered to require remediation. Undoubtedly some of these issues were also relevant at the time of the 1999 NoV outbreak, but had not been investigated in depth at the time. Access to information from Councils (and knowing what information to ask for) may be one contributing factor as to why the sanitary survey process had failed to adequately recognise and document the risks of viral contamination that were revealed after the investigation in 2001. It is also noted that the annual review process does not require a detailed sanitary survey to be completed, and in this case the result was an assessment of risk that was not sufficiently reflective of the current situation in the growing area catchment.

The three NoV outbreaks in this growing area also illustrate the reliance of the shellfish programme on the performance of Council in two areas: firstly on their adherence to the agreement to immediately report to the Food Authority any sewage spills that might impact on the growing area, and secondly, on their diligence in maintaining infrastructure and managing potential contamination sources.
SECTION 7  CASE STUDY: GROWING AREA 4

7.1  Description of Growing Area and its Catchment

Growing Area 4 is located within a river estuary (River A) which is divided into two quite narrow channels by an island. The upstream boundary of the growing area lies at the upstream confluence of the two channels, and the downstream boundary extends approximately 300 m beyond the downstream confluence of the channels. The growing area includes all of the southern channel, and oyster farms within the upstream and downstream ends of the northern channel. The total length of the growing area is approximately 9.3 km and the widest point is 201 m. All oyster farms in both channels are located adjacent to the shoreline.

A small town (Town A, population approximately 3,000 in 2008) lies adjacent to the downstream section of the growing area at the confluence of the two channels, and is separated from the ocean by a lagoon bounded on the ocean side by the southern head of the estuary which is comprised of sand dunes. River A shares a common ocean entrance with another sizeable river (River B) and the two rivers join at Town A.

The river system has a combined catchment of 1,119 km$^2$, of which the River A catchment contributes 330 km$^2$. The catchment of the two rivers extends some 60 km to the west and is approximately 30 km wide from north to south. The upper catchment is steep, largely forested and contained partially within National Parks. Agriculture increases in prevalence in the mid- and lower catchment, and the lower sloping floodplain areas are used mainly for farming (predominantly cattle). Only a small percentage of the catchment is urban, and then only in pockets comprised of small towns. Town A is the only urban area adjacent to River A, with the other towns lying in the River B sub-catchment. Part of the land on the island adjacent to the growing area has been subdivided into about 50 residential lots, and the remainder is farmland or lifestyle lots.

Development pressures have increased in recent years, and significant growth of Town A has occurred over the last 15 years. Along with the towns in the sub-catchment of River B, Town A at the mouth of the estuary is a popular holiday destination and the population increases significantly during holiday periods.

Modelling suggests that the tidal excursion for the River A main (south) arm from the ocean on a spring tide is approximately 9 km. Tidal excursion up the north arm of the river is reduced in comparison to the main arm (approximately 7.5 km), and does not travel the full length to the confluence of the branches. Tidal penetration extends approximately 24 km from the ocean entrance.

Town A has a reticulated sewage treatment system. The wastewater treatment plant provides secondary treatment (intermittently decanted extended aeration) followed by UV disinfection. Treated effluent is discharged into the head of the lagoon that opens into River A near the river mouth, downstream of the oyster growing area. It has been observed that a weir across the mouth of the lagoon retards the flow of water on the outgoing tide, causing the tidal movement in the lagoon to lag behind that in the River A. Consequently, on the early incoming tide when water is flowing from the open sea into River A, the water from the lagoon is still ebbing. This results in the transport of water from the lagoon up the River A.
All dwellings not serviced by the reticulated sewerage system, including those on the banks of River A outside the urban area and in a residential area on the island, have on-site sewage systems.

Agricultural run-off (particularly from cattle) potentially impacts on water quality in the growing area.

### 7.2 Management of Shellfish Quality Prior to the Norovirus Event

#### 7.2.1 Management Programme

Oysters have been farmed in Growing Area 4 since 1997. A comprehensive sanitary survey for the purposes of growing area classification was undertaken in 2006. Actual and potential pollution sources identified in the sanitary survey report include urban stormwater, on-site sewage systems, WWTP discharges, occasional system failures of the sewerage reticulation system supporting the Town A WWTP (e.g. sewage pump stations), agricultural runoff and direct contamination from unfenced cattle. Based on this, the area was classified as “Conditionally Restricted”, and oysters harvested from the area were required to be depurated, or relayed in an approved area, prior to sale for consumption.

The following harvest criteria were applied in Growing Area 4 in 2008: the area was closed to harvest on rainfall of 30 mm or more in 24 hours, or 50 mm or more rainfall in 48 hours, or salinity < 18ppt at any growing area sampling site. To reopen after a rainfall event, salinity must be > 18ppt at all sample sites within the growing area, water samples taken from each of 7 water sampling sites must contain faecal coliform levels of < 70 MPN/100ml, and oyster samples collected from each of 3 shellfish sampling sites must contain *E. coli* levels of < 1,000 MPN/100g.

#### 7.2.2 Conditions prior to the harvest of implicated oysters

The oysters implicated in the NoV illness event were harvested on 27<sup>th</sup> June 2008 and completed depuration on 29<sup>th</sup> June 2008. Growing Area 4 had been closed to harvest at 9am on the 3<sup>rd</sup> June 2008 following approximately 70mm of rainfall in the previous 24 hour period. Figure 7.1 shows the daily rainfall recorded at three rainfall stations in the 10 days prior to the closure of the growing area due to rainfall, and for the subsequent 22 days.

Water samples taken from the growing area on 4/6/08 showed high faecal coliform levels (see Table 7.1). A report from the Food Authority notes “The management protocol for an area affected by a sewage spill in this region is a mandatory 21 day closure of the growing area. Given that there had been no sewage spills reported to the [Food Authority] during this time and the catchment is agriculturally influenced, the high results recorded on 04/06/08 were attributed to agricultural runoff”. In spite of this, the area was required by the Food Authority to undertake three additional rounds of sampling with significant ‘rest’ periods in between to confirm that levels of bacteriological indicators in the oysters and growing waters were acceptable before reopening to harvest. The results of these are provided in Table 7.1. The bacteriological results allowed the area to reopen on 26<sup>th</sup> June, 22 days after the closure to harvest was instigated.
Figure 7.1: Daily rainfall for the month prior to the harvest of oysters implicated in norovirus illness event. Rainfall Station 1 is located close to the growing area, and Stations 2 and 3 are further inland in the same catchment. Daily rainfall is reported at 9am each day.

![Daily Rainfall for Previous Month](chart.png)

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</tbody>
</table>

Table 7.1: Results of bacteriological sampling prior to re-opening Growing Area 4 after a significant rainfall event on 3/6/08. Blue shading = Meets criteria for oyster harvest and depuration; Orange shading = Value exceeds criteria for oyster harvest and depuration. Water faecal coliform limit = 70 MPN/100ml; Shellfish E. coli limit = 1,000 MPN/100g.

### 7.3 Epidemiology of Norovirus Event

In July 2008 two illness events were linked to oysters provided by the same oyster supplier (a vertically integrated business comprised of oyster farming operations and a processing facility). The
implicated oysters were all from the same batch harvested from the Growing Area 4 on the 27\textsuperscript{th} June 2008.

The complaints were received on the 9\textsuperscript{th} and 18\textsuperscript{th} of July from groups that had dined in towns in the River A region. These incidents were referred to the local public health unit for further investigation on the 10\textsuperscript{th} July and 18\textsuperscript{th} July 2008 respectively.

**Illness Event 1:**

The first incident occurred on 6\textsuperscript{th} July in Town A. A group of 12 people attended a function and ate oysters. Four became ill with vomiting and diarrhoea approximately 26-29 hours after the meal. It was unclear at that time whether the incident was linked to food or person-to-person viral gastroenteritis.

The clinical symptoms reported were consistent with NoV infection, but no clinical samples were collected for analysis and no leftover oysters were available for sampling.

**Illness Event 2:**

The second incident occurred in Town B. A group of 27 people attended a function on 13\textsuperscript{th} July, and 10 became ill with nausea, vomiting and diarrhoea approximately 36 hours after the meal. The clinical symptoms reported were consistent with NoV infection. The local area health service conducted interviews of 23 people in the group. All people who were ill had consumed oysters. Analysis of the data on illness and foods consumed was undertaken using Fisher’s Exact Test, which determined that the foods that were associated with a significant likelihood of causing the symptoms were oysters (highly probable, p = 0.007) and ice cream, which was identified as a significant but much less likely possibility (p = 0.03).\textsuperscript{16}

No clinical samples were collected for analysis and no leftover oysters were available for sampling.

**7.4 Initial Investigation and Action by Food Authority**

Personnel from the Food Authority undertook investigations at the implicated restaurants, and at the oyster processor and farm on the 23\textsuperscript{rd} and 24\textsuperscript{th} of July.

Investigations at the restaurant level found no evidence of staff illness or other risk factors normally associated with NoV.

Investigations at the processor level revealed that one staff member had been ill at the time that the implicated batch was processed, but this staff member did not process the implicated batch. Contamination at the processing level could not be ruled out as a possible cause of the outbreak. However, because of the elapsed time period between the illnesses and the investigation this possibility could not be confirmed.

\textsuperscript{16} Relationships with p<0.05 are regarded as significant.
The oyster farmer was interviewed, and harvest and dispatch records were examined in detail. The investigation found that the batch of oysters had been harvested in accordance with the established food safety protocols. The growing area was open at the time of harvest, with recent faecal indicator monitoring within established guidelines for the harvest and depuration of oysters.

The depuration plant where the oysters had been purified was also inspected, along with associated records. The oyster farmer had undertaken a post-depuration end product test on an oyster sample from the implicated batch. This returned an *E. coli* result of < 50 MPN/100g.

Growing Area 4 was closed to harvest on 23rd July 2008 pending the results of further investigation. As a precautionary measure oyster farmers in Growing Area 4 were directed to withdraw any product harvested prior to the closure from sale until the outcome of the environmental investigation was known.

### 7.5 Results of sampling from implicated growing area during the investigation:

The investigation into the potential sources of human contamination in the growing area took some time, and a series of oyster samples were tested for NoV through this period.

**Samples of oysters harvested 8th July 2008:**

On 24th July 2008, a sample of oysters that had been harvested from Growing Area 4 on the 8th July (11 days after the implicated batch) was collected from the producer’s cool room and tested for NoV. No NoV was detected in the sample.

**Oysters sampled 24th July 2008:**

Oysters were sampled from three sites in Growing Area 4 on 24th July 2008 and tested for NoV. The samples from all three sites were negative for NoV genogroup I. However, NoV genogroup II was found in oyster samples from two out of three sites. Faecal coliform levels in concurrent water samples from seven sites within the growing area were all within the regulatory limit, as were *E. coli* levels in concurrent oyster samples. No *Salmonella* was detected in concurrent oyster samples.

**Oysters sampled 14th August 2008:**

Following the receipt of two positive NoV results in the previous sample round, further sampling for NoV was undertaken in the vicinity of Growing Area 4 on the 14th August to determine the extent of the viral contamination in the growing area. Seven oyster samples were collected: six from oyster farms, and one sample of feral oysters. The locations of the sampling sites were distributed throughout the whole growing area.

All six samples from the oyster farms had positive NoV results, but no NoV was found in the sample of feral oysters. The positive samples contained NoV GII, with one sample also positive for NoV GI. It was noted by the Food Authority that the difference in the results between samples from the oyster farms and feral oysters could have been influenced by the position of the feral oyster sampling site, which was located close to the bank out of the main current flow.

**Oysters sampled from outside Growing Area 4 - 25th September 2008**

The high number of positive results for NoV recorded on the 14th August suggested more widespread contamination than was initially suspected. On the 25th September 2008 oyster samples were collected from the River B, and from the entrance to the creek into which Town A WWTP
discharges to a lagoon, to investigate the possibility that either River B or the creek were continuing sources of viral contamination.

The oyster sample from River B was analyzed for a suite of enteric viruses including NoV, Hepatitis A, enterovirus and adenovirus. The sample from the creek was analyzed for NoV only. No NoV was detected in the oyster sample from the creek. The River B oyster sample was positive for NoV GIII, which is the genogroup of NoV associated with cattle, but no human enteric viruses were detected.

**Oyster samples from Growing Area 4 tested for noroviruses – 28th October 2008**

A fourth set of samples were taken on the 28th October, fourteen weeks from the initial positive samples collected on the 24th July 2008. Seven samples were collected from the same sites as the 14th August samples. Six sites were negative for NoV, but one site was positive. This was the third positive result at this site. The Food Authority concluded that it was unclear whether the reduced number of positive results was due to a reduction in faecal contamination in the area or a reduced incidence of NoV in the community.

**2009 Sampling for Noroviruses**

A sampling plan was developed for River A comprising 5 replicate oyster samples to be collected from each of 7 sites on 6 occasions. The sampling plan was developed in conjunction with a research organisation.

The results of virus monitoring over 2009 provided additional information about the nature of the faecal contamination in the growing area. A full round of negative results was returned from oyster samples in February 2009. River A was subsequently impacted by a series of major floods from early March through to June 2009. Despite the abnormal conditions, sampling did continue under what was perceived by the Food Authority as extremely adverse conditions. During this period there were 2 positive NoV results out of 72 oyster samples tested. This was thought to be a low number of positive results considering the frequency and magnitude of the floods that had impacted the river over a four month period.

By early August 2009 it was agreed that the catchment was sufficiently ‘dry’ to provide a good assessment of the virus status of the growing area under normal conditions. A round of samples taken on the 5th August 2009 returned 12/35 positive NoV results, with positive results from every sample site.

All oyster samples were negative for NoV in the next sampling round on 17th September 2009.

The Food Authority concluded that the August 2009 round of positives was significant in providing several key pieces of information (quoted from report by Food Authority):

1. The August 2009 round of positives was taken under ideal conditions when the harvest area would normally be opened. It shows that normal management regimes for shellfish harvest areas cannot predict virus contamination in River A.
2. The large number of negatives received in the September sample suggests that norovirus does not persist in oysters at detectable levels for more than several weeks. This suggests that the 2008 positive samples were caused by an on-going pollution source as opposed to a one-off spill.
3. The August 2009 round was clearly due to fresh virus contamination and not due to a single large event associated with the initial illnesses nor due to a large flood event. This round of
positives provides clear evidence of on-going contamination of the river under ‘normal’ conditions.

7.6 Investigation of Potential Pollution Sources

Establishment of Working Group
A Working Group was formed under the Incident Response Protocol for emergencies in aquaculture. This group contained representatives from the state, local council, oyster growers, food authority, health authority, environmental authority and primary industries authority. The Working Group’s primary purpose was “to work with all stakeholders to identify and rectify pollution sources in [River A], which in turn would address public health implications and satisfy the [Food Authority] re-opening criteria for the [GA 4] oyster industry.”

The Working Group endorsed the following steps to re-open the growing area to harvest:

i) all potential pollution source(s) identified, thoroughly investigated and remediated;
ii) standard water quality monitoring results within established guidelines, and
iii) three consecutive clear virus sample rounds, to be collected when the area would be in the open status following rainfall.

These steps were consistent with those used to address incidents in other growing areas in the region.

Initial investigation of potential pollution sources by Working Group
The growing area remained closed to harvest while sources of contamination were investigated. This investigation was carried out in the latter months of 2008 and early in 2009 under the auspices of the Working Group, but the work was principally undertaken by Council officers. The potential pollution sources considered included the Town A WWTP, the reticulated sewerage system, on-site sewage management systems, boats, campers, and oyster punts and sheds. A draft report “designed to provide a summary of the group’s activity and forward information on the issue to the [Food Authority]” was prepared by the Working Group and presented to the Food Authority in June 2009. The report concluded that none of the potential sources investigated was likely to be a source of NoV contamination to Growing Area 4.

Sanitary Survey and peer review of Working Group Report
In May 2009 the Food Authority engaged a consultant to undertake a sanitary survey of Growing Area 4, and an initial shoreline survey was undertaken by the consultant and Food Authority officers late in the month. In addition, the Council provided the consultant with information about their management of on-site sewage systems, the Town A Wastewater Treatment Plant (WWTP) and sewerage reticulation system. They also provided copies of incident logs, on-site sewage systems inspection reports, consultants’ reports, correspondence, plans (showing all on-site sewage systems in the catchment, plans of all the reticulation system) and operational data, and they facilitated site visits. Three selected on-site sewage systems close to the river were dye-tested by the Food Authority, and a preliminary study of the movement of water from the lagoon into River A at the turn of the low tide was made. The consultant also interviewed local residents and a local plumber.

This sanitary survey work raised some concerns about the conclusions in the draft report for the Working Group, and the consultant recommended that a more in-depth investigation of potential
pollution sources be made. Specific concerns that arose from the Food Authority/Consultant’s investigation included:

- Maintenance issues at the WWTP, including the low level of UV treatment delivered, and valve failures that had allowed partially treated effluent to be discharged;
- Maintenance of Town A reticulation system, particularly with respect to pump station overflows close to the river (problems with pumps, level alarms, and deliberately masked alarm lights);
- The very close proximity of some old septic tanks associated with historic holiday homes to the river (some within 5 m);
- The design of on-site systems on the island in relation to soil type (pooling of water had been observed), and the observed failure of some on-site systems that had been inspected by the Council earlier in the investigation; and
- Reports from the public of sewage spills from two caravan parks adjacent to the river.

Consequently completion of the Working Group report was put on hold until further investigatory work was undertaken by the Consultant and Food Authority in conjunction with the Council. This included:

- Development of a system of prioritization of >300 on-site sewage systems for more in-depth investigation. As a result of this process, an expert consultant was engaged to comprehensively investigate the performance of some of the high priority on-site sewage systems, which were located on the island;
- Dye testing of the old septic systems in historic holiday homes close to the river, using charcoals packets to detect the release of dye for up to a week after deployment (these systems had immediately been assessed as a high risk);
- A review of the Council systems relating to the management of on-site sewage systems and the WWTP;
- Closer inspection and dye testing of the sewage reticulation systems at two caravan parks adjacent to the river.

The results of this work are outlined below.

**Investigation of on-site sewage systems on Island X by an expert consultant**

The Council and consultants developed a matrix for identifying the on-site sewage systems likely to present the greatest risk to water quality in the estuary. The expert consultant was engaged to review a selection of the most highly prioritized systems. The scope of the work undertaken by the consultant included a desk-top review, site inspection of the 23 properties, drilling of at least one borehole per property to assess soils and groundwater conditions, preliminary risk modeling to assess whether systems were causing virus contamination in the river, assessment of remedial options, concept designs and indicative costs, and an assessment of whether the risk matrix could be used in alternative areas administered by the Council. Twenty-three on-site sewage systems were investigated. The study showed that:

- Of the 23 properties investigated, 22 contained systems that were operating, and one was disused.
- Soils are fairly uniform across the island, consisting of a strong duplex profile of loam over clay, with a limited area of loamy sand soils and coffee rock along the north eastern margin of the study area.
• Perched groundwater was occasionally encountered at the base of the loam, top of clay, and was inferred for the majority of the low lying portions of the island at between 0.3 m and 0.6 m depth. Permanent groundwater was encountered below 0.8 m but was typically greater than the 1.2 m depth investigated.

• Almost the entire area investigated is subject to 1% AEP (annual exceedence probability) flooding (i.e. there is a 1 in 100 chance that in any given year flooding will occur).

• All properties investigated had at least one and typically three or more site and soil features of a High Limitation for on-site effluent disposal (i.e. features at the site make it unsuitable/risky for on-site effluent disposal).

• Seven of the 23 systems investigated consisted of aerated wastewater treatment systems with subsurface or surface drip irrigation disposal. The remaining 16 systems consisted of a septic tank and absorption trench or trenches. All systems investigated were found to be deficient either in maintenance of the treatment system, or type, or size, and/or location of the disposal area.

Required remediation work was identified, ranging in cost between $6000 and $14000 per system, for all except one property (which required only ongoing annual inspections by the Council). Required remediation work was as follows:

• For properties with septic tanks and absorption trenches:
  o Retrofitting of existing septic tanks by the addition of a sand filter or subsurface flow reedbed, installation of a collection well, and disposal by subsurface irrigation onto raised beds;
  o Retrofitting of existing septic tanks by the addition of a collection well, and disposal by sand mounds; or
  o Removal of septic tanks and installation of a secondary treatment unit (examples provided) and disposal by subsurface irrigation onto raised beds or sand mount.

• For properties with existing secondary treatment aerated wastewater treatment systems (AWTS) and irrigation areas:
  o In most cases pump-out of full primary chambers, confirmation of regular maintenance and use of chlorine/UV.
  o Upgrading of disposal areas by the addition of additional subsurface irrigation lines onto raised beds located at appropriate buffer distances to the nearest waterways or drainage lines.

The report recommended that all except 3 systems located on rural properties on the far end of the island should be removed and that connection to Town A reticulated sewerage should be implemented. It suggested that the Council undertake a cost/benefit analysis of connection to Council sewer versus upgrading on-site sewage systems on the island.

Following in-depth investigation of a further 20+ on-site sewage systems by the expert consultants that produced similar findings to their initial investigation, a cost benefit analysis was undertaken by the Council, and it was decided that all properties in the urban subdivision of the island (42 properties) should be connected to the Council sewer system. At the time of conducting this case study in 2012, this work still has to be completed.
• **Dye testing of historic holiday homes on Crown land on the riverbank near Town A**

Bromine salt and fluorescein dyes were flushed down the toilets of 13 historic holiday homes located on Crown land within metres of the river bank in January 2010, a time when all the residences were occupied. The release of dye from the septic systems was monitored by visual observation immediately after dye deployment, and by the use of packets of activated charcoal placed in the estuary at three sites along the coast adjacent to the houses. Deployment and retrieval of the charcoal packets was timed to provide observation of dye release within 1 day, over 2-3 days, and from 4-7 days after the dye injection. Analysis of the eluants from the charcoal showed that effluent from holiday houses entered the river within one day after dye deployment.

In the short term, holding tanks serviced by a pump-out operator have been installed at each of the premises, pending connection to Town A sewerage reticulation system.

• **Review of the Council management of on-site sewage systems**

The performance standards relating to on-site sewage systems are documented in various regulations, standards and guidelines (see Section 2.8 earlier). The stated policy of Council with respect to on-site sewage systems was consistent with the requirements of these regulations, standards and guidelines. The scope of responsibility of Council covers the installation, construction and alteration to on-site sewage systems, and the operation of such systems. However the Consultant’s review identified very significant issues in the implementation of the policy.

Management of on-site sewage systems by the Council is based on the following measures:
- The requirement for Council approval to install, construct or alter on-site sewage systems;
- The requirement for approval to operate an on-site sewage system; and
- Periodic inspections of each on-site sewage system by a Council Environmental Health Officer. The frequency of inspection of each system is determined by an assessment the risk of its not meeting the required performance standards.

Tables 7.2 and 7.3 outline the results of the review of the Council’s management of on-site sewage systems in relation to the critical control points in the design and operation of on-site sewage systems respectively.
<table>
<thead>
<tr>
<th>Property owner responsibility</th>
<th>Required control</th>
<th>Current practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Collection of data for key factors that influence on-site sewage systems design. Needs to meet minimum requirements specified by regulation.</td>
<td>Have all key factors been included?</td>
<td>No controls specific to on-site sewage systems rigorously applied – information requirements are not specified in application form. Minimum information requirements not always met in completed applications. Some factors checked at site inspection, but there is no documented process of checks. Reliance on applicant’s site report by “qualified person” for other technical data (e.g. soil data, geotechnical data etc.). No clear definition of qualifications required in “qualified person”.</td>
</tr>
<tr>
<td>Interpretation of data to develop appropriate design for purpose, site and environmental conditions</td>
<td>Will the required performance standards be consistently met with this design?</td>
<td>Not all aspects of design are checked by Council personnel due to lack of relevant expertise – reliance on applicant’s report by “qualified person” in the more technical aspects of design. No clear definition of qualifications required in “qualified person”.</td>
</tr>
<tr>
<td>Construction / installation / alteration to design</td>
<td>Does the on-site sewage system construction / installation / alteration match the approved design and associated conditions of approval?</td>
<td>No itemized or documented inspection process specific to on-site sewage systems. In some cases, completion of required in-progress inspections may not occur due to resource or communication issues.</td>
</tr>
</tbody>
</table>

**Table 7.2:** Critical control points in management of construction, installation and alteration of on-site sewage systems (where hydraulic loading is to be increased) and their management by the Council at the time of the consultant’s review in 2009.
<table>
<thead>
<tr>
<th>Property owner responsibility</th>
<th>Control points</th>
<th>Current practice</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proper practices in the use of on-site sewage systems</td>
<td>Operator education and access to information</td>
<td>No formal qualification or training required. No systematic provision of information to operators, and very limited information provided on Council website. EHOs provide advice at inspections when operator is present only. Verbal or printed information available on request.</td>
</tr>
<tr>
<td></td>
<td>Inspection by Environmental Health Officer</td>
<td>Inspections have not been undertaken at the frequency required by Council policy. No documented protocol is used for assigning site sensitivity and thus required inspection frequency. No rigorous system to identify new property owners and to ensure that all new property owners gain approval to operate. Checklists and documentation currently associated with inspections do not cover all required features.</td>
</tr>
<tr>
<td></td>
<td>Conditions of consent</td>
<td>Maintenance records are not rigorously checked to ensure compliance with conditions of consent.</td>
</tr>
<tr>
<td></td>
<td>Maintenance records checked by Council</td>
<td>Inspections have not been undertaken at required frequency.</td>
</tr>
<tr>
<td></td>
<td>Inspection by Environmental Health Officer</td>
<td>Compliance with some conditions of consent such as use of water-saving devices are difficult to check, but may be evident from other observations.</td>
</tr>
<tr>
<td>Maintain on-site sewage systems</td>
<td>Conditions of consent</td>
<td>Inspections have not been undertaken at required frequency.</td>
</tr>
<tr>
<td>Retain features of approved design (e.g. use of water-saving devices, stormwater diversion, planting/landscaping etc)</td>
<td>Conditions of consent</td>
<td>Inspections have not been undertaken at required frequency.</td>
</tr>
<tr>
<td></td>
<td>Inspection by Environmental Health Officer</td>
<td>Compliance with some conditions of consent such as use of water-saving devices are difficult to check, but may be evident from other observations.</td>
</tr>
</tbody>
</table>

Table 7.3: Critical control points in the operation of on-site sewage systems and their management by Council at the time of the consultant’s review in 2009.
• **Investigation of the sewer system at two caravan parks**

Two caravan parks were situated on the banks of the river not far from the farm implicated in the NoV illness outbreak. Both were serviced by the Council reticulated sewerage system. However, the sewerage systems within both parks incorporate a collection well and pump, necessary to pump sewage into the Council sewer. These pump systems were owned, operated and maintained by the Caravan Parks.

In response to several reports of concern from members of the public regarding the observation of effluent from the Caravan Parks impacting on the river, the reticulation system in each park was dye tested using Rhodamine WT and bromide by Council and the Food Authority on the same day in January 2010, using charcoal packets to detect dye exfiltrating from the sewer. This study showed that effluent from one or both of the parks was entering the river. Subsequently, one of the Caravan Parks was redeveloped as a subdivision, and a new sewerage system was laid. The system in the other park was investigated in more detail by inserting a camera into the sewer. The sewer leading from the amenities block to the pump station was found to be blocked and broken by root intrusion, resulting in effluent leakage. This was cleared, and the system was re-tested in a further dye study, which still produced a positive result (presumably because the pipe was broken). A repeat dye test by expert consultants after further work produced a negative result.

### 7.7 Current Status

The Growing Area, which had been under emergency closure to harvesting following the illness event, has been reclassified as Prohibited.

A significant amount of work has been undertaken by the Council in remedying issues and sources of viral contamination that were identified as potentially impacting on oyster growing areas. The UV lamps at the WWTP have been replaced, and the UV disinfection system upgraded to provide a minimum received dose of 50 mWs cm\(^{-2}\) (increased from the previous minimum of 30 mWs cm\(^{-2}\) which was not being consistently achieved due to the lamps being at the end of their designed operating life). Pump stations in the sewerage reticulation system are now telemetrically alarmed, and there are back-up pumps available in the event of pump failure. The main reticulation system was pressure tested, and repairs made as necessary. The historic holiday homes on the banks of the river near Town A no longer discharge effluent into the environment, and the leak in the sewer at the Caravan Park has been fixed. However, the 42 properties in the subdivision on the island that are serviced with on-site sewage systems inappropriately designed for the environmental conditions have yet to be connected to the Council sewerage reticulation system. At this stage Growing Area 4 remains classified as Prohibited.

The Food Authority has identified a path to reclassify the harvest area as “Conditionally Restricted” again, as set out below:

1. **Risk assessment of the River A, investigation and remediation of likely sources of contamination.**

2. **Viral testing during adverse conditions (after the area would notionally be open, this will involve a round of bacteriological sampling to “notionally open” the area) 5 samples each site (5 samples per site. 7 sites x 5 samples = 35 samples per round) to give sufficient statistical sensitivity.**
a. **High Rainfall**  
b. **Holiday Periods**  
c. **Time when Norovirus is in the community**  
d. **Lagoon – WWTP outfall**

3. **Written report showing issues identified in risk assessment have been remediated / reviewed.**

4. **Comprehensive sanitary survey report completed that finds the area suitable as shellfish harvest area.**

### 7.8 Case Analysis

The harvest criteria combined with the depuration process failed to protect consumers from an infective level of norovirus in oysters in that the final product met the required *E. coli* standard but still contained infective virus. It has been acknowledged for many years that faecal coliforms/*E. coli* indicators do not reliably predict the presence of viral pathogens on a sample-by-sample basis. In this case the unreliability of the *E. coli* indicator was likely due to the longer persistence of NoV than *E. coli* in oysters, as discussed in Section 2.2.2 earlier. Depuration for 36-48 hours is known to be an inadequate time for the depuration of viruses from oysters and human volunteer studies have shown that depurated oysters can cause NoV illness (Grohmann et al, 1981).

The risk of the potential sources of human enteric virus contamination in the catchment of the growing area was not correctly assessed by the Food Authority. This case study differs from all the others in this project in that, as a consequence of there being consistently higher background levels of faecal coliforms/*E. coli* in water and shellfish, GA 4 has a Conditionally Restricted rather than Conditionally Approved classification. Based on the relationship between the geometric means of levels of *E. coli* and NoV in oysters observed by Lowther (2011) (see Section 2.4.2), this suggests that the risk of occurrence of significant levels of NoV might be higher in GA 4 than in other areas in this study. Although the sanitary survey report prior to the illness event had noted the presence of all the potential sources of contamination (e.g. on-site systems, WWTP, caravan parks, pump stations etc.), an assumption had been made in the classification and management of the growing area that these would not provide sources of human faecal contamination to the growing area (except, in some cases, as a result of spills, of which the Food Authority would be notified). Background levels of faecal coliforms observed in water and oyster samples (which were in compliance with the growing area’s classification as Conditionally Restricted) were attributed to animal sources (e.g. cattle) that were readily observable in the catchment. The Food Authority has indicated that in the course of the sanitary survey, having been assured by the Council that there were no ongoing sources of human sewage impacting on the river, they experienced some difficulty in obtaining sufficient details of the potential pollution sources from the Council to allow an independent assessment. This difficulty was also reflected in the Council’s contribution to the first draft of the Working Group report. In practice, the Food Authority cannot rigorously investigate some potential pollution sources without the cooperation of Council – for example, the Food Authority staff has no right to enter private property to inspect on-site sewage systems or sewers etc. Consequently, the extent of a site-specific investigation by the Food Authority may be limited to observation of impacts rather than causes (for example, in more recent times the development of improved faecal source tracking techniques has allowed the distinction between human faecal contamination and faecal contamination from other sources). In the case of the sanitary survey for Growing Area 4, the Food Authority was reliant on information provided by the Council.
It is of note that the initial advice that the Council provided to the Working Group indicated that after investigation there were no ongoing sources of human sewage to the river. The outcomes of closer investigation by outside parties varied very significantly from this advice.

**The Council did not to adhere to their own policies, standards and guidelines, which resulted in faecal contamination of the growing area.** The issues giving rise to this situation are most clearly demonstrated in the problems associated with the on-site sewage systems, but were equally applicable across other aspects of the management of wastewater by the Council:

1. The management systems within the Council were found to be inadequate at multiple critical control points and could not ensure that on-site sewage systems were either designed or operated in a manner to consistently achieve the performance standards required by regulation.

2. The outcome of inspections of on-site sewage systems on the island by expert consultants was different in almost every case from that of Council officers. This suggests differences in skill levels and/or intensity of investigation applied to the completion of this task.

   In some instances the Council’s expectation of the expertise of their staff appeared unrealistically high. For example, Council policy required that in sensitive areas (such as close to aquaculture), the set-back distances of on-site sewage disposal fields to waterways should be calculated using a formula known as the Beavers-Gardner formula, which models the movement of viruses through soils (Beavers & Gardner, 1993). Not surprisingly, on enquiry by the consultant, the Council staff admitted that none of them knew how to undertake this complex calculation, and that it was normally not used in permit application processes because the input data were not readily available.

3. The performance of the Council in implementing its stated policies was also influenced by lack of resources. For example, in an examination of the failure of Council officers to undertake inspections of on-site sewage systems at the required frequency, an analysis of the time required to complete all inspections was undertaken. This showed that the available resources in terms of manpower were a little more than a third of what would be required to complete all the work. However, the issue of how to manage this critical control point in on-site sewage systems performance with less financial resources had not been addressed in Council planning.

The epidemiological evidence available in the NoV illness event in this case study did not meet the internationally accepted NSSP definition of a NoV outbreak linked to the consumption of oysters from Growing Area 4. The discovery of NoV in oyster samples taken from the growing area on several occasions added to the concern of the Food Authority about virus contamination of the area, prompting an in-depth investigation of potential sources. The value of this case study lies not just in the elucidation of the specific contamination source implicated in a NoV outbreak, but in the observation of the differences in conclusions drawn from a routine sanitary survey and those from an in-depth multi-party investigation prompted by an issue of public health.
SECTION 8  CASE STUDY: GROWING AREA 5

8.1 Description of Growing Area and its Catchment

Growing Area 5 (GA 5) lies in a harbour that is approximately 5 km long and 5 km wide. Most of this area is sub-tidal, with about 540 hectares of inter-tidal area on the eastern and northern parts of the harbour. Two entrances to the harbour are separated by an island at the harbour mouth. The water depth at the southern harbour mouth is 10-20m, and depth decreases steadily towards the head of the harbour.

At the time of the 2009 NoV outbreak, the growing area was made up of six individual oyster farms, two on the southern of the harbour and four on the northern side.

The large catchment of the harbour is a mixture of low density agriculture and steep hills covered with secondary bush. Within the catchment there is a small town of approximately 1500 persons. Some of the properties within the catchment have on-site sewage systems, but much of the town is serviced by a Wastewater Treatment Plant (WWTP) owned and operated by the Council. The sewerage reticulation system uses five pump stations which operate in series and serve four catchment areas to deliver the sewage to the treatment plant.

The WWTP is designed with a capacity of 1,100 m$^3$/day. The current operational capacity is 900 m$^3$/day. The plant provides primary, secondary and tertiary treatment. The primary and secondary treatment is by aerated lagoon. The lagoon has approximately 20 days retention and is aerated for 14 hours per day. There are three holding ponds (retention) and one sludge backwash pond. Tertiary treatment by a Terraviva Works Filter System, consisting of a flocculation tank, two adsorption clarifiers, two polishing filters (containing coarse pumice material), three clearwater tanks (one for backwashing) and ultraviolet treatment (a Wedeco unit with Spectrotherm SLR 32143 lamps, 1 channel, 2 banks, 2 modules, 16 lamps). In summer the mean received UV dose is 428mJ/cm$^2$ while in winter the mean received UV dose is 628.6mJ/cm$^2$.

The plant originally had a root zone media marsh (biobed) system. The biobeds are now used as retention ponds for sludge disposal from the backwashing process.

The outfall location is in a stream (Stream XXX) that ultimately discharges into the harbour that contains the oyster farms. The outfall is approximately one kilometre from the oyster farms in the southern part of the growing area.

A wastewater treatment plant operator is employed to carry out daily checks and maintenance at the plant. The effluent is sampled monthly for biochemical oxygen demand, ammonia nitrogen, suspended solids, E. coli and faecal coliforms in compliance with conditions of the discharge consent. As part of the Council’s own quality control system, monthly samples are taken upstream and downstream of the discharge point.

The Sanitary Survey report for GA 5 notes that the Stream XXX travels through the southern harbour farms on an outgoing tide to the entrance to the Harbour. This stream is considered to be the predominant source of contamination for the southern farms in the harbour.

On an incoming tide, water enters the Harbour and circulates in a clockwise direction. An incoming tide can back up the freshwater at the southern oyster farms. This contaminated water can be driven on the northern harbour farms, but only during a high rainfall event e.g. >80 mm of rain.
Although the general region is used for recreational boating activity, the area around the oyster farms is not frequented by boats due to the shallow waters. The boating activity is undertaken in the deeper, more scenic waters of the greater harbour. There are no marinas in the Harbour.

### 8.2 Classification Status

The growing area was first classified in 1979 based on the United States National Shellfish Sanitation Programme requirements of the time. Since then the Sanitary Survey has been fully updated every 12 years. At the time of the 2009 NoV event the next full sanitary survey report was due in December 2011.

The area is classified as “Conditionally Approved” due to the actual and potential pollution from general catchment runoff and the Wastewater Treatment Plant. There is a Management Plan which uses rainfall criteria to nominate the safe harvest periods.

The potential and actual pollution sources listed in the Sanitary Survey are:

iv) General land runoff, particularly from a stream that runs through the catchment.

v) General pollution associated with a small town within the catchment (population approximately 1,500 persons).

vi) Wastewater Treatment Plant that services the town.

There is a signed written agreement that the Authority responsible for the WWTP that they will notify the Food Authority of any malfunctioning likely to result in contamination of the shellfish growing area.

### 8.3 Annual Updates

#### 8.3.1 Background

As part of the Shellfish Quality Assurance Programme, monthly seawater and shellfish samples must be taken when the Growing Area is open for harvesting. The sample results must be reviewed annually and a shoreline survey undertaken to confirm the classification status.

Growing Area 5 has maintained its “Conditionally Approved” classification. All the sampling, shoreline survey and administration reporting steps have been in full compliance with regulatory requirements since it was first classified in 1979, and the results of these samples have been within the microbial limits for a “Conditionally Approved” classification.

#### 8.3.2 Routine compliance monitoring

Compliance with the growing area classification is monitored using the Adverse Pollution sampling strategy and the growing area is sampled on a monthly basis at four water sampling sites and at two shellfish sampling sites.
The area has historically been in compliance with the microbiological requirements for water and shellfish. Tables 8.1 and 8.2 show the results for 2006-2009 as presented in annual reports.

<table>
<thead>
<tr>
<th>Year</th>
<th>Measure of Compliance</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Site 1</td>
</tr>
<tr>
<td>2006</td>
<td>n</td>
<td>30</td>
</tr>
<tr>
<td></td>
<td>Median (MPN/100 ml)</td>
<td>&lt;1.8</td>
</tr>
<tr>
<td></td>
<td>% &gt; 43 MPN/100 ml</td>
<td>0</td>
</tr>
<tr>
<td>2007</td>
<td>n</td>
<td>26</td>
</tr>
<tr>
<td></td>
<td>Median (MPN/100 ml)</td>
<td>&lt;1.8</td>
</tr>
<tr>
<td></td>
<td>% &gt; 43 MPN/100 ml</td>
<td>0</td>
</tr>
<tr>
<td>2008</td>
<td>n</td>
<td>28</td>
</tr>
<tr>
<td></td>
<td>Median (MPN/100 ml)</td>
<td>&lt;1.8</td>
</tr>
<tr>
<td></td>
<td>% &gt; 43 MPN/100 ml</td>
<td>0</td>
</tr>
<tr>
<td>2009</td>
<td>n</td>
<td>31</td>
</tr>
<tr>
<td></td>
<td>Median (MPN/100 ml)</td>
<td>&lt;1.8</td>
</tr>
<tr>
<td></td>
<td>% &gt; 43 MPN/100 ml</td>
<td>0</td>
</tr>
</tbody>
</table>

Table 8.1: Results of analysis of data from water samples tested for faecal coliforms for purposes of compliance with growing area classification from 2006-2009. Each set of results is based on analysis of data from the three preceding years. Sample sites 1 & 2 are located in the southern farms in the Growing Area, and sample sites 3 & 4 in the north.

<table>
<thead>
<tr>
<th>Year</th>
<th>Measure of Compliance</th>
<th>Results</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Site 5</td>
</tr>
<tr>
<td>2006</td>
<td>n</td>
<td>27</td>
</tr>
<tr>
<td></td>
<td>Median (MPN/100g)</td>
<td>20</td>
</tr>
<tr>
<td></td>
<td>% &gt; 700 MPN/100g</td>
<td>7.4</td>
</tr>
<tr>
<td></td>
<td>n greater than 230 MPN/100g</td>
<td>4</td>
</tr>
<tr>
<td>2007</td>
<td>n</td>
<td>24</td>
</tr>
<tr>
<td></td>
<td>Median (MPN/100g)</td>
<td>30</td>
</tr>
<tr>
<td></td>
<td>% &gt; 700 MPN/100g</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>n greater than 230 MPN/100g</td>
<td>4</td>
</tr>
<tr>
<td>2008</td>
<td>n</td>
<td>26</td>
</tr>
<tr>
<td></td>
<td>Median (MPN/100g)</td>
<td>40</td>
</tr>
<tr>
<td></td>
<td>% &gt; 700 MPN/100g</td>
<td>Nil</td>
</tr>
<tr>
<td></td>
<td>n greater than 230/100g</td>
<td>3</td>
</tr>
<tr>
<td>2009</td>
<td>n</td>
<td>31</td>
</tr>
<tr>
<td></td>
<td>Median (MPN/100g)</td>
<td>&lt;18</td>
</tr>
<tr>
<td></td>
<td>% &gt; 700 MPN/100g</td>
<td>Nil</td>
</tr>
<tr>
<td></td>
<td>n greater than 230 MPN/100g</td>
<td>Nil</td>
</tr>
</tbody>
</table>

Table 8.2: Results of analysis of data from oyster samples tested for E. coli for purposes of compliance with growing area classification from 2006-2009. Each set of results is based on analysis of data from the three preceding years. Sample site 5 is located in the farms in the north of the Growing Area, and sample site 6 in the southern farms.
8.4 Performance of Wastewater Treatment Plant

As part of their own quality control testing the Council takes monthly samples above and below the WWTP treated effluent point in Stream XXX. These samples are tested for suspended solids, chemical and biological oxygen demand, ammonia/nitrates, faecal coliforms, E. coli, temperature and pH. Monthly reports, and an annual report, are prepared on these results.

Each year the WWTP is audited by an independent consultant for the Council. The following is taken from their 2008/9 report which covered the period May 2008 to 30 April 2009, and incorporates the findings of a site visit on 23 February 2009.

“The 2009 report found that the plant was not in compliance with its consent conditions because the ammonia results were not in compliance with the consented discharge limits and because some reporting requirements from the 2008 report were still outstanding. The main reason behind the ongoing non-compliance is limited treatment capacity at the plant. The Authority responsible for the WWTP have been investigating the options available to improve the treatment capacity and discharge quality. A key decision milestone is the upcoming expiry of the resource consents.”

There is evidence that the WWTP agreement to notify the Food Authority and the industry has been activated on a number of occasions, including 2006, 2007, 2008 and 2009 due to broken and blocked sewerage pipes and electricity outages which caused pump stations to overflow. On these occasions it appears that the notifications were generally timely, shellfish harvesting was stopped, and adequate investigations were undertaken to determine pollution levels before the harvest areas were formally reopened.

The following notes associated with the WWTP were made in the Food Authority 2008 Annual Review Report:

1) On 4 January 2008, the [Food Authority] was notified of a burst rising sewer main that resulted in a minor wastewater spill on the beach in the oyster growing area catchment. The break and minor spill had been occurring for several days before being detected. The flow was small and disappeared into rocks at the entry point on the beach, and did not reach the tidal margin in overland flow. The rising main was repaired by the Council and the area of contamination disinfected. This spill was not in the vicinity of a shellfish growing area and no further action was required.

2) On 30th July 2008 the [Food Authority] was notified of an overflow of partially treated effluent from the secondary treatment retention ponds at the Wastewater Treatment Plant. There was also a minor overflow of the main aeration pond into adjacent flooded paddocks. The amount of effluent spilt was very small and the integrity of the ponds remained intact. The spill occurred during a high rainfall event of 192 mm over 48 hours. All the growing areas were closed for rainfall and had reopened by 6 August 2008.

On 6 August 2008, a monthly sample run was carried out for all growing areas after reopening. The E. coli levels in the oysters at [GA 5] were 70 MPN/100g.

This event was not managed as a “sewage event” in accordance with [the regulations] due to the small amount of effluent spill and the high dilution factors following the rainfall.

3) The rising main from XXX pump station was replaced in August 2008.
4) *The plant was inspected on 30 October 2008 by the [Food Authority] with the Council as part of the annual growing area shoreline survey. Conditions at the WWTP were considered satisfactory under the requirements of the [shellfish regulations]*.

### 8.5 Epidemiological Details of Illness Outbreaks

An illness event in 2009 was the first epidemiological event to be associated with the oysters from this harbour. The 2009 NoV event comprised two separate illness outbreaks associated with oysters from the growing area.

The first outbreak was reported to the public health authorities on the 21st July, 2009 (12 persons suffering from vomiting and diarrhoea). The oyster harvest date implicated was the 7th July, 2009.

The next illness outbreak (3 persons) was notified to the public health authorities on the 5th August and implicated oysters that had been harvested on the 17th July, 2009.

Retrospective cohort studies were conducted for the two gastroenteritis outbreaks. Faecal samples and samples of oyster meat were analysed. 10 out of 16 people who had eaten at Event 1, and 3 out of 15 people who had eaten at Event 2 experienced gastroenteritis. The symptoms, duration of illness and incubation periods were consistent with NoV gastroenteritis in both outbreaks. The consumption of oysters was strongly associated with an increased risk of illness, with a p value of 0.002 for oysters in Outbreak 2. Faecal samples were positive for NoV genogroup I (GI). Oysters from both outbreaks were traced back to the same growing area. Samples of oyster meat from one of the restaurants and samples from the same date from the same farm (library samples held by the processor) were positive for NoV GI. Both illness outbreaks were associated with the same farm in the larger growing area.

In total 15 persons became ill with the causative organism in all cases found to be NoV GI and an attack rate of 71%.

### 8.6 Outbreak Investigations

#### 8.6.1 Investigation steps and timelines

<table>
<thead>
<tr>
<th>Date (2009)</th>
<th>Action related to outbreak</th>
</tr>
</thead>
<tbody>
<tr>
<td>2nd July</td>
<td>Pipework broken at WWTP which is considered to be the likely cause of the NoV events</td>
</tr>
<tr>
<td>7th July</td>
<td>Implicated harvest date for Event #1</td>
</tr>
<tr>
<td>15th July</td>
<td>Implicated oysters in Event #1 consumed</td>
</tr>
<tr>
<td>17th July</td>
<td>Implicated harvest date for Event #2</td>
</tr>
<tr>
<td>22nd July</td>
<td>Health Authorities notified of Event #1</td>
</tr>
</tbody>
</table>
23rd July | Oyster industry notified and undertook voluntary closure. Oyster samples from harvest date 7/7/09 (?) taken from library stock held at oyster processing plant and from supplier premises (both samples subsequently found positive for NoV GI).

25th July | The Food Authority in association with the industry closed the growing area at 0900 hrs on the 25th July (four days after the initial information became available).

29th July | The Council was asked if there had been any incidents at the WWTP that may have contaminated the harbour. No issues were identified.

30th July | Laboratory confirmation that faecal samples positive for NoV GI.

30th July | Food hygiene inspection undertaken at oyster supplier premises for Event #1. No defects found.

2nd August | Food consumed implicated in Event #2 (From stock in restaurant freezer that restaurant staff had omitted to destroy).

5th August | Health Authorities notified of Event #2.

5th August | Leak caused by pipe damage found at the WWTP.

6th August | Food Hygiene inspection of premises associated with Event #2. No defects found.

12th August | Shoreline survey undertaken to identify any other potential pollution sources.

8th September | Samples taken from farms to ensure final clearance (tested for *E. coli* and NoV).

16th September | Area officially reopened.

Table 8.3: Timeline showing the sequence of events through the norovirus outbreak and subsequent investigations.

### 8.6.2 Review of historical environmental data

**Harvest status of the farms:**

The 2009 rainfall harvest restrictions were:

<table>
<thead>
<tr>
<th>Rainfall by time</th>
<th>Closure time</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.0-22.9 mm in 24 hours</td>
<td>No restriction</td>
</tr>
<tr>
<td>23.0-89.9 mm in 24 hours</td>
<td>Closed three days</td>
</tr>
<tr>
<td>90.0-129.9 mm in 24 hours</td>
<td>Closed four days</td>
</tr>
<tr>
<td>&gt;130.0 mm in 24 hours</td>
<td>Closed six days</td>
</tr>
</tbody>
</table>

Table 8.4 Harvest criteria based on rainfall at the time of the norovirus event in GA 5.
The oyster farm was officially “Open” for harvest at the time of implicated harvest dates (July 7th and 17th). Table 8.5 shows the rainfall history for the period 1st - 23rd July. There was a rainfall event of 31mm that closed the area for the period 12-15th July 2009.

The sanitary survey noted that an incoming tide can cause the back up of contaminated water from Stream XXX at the southern oyster farms. This contaminated water can be driven on the northern farms in the harbour, but only during a high rainfall event e.g. 80 mm of rain. There were no rainfall events at this level in July 2009.

<table>
<thead>
<tr>
<th>DATE (2009)</th>
<th>RAINFALL (mm)</th>
<th>COMMENT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1st July</td>
<td>Nil</td>
<td></td>
</tr>
<tr>
<td>2nd July</td>
<td>1</td>
<td>Broken pipework starts contamination</td>
</tr>
<tr>
<td>3rd July</td>
<td>Nil</td>
<td>Harvest, no illness reported</td>
</tr>
<tr>
<td>4th July</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>5th July</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>6th July</td>
<td>3.5</td>
<td></td>
</tr>
<tr>
<td>7th July</td>
<td>0.5</td>
<td>Harvest associated with illness</td>
</tr>
<tr>
<td>8th July</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>9th July</td>
<td>8.5</td>
<td></td>
</tr>
<tr>
<td>10th July</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>11th July</td>
<td>Nil</td>
<td></td>
</tr>
<tr>
<td>12th July</td>
<td>31</td>
<td>Rainfall at closure level</td>
</tr>
<tr>
<td>13th July</td>
<td>7</td>
<td>Closed to harvest</td>
</tr>
<tr>
<td>14th July</td>
<td>12</td>
<td>Closed to harvest</td>
</tr>
<tr>
<td>15th July</td>
<td>12.5</td>
<td>Closed to harvest</td>
</tr>
<tr>
<td>16th July</td>
<td>7</td>
<td></td>
</tr>
<tr>
<td>17th July</td>
<td>4.5</td>
<td>Harvest associated with illness</td>
</tr>
<tr>
<td>18th July</td>
<td>30.5</td>
<td></td>
</tr>
<tr>
<td>19th July</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>20th July</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>21st July</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>22nd July</td>
<td>2.5</td>
<td></td>
</tr>
<tr>
<td>23rd July</td>
<td>5</td>
<td></td>
</tr>
</tbody>
</table>

Table 8.5: Rainfall history of growing area and associated actions before norovirus outbreak.

*Sample results prior to the illness event*

Samples for microbiological analysis were taken on the 3rd June 2009 (the month before the illness outbreak). The results of faecal coliform analysis for all water samples were <1.8 MPN/100 ml and the *E. coli* results from oyster samples at both shellfish sites were <20 MPN/100 g. A sampling round due at the beginning of July was not undertaken due to environmental conditions.

The growing area was officially closed at 0900 hrs on the 25th July 2009 due to the NoV outbreak.

A routine monthly sampling round was undertaken on the 27th July 2009 and all water samples were found to have faecal coliform levels <1.8 MPN/100 ml. The oyster sample at the northern end of
the harbour had an *E. coli* level of 20 MPN/100 g. Unfortunately no oyster samples were taken at the southern end of the harbour during this sampling round as there were insufficient oysters in the bag at the sample site.

### 8.7 Post Harvest Investigation

All the food premises associated with the two outbreaks were inspected. This included the oyster processing plant, the oyster wholesaler and the restaurant facilities. All facilities complied with the appropriate food hygiene regulations. In particular staff were questioned about the method of storage and handling of oysters, and the likelihood of cross-contamination of foods. No problems were identified, and given that the common factor was the source of the oysters in the two outbreaks (common farm) and the positive NoV results it was considered that the contamination problem was likely to have originated in the growing area.

The oyster processing company also undertake batch tests of all harvests as part of their own quality assurance programme to ensure that the product meets the market requirement for an *E. coli* level <230 MPN/100g. The July batch sample results for the implicated growing area are shown in Table 8.6. The processor has observed that post-harvest test results for *E. coli* in oyster samples are generally in the range of 20-70 MPN/100g, so the two successive *E. coli* results of 220 MPN/100g from Farm 2 were unusual. We note however, that the third sample, which was taken from Farm 2 on the same day as oysters implicated in the NoV outbreak, did not have *E. coli* levels that were unusually elevated. Farms 1 and 2 are located in the northern and southern parts of the growing area (the southern part of the growing area was implicated in the illness event).

<table>
<thead>
<tr>
<th>Date</th>
<th><em>E. coli</em> level in oyster samples (MPN/100g)</th>
<th>Status of Growing Area</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Farm 1</td>
<td>Farm 2</td>
</tr>
<tr>
<td>3 July 2009</td>
<td>40</td>
<td>220</td>
</tr>
<tr>
<td>6 July 2009</td>
<td>&lt;20</td>
<td></td>
</tr>
<tr>
<td>7 July 2009</td>
<td>&lt;20</td>
<td>220</td>
</tr>
<tr>
<td>9 July 2009</td>
<td>&lt;20</td>
<td></td>
</tr>
<tr>
<td>17 July 2009</td>
<td>&lt;20</td>
<td>40</td>
</tr>
<tr>
<td>22 July 2009</td>
<td>&lt;20</td>
<td></td>
</tr>
</tbody>
</table>

Table 8.6: Results of analysis of samples of processed oysters harvest from two farms in Growing Area 5 in July 2009.
8.8 Environmental Investigations Associated with Illness Outbreaks

Investigations were undertaken by the Food Authority on 12th August 2009 in an attempt to identify any actual or potential pollution sources. Surveys involved a visual inspection of the wastewater treatment plant, a nearby mussel depot, and the shoreline in the area surrounding the growing area.

All potential sources of contamination around this time period were considered as follows:

**Boating Activity**
Due to low boating activity as a result of the winter season and because of the shallow waters surrounding the implicated farm it was considered highly unlikely that discharge from boats was the cause of virus contamination.

**On-site sewage systems**
On-site sewage systems in the general area were inspected by the Food Authority as a result of the illness event. Due to their distance from the marine waters they were considered to be a low contamination risk, and no malfunctioning systems were identified.

**Wastewater Treatment Plant**
The WWTP were first contacted by the Food Authority about the illness outbreak on the 29th July 2009. At the time the WWTP responded that they were not aware of any problems with regards spillage or the plant operating outside the normal tertiary treatment regime.

On the 5th August, 2009 some children noticed discoloured water entering Stream XXX while a digger was operating at the WWTP. The children alerted the workers at the WWTP and it was then identified that a problem had occurred. As a result on the 5th August 2009 the Council advised:

"Late this afternoon, our investigations into the source of the suspected stream contamination have discovered an unknown historical drainage pipe below the base of the wastewater treatment plant final retention pond. It is suspected that this pipe was breached at the pond whilst excavating a sump below the water level for a submersible pump attached to the membrane filtration unit that was recently installed in order to bypass and carry out critical maintenance on the existing works filter systems".

The excavation work in the pond, which was assumed to have caused the damage, had been undertaken on 2nd July 2009. On the 5th August, as soon as the Council became aware of the discharge of partially-treated sewage to the stream from the WWTP, immediate action was undertaken to locate and stop the discharge. The local Council fully assisted with the subsequent Regional Council investigation.

The local Council then acknowledged that approximately 10,000–15,000 m$^3$ of partially treated sewage had been discharged into the Stream XXX during the period 2nd July – 5th August 2009 (approximately 35 days). Stream XXX flows directly into the Harbour. The oyster farm implicated in the NoV outbreak is the closest farm to the Stream.

The Council took water samples above and below the discharge point on the 5th August when the leak was found. The test results are shown in Table 8.7. Without a measure of the variability of the annual data it is not possible to ascertain whether the results from the 5th August were unusual and would have allowed the Council to determine that the pond at the WWTP had been breached.
Table 8.7: Results of analysis of water samples taken by the local Council from Stream XXX on 5th August 2009 in comparison to annual mean results from compliance monitoring.

<table>
<thead>
<tr>
<th>Sample Site</th>
<th>Measurand</th>
<th>Sample taken 5th August 2009</th>
<th>Mean based on previous years monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>50 metres upstream</td>
<td>(E. coli) (cfu/100ml)</td>
<td>86</td>
<td>266</td>
</tr>
<tr>
<td>75 metres downstream</td>
<td>(E. coli) (cfu/100ml)</td>
<td>280</td>
<td>291</td>
</tr>
<tr>
<td>50 metres upstream</td>
<td>Faecal coliforms (cfu/100ml)</td>
<td>410</td>
<td>413</td>
</tr>
<tr>
<td>75 metres downstream</td>
<td>Faecal coliforms (cfu/100ml)</td>
<td>340</td>
<td>390</td>
</tr>
<tr>
<td>50 metres upstream</td>
<td>Ammonia-Nitrogen (N mg/L)</td>
<td>&lt;0.4</td>
<td>&lt;0.4</td>
</tr>
<tr>
<td>75 metres downstream</td>
<td>Ammonia-Nitrogen (N mg/L)</td>
<td>&lt;0.4</td>
<td>&lt;0.4</td>
</tr>
<tr>
<td>50 metres upstream</td>
<td>Suspended solids (mg/L)</td>
<td>6</td>
<td>3.5</td>
</tr>
<tr>
<td>75 metres downstream</td>
<td>Suspended solids (mg/L)</td>
<td>&lt;1.0</td>
<td>3.5</td>
</tr>
</tbody>
</table>

8.9 Food Authority Conclusions and Actions Arising from Outbreak Investigations

8.9.1 Conclusions

Following is a summary of the conclusions formed by the Food Authority as a result of their investigations.

- Finding NoV genogroup I in the faecal specimens and left over oysters in one outbreak event, and in oysters harvested from the implicated farm on the date of harvest of the oysters implicated in the other outbreak, confirmed the oysters as the most likely source of both outbreaks.

- Investigation of the food suppliers and restaurant did not indicate any source of contamination. NoV genogroup I was identified in oyster meat obtained from the oyster growing area which had supplied oysters to both implicated functions.

- Routine batch testing of the oysters uses \(E. coli\) as a surrogate for all potential faecal pathogens. Testing at the growing area prior to product sale had found \(E. coli\) within the
acceptable range but at an increased level from previous tests. This could have served as a warning of contamination.\textsuperscript{17}

- Despite no clear source of contamination initially being found, the strong evidence pointing to the oysters as the source of the NoV led to the growing area being closed for further investigation. This action may have prevented further outbreaks from occurring.

- The finding of the leaking effluent pipe pointed to an obvious source for the contamination.

\textbf{8.9.2 Actions as a result of the investigations}

1) The sewerage system was repaired so that no further leakage would occur.

2) The growing area remained officially closed until at least 28 days after the repairs were completed at the WWTP. Four oyster samples were taken from the growing area on the 8\textsuperscript{th} September 2009 and tested for NoV. All four samples were negative for NoV so the growing area was reopened.

3) As the regional Council considered the spillage a “significant non-compliance issue” according to the WWTP resource consent they requested an independent report on the incident. On receiving this report the Legal division of the Regional Council determined that there was enough evidence to take legal action against the local Council for the spillage. However, at a Regional Council meeting the councillors decided not to take legal action but to issue a written warning to the local Council on the need to undertake due diligence when such works were being undertaken.

4) As a result of the environmental investigations following the outbreak the Food Authority decided to split the northern and southern farms in this harbour into two separate growing areas (with their own official number). The rationale for this split was that the two areas are impacted differently by the flow from the Stream XXX.

5) Following this NoV incident the oyster processing company reviewed their protocols for managing elevated microbial results from their batch sampling. A review of the previous 12 months results from this harvest area determined the normal \textit{E. coli} range to be 20-70 MPN/100 g. Therefore in retrospect the two samples of the 3\textsuperscript{rd} and 7\textsuperscript{th} July which produced \textit{E. coli} results of 220 MPN/100 g were elevated. The new company protocol requires a retest of any batch which returns an \textit{E. coli} result higher than 130 MPN/100 g.

\textbf{8.10 Case Analysis}

It appears in this event that the discharge of between 10,000 and 15,000 cubic metres of partially treated effluent from the WWTP from 2\textsuperscript{nd} July – 5\textsuperscript{th} August 2009 was the cause of the NoV contamination that resulted in food poisoning in oyster consumers. The discharge was caused as a result of works within Pond 4 while upgrades to sand filters were being completed. The works

\textsuperscript{17} We suggest that this point is debatable given that a third sample, which was taken from oysters harvested from the same farm on the same day as those implicated in the NoV outbreak, did not exhibit noticeably elevated levels.
breached a drainage pipe beneath the pond lining. The pipe was not part of the treatment plant’s operational treatment system, and its presence was unknown.

There appears to have been significant difficulty in finding the source of contamination in this event, and the eventual discovery of the source was somewhat serendipitous. We note that due to commitments of Food Authority management personnel, there was a considerable delay (21 days) between the discovery that the oysters in the growing area had been impacted by NoV contamination and the instigation of a comprehensive shoreline investigation by the Food Authority. In this case the delay did not impact on the ability to identify implicated contamination sources – in the interim the Food Authority had made enquiries by phone and the industry had undertaken considerable shoreline investigations. However, this may not hold true for all contamination sources associated with NoV outbreaks arising from growing area contamination. In shoreline investigations the industry can provide invaluable local knowledge, but in general they have no training in shoreline surveys so their input is strengthened when complemented by expertise held by Food Authority officers.

The history of the management of the risk of effluent discharge from the WWTP suggests that generally the communication processes in place to manage the risk of spillage from the plant on the oyster growing area are effective. In this instance the problem arose because the WWTP operators were unaware that there was a spillage occurring. Arguably the Council should have planned the process of upgrading the plant more thoroughly to ensure that all possible risks of spillage were appropriately managed. The monthly monitoring in the Stream XXX failed to alert the Council of the breach in the pond. Influent and effluent flows at the WWTP are required to be monitored as a condition of their resource consent. Given that it was 35 days before the breached pipe was discovered, and the estimated sewage volume discharged through the breached pipe equated to a daily flow of approximately 30%-50% of the mean daily flow of treated effluent, it is surprising that the discrepancy in flow data did not alert the Council to the breach in the system. This suggests that the influent and effluent flow monitoring did not act as effective controls in detecting breaches in the WWTP system at the time when the upgrade work on the plant was in progress. No measures to improve the effectiveness of the management of the risk of unconsented discharge from the WWTP were noted in the Food Authority reports.

Environmental conditions prevented routine sampling of water and oysters from the growing area by the Food Authority in early July 2009, and oyster samples were unable to be taken from the southern sample site in the growing area (where the implicated farm is situated) on 27/7/09 because there were too few oysters set out in the sampling bag. Although the sample round on 27/7/09 fell within the period during which the spillage from the WWTP was occurring, the E. coli results from the oyster sample from the northern part of the growing area provided no indication of virus contamination, nor did the faecal coliform results in water samples from either site, which were all below the level of detection. Had oyster samples been taken from the southern site, it is uncertain whether E. coli levels would have indicated the risk of NoV contamination as oyster samples taken by the oyster processor from batches of harvested in July 2009 from the implicated farm had E. coli levels below the regulatory level of 230 MPN/100g. In hindsight it was noted that these E. coli levels in two successive post-harvest samples taken by the processor during the period of the discharge were slightly elevated above background levels, but no action was required or taken based on this at the time. We note the absence of training within the industry on this type of issue.

The SQAP monitoring programme is designed to confirm compliance with a growing area classification, not to ensure directly that harvested product is safe for consumption. It is thus not effective in detection of sewage spills of which the Authorities are unaware unless sampling
happens by chance to occur concurrently or soon after, the spillage. In this case, although there were problems with sample collection by the Food Authority during the period of the discharge, the water sample results and the results of shellfish testing for *E. coli* by the processor, were compliant with the required standards. Generally it would be expected that the reliability of faecal coliforms/*E. coli* as indicators of enteric viruses would increase with decreasing spatial and temporal separation from the contamination source. In this case, shellfish and water samples were taken concurrently with the discharge, but with respect to the management of the risk of virus contamination, the distance of approximately 1 km between the discharge source and the sample site was sufficient to negate the effectiveness of the faecal coliform/*E. coli* standards used in the regulatory management of the Shellfish Quality Assurance Programme.

The voluntary measures subsequently introduced by the processor, in which elevated *E. coli* levels in post-harvest samples trigger further coliform testing, are unlikely to reliably manage the risk of NoV contamination.

We note that extent of the illness event was exacerbated by an event beyond the control of the Shellfish Quality Assurance Programme: the second illness outbreak occurred after the closure of the growing area, as a result of product harvested in the time between the first outbreak and the growing area closure. This could have been prevented if the retailer had thoroughly checked all product when informed of the product recall.
SECTION 9: ANALYSIS ACROSS CASES

9.1 Cross-Case Analysis

9.1.1 Issues relating to shellfish standards

Analysis of groups of cases was undertaken with respect to a number of issues that emerged from the individual case analysis documented in the preceding sections. Table 9.1 (see following page) summarises some of the characteristics of growing areas across all cases with respect to standards within the shellfish programme.

Compliance with Growing Area Classification

All growing areas implicated in NoV outbreaks across these case studies were compliant with their classification based on the results of monitoring for faecal coliforms/E. coli in water and shellfish samples. The compliance sample data, and the required methodological analysis of the data, failed to predict the risk of NoV contamination in oysters by indicating any non-compliance with the growing area classification. When non-compliant monitoring results (e.g. results elevated above faecal coliforms median of 14 MPN/100 ml in water or E. coli levels of 230 MPN/100g in shellfish in “Conditionally Approved” growing areas) are observed, the circumstances around these samples are investigated by the Food Authority and recorded in the Annual Review Report. If this investigation results in a revision of harvest criteria, then the subsequent statistical analysis to assess compliance with the growing area classification includes the retrospective exclusion of the elevated results observed when the area would not have been open to harvest based on the current criteria. This means that the required statistical analysis of the compliance data undertaken at each Annual Review does not reflect any long-term deterioration in water quality in the growing area provided that any elevated E. coli/faecal coliform levels appear to be managed by the current harvest criteria.
<table>
<thead>
<tr>
<th>Growing Area classification</th>
<th>GA 1</th>
<th>GA 2 Case 1</th>
<th>GA 2 Case 2</th>
<th>GA 3 Case 1</th>
<th>GA 3 Case 2</th>
<th>GA 3 Case 3</th>
<th>GA 4</th>
<th>GA 5</th>
</tr>
</thead>
<tbody>
<tr>
<td>Routine monitoring results compliant with classification</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Shellfish harvested in compliance with harvest criteria</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
<td>Y</td>
</tr>
<tr>
<td>Harvest criteria tightened in previous 3 years</td>
<td>Y (3 yrs previously)</td>
<td>Y (same yr as outbreak)</td>
<td>Y (3 yrs previously)</td>
<td>Y (several times within previous yr)</td>
<td>Y (3 yrs previously)</td>
<td>Y (several within previous yr)</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Improvement to harvest criteria not mandatory but being considered at time of outbreak/ Concerns expressed in Annual Report</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>N</td>
<td>N</td>
</tr>
<tr>
<td>Previous history in last 12 months of intermittent elevated faecal coliform/E. coli results that were not definitively resolved by field investigations</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>Y</td>
<td>Y</td>
<td>N</td>
<td>N/A</td>
<td>N</td>
</tr>
<tr>
<td>Processor’s batch test E. coli results &gt;230 MPN/100g</td>
<td>N/A</td>
<td>N</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N (after depuration)</td>
<td>N</td>
</tr>
<tr>
<td>Processor’s batch test E. coli results ≤230 MPN/100g</td>
<td>N/A</td>
<td>N</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
<td>N (after depuration)</td>
<td>Y (2/3 sample occasions</td>
</tr>
</tbody>
</table>

Table 9.1: Cross-case summary of observations relating to shellfish programme standards in each growing area at the times when NoV outbreaks occurred.
Compliance with harvest criteria

In all cases, oysters implicated in the NoV outbreaks were harvested in compliance with the growing area harvest criteria of the time. These criteria are established using bacterial indicators of faecal contamination (i.e. faecal coliforms or *E. coli*) in water and shellfish. The source of these coliform indicators (i.e. whether from human, cattle, etc) is not distinguished within the monitoring programme, and in interpretation of monitoring results there is no weighting of risk based on presumed sources.

In instances in which human enteric viruses are a component of run-off entering a growing area, harvest closure times, which are based on the water clearance and shellfish depuration times of faecal coliform/*E. coli* indicators, would be too short to allow for the depuration of NoV from oysters. These case studies illustrate that NoV outbreaks can occur if the tacit assumption drawn from the sanitary survey that there are no significant levels of human sewage contamination in run-off impacting on growing waters is incorrect.

Changes in harvest criteria / On-going concerns below trigger level for non-compliance:

In several growing areas (e.g. GA 1, GA 2, GA 3) difficulties with compliance with water and/or shellfish standards resulted in revision of the harvest criteria prior to NoV outbreaks (in some cases trending toward increasingly complex harvest criteria, such as in GA 3), suggesting the possibility of decreasing water quality and/or patterns of faecal contamination that were difficult to manage based on simple harvest criteria.

Information from the Annual Reports suggests that in four cases (GA 1, GA 2 Case 1, GA 3 Cases 1 & 2) there were on-going concerns about the ability of the harvest criteria to effectively manage shellfish quality at harvest as a result of intermittent elevated faecal coliform/*E. coli* results. These issues had not been definitively resolved by field investigations. GA 5, which was subject to a NoV outbreak arising from the breach of a pipe under a pond in the WWTP by a contractor (an unexpected event unrelated to the environmental conditions or routine run-off in the catchment) was the only Conditionally Approved area in which the harvest criteria had not been revised in the previous three years and/or where there were no on-going concerns arising from routine monitoring results.

Compliance with standards based on bacterial indicators

In all cases in which data were available from “Conditionally Approved” growing areas (e.g. Growing Areas 1, 2, 3 and 5), water and oyster samples taken from the growing area either when NoV contamination was known to be present in oysters, or when the source of NoV contamination was known to be impacting on the growing area, had faecal coliforms/*E. coli* levels below the regulatory level of a median 14 MPN/100 ml (faecal coliforms in water), 300 MPN/100g (faecal coliforms in flesh), or 230 MPN/100g (*E. coli* in flesh). In most cases, bacterial indicator levels were not elevated above background levels at all. In one case (GA 5), post-harvest batch testing of oysters by the processor from oysters harvested during the sewage spillage did show elevated *E. coli* levels, but the levels were below 230 MPN/100g and no action was required or taken. These results demonstrate that the standards based on *E. coli/faecal coliform* indicators do not reliably protect against the risk of NoV contamination. The results from the case studies are consistent with a large body of evidence from research which shows that on a sample-by-sample basis coliform bacteria are not reliable indicators of the presence of human enteric viruses in either shellfish or their...
growing waters (e.g. Metcalf, 1978; Gerba, 1979; Goyal et al., 1979; Dore & Lees, 1995; Burkhardt et al., 2000).

In the case in which an oyster depuration process was applied after harvest (GA 4), the post-depuration oyster sample contained no detectable faecal coliforms and met the required bacterial standard, but the oysters were implicated in a NoV outbreak. Assuming the NoV contamination occurred in the growing area, this is consistent with a large body of evidence from research which shows that commercial depuration processes over 48 hours are not effective in reducing human enteric viruses to a safe level (e.g. Canzonier, 1971, Grohmann et al., 1981; Power & Collins 1989; Power & Collins, 1990; de Medici et al, 2001).

The above outcomes show that because of the unreliability of faecal coliform/E. coli indicator standards with respect to virus contamination, the current shellfish programme is strongly reliant on its sanitary survey component in managing the risk of contamination of shellfish by human enteric viruses.

9.1.2 Issues relating to sources of contamination

Awareness of potential sources of contamination
With one exception (e.g. the use of contaminated creek water as wash water for harvested oysters in GA 2 Case 2), in all the case studies the presence of the actual or potential sources of NoV contamination that were identified in the outbreak investigation had previously been acknowledged in a broad sense in Sanitary Survey Reports as potential risks – i.e. the presence of wastewater treatment plants and reticulation systems, on-site sewage systems, and boats in the growing area catchment. In these cases the investigation prompted by an illness outbreak resulted in the revelation of more detailed information that could have significantly impacted on the assessment and management of risk of virus contamination of the growing area had it been known earlier. This is particularly evident in those investigations that were undertaken in close collaboration with the Council and their consultants (e.g. GA 2 Case 2, GA 3 Case 3 and GA 4).

Sources of viral contamination
The commonalities across the case studies provide some insight into the reasons for the failure of the shellfish management programme to prevent NoV contamination of oysters in the growing area. The range of implicated sources across the case studies included discharges from on-site sewage systems, effluent from wastewater treatment plants, spillages from sewerage reticulation systems, and discharges from boats. Table 9.2 summarises the sources of NoV contamination implicated in each case. These data indicate that on-site sewage systems are the most commonly implicated source of NoV contamination.
<table>
<thead>
<tr>
<th>Case</th>
<th>On-site Sewage Systems</th>
<th>WWTP</th>
<th>Sewerage Reticulation System</th>
<th>Boats</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td>GA 1 Case 1</td>
<td>√</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GA 2 Case 1</td>
<td>√</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GA 2 Case 2</td>
<td>√</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GA 3 Case 1</td>
<td>√</td>
<td>?</td>
<td>√</td>
<td></td>
<td></td>
</tr>
<tr>
<td>GA 3 Case 2</td>
<td>?</td>
<td>?</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GA 3 Case 3</td>
<td>√</td>
<td>√</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GA 4 Case 1</td>
<td>√</td>
<td>√</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>GA 5 Case 1</td>
<td>√</td>
<td></td>
<td></td>
<td></td>
<td>Pipe ruptured by contractor working at WWTP</td>
</tr>
</tbody>
</table>

Table 9.2: Summary of the sources of norovirus contamination implicated in each case study. The shading is an assessment of the level of evidence supporting each implied source. Blue shading = possible source within catchment, no actual effluent discharge observed within relevant time frame; Yellow shading = Effluent of a quality highly likely to contain norovirus known to be discharged and hydrodynamic studies support its possible transport to the growing area; Orange shading = Discharge of raw or minimally treated effluent observed by visual observation and/or dye study and/or monitoring results, and hydrodynamic studies have shown that effluent could be transported to the growing area close by.

**Consideration of seasonality with case studies**

The case studies were reviewed to ascertain if there was any commonality in the season of the year that the outbreaks occurred. This information is summarised in Table 9.3.

<table>
<thead>
<tr>
<th>Case Study</th>
<th>Month</th>
</tr>
</thead>
<tbody>
<tr>
<td>GA 1 Case 1</td>
<td>September</td>
</tr>
<tr>
<td>GA 2 Case 1</td>
<td>June</td>
</tr>
<tr>
<td>GA 2 Case 2</td>
<td>June/July</td>
</tr>
<tr>
<td>GA 3 Case 1</td>
<td>November</td>
</tr>
<tr>
<td>GA 3 Case 2</td>
<td>November/December</td>
</tr>
<tr>
<td>GA 3 Case 3</td>
<td>August</td>
</tr>
<tr>
<td>GA 4 Case 1</td>
<td>June</td>
</tr>
<tr>
<td>GA 5 Case 1</td>
<td>July</td>
</tr>
</tbody>
</table>

Table 9.3: Summary of the case studies showing the month of the year that the implicated oysters were harvested. Data from Growing Area 5 have been excluded. Blue highlighting indicates case studies in which on-site sewage systems were implicated as contamination sources and in which it is known that there was a previous closure to harvest due to a rainfall event prior to compliant harvest of implicated oysters.
Five out of eight cases occurred during the winter months of the year (June, July, August). International data suggest that NoV are more prevalent in shellfish during the winter months, which could be related to higher levels of illness in the community during winter (e.g. Lowther, 2011).

Table 9.3 shows that in Growing Areas 1-5, all oysters implicated in NoV illness events were harvested between June – early December (winter/spring season). For all cases in which data were available, information indicates that rainfall sufficient to close the growing area to harvest had occurred prior to the event (although in all cases the areas were officially open for harvest) (no data were available for GA 3 Case 1). Table 9.2 shows that for all of the case studies except GA 3 Case 2 and GA5 Case 1, on-site sewage systems were implicated as potential NoV contamination sources (we note that there was some possibility of the implication of on-site sewage systems in GA 3 Case 2 also). The blue highlighting of cases in Table 9.3 indicates cases in which on-site sewage systems were potential NoV sources and in which a previous rainfall event had occurred. Rainfall is a conduit for pollution to reach the harvest area. However, chronic rainfall during winter and early spring is especially problematic as it can cause soils to become saturated which often means failing on-site disposal systems. The combination of cold ambient conditions, low levels of natural UV from sunlight, saturated soils and chronic rainfall not only provides the conditions for the failure of on-site disposal systems, but also provides the best conditions for the viruses to survive in the environment. Winter - late spring is also the major harvest season for oysters as they are in prime condition before spawning in early summer.

**On-Site Sewage Systems**

Table 9.4 summarises the kinds of deficiencies identified in the reports on the investigations of the performance of on-site sewage systems following NoV outbreaks in each growing area. This shows that deficiencies at several levels in the management of on-site sewage systems led to discharge into waterways and the implication of NoV contamination of oyster growing areas. These included:

- Inadequate maintenance, which is the responsibility of the system operator, but in some cases (e.g. GA 4), should have been monitored by the Council;
- The operation of systems of a design inadequate to prevent contamination of watercourses and not approved by Council;
- The modification of approved systems, or the installation of systems in a manner that is not compliant with the approved design; and
- Failure of systems (particularly effluent disposal fields) designed and installed in accordance with Council requirements.

In one case (GA 4), a comprehensive review of Council systems revealed that, with the exception of design standards, which were not reviewed, at each potential control point their management protocols for on-site sewage systems were inadequate to effectively prevent environmental contamination. This was of significant concern, as ostensibly their published management strategy for on-site sewage systems appeared to manage the risk of virus contamination of oyster growing areas well.
Reasons for defective on-site sewage systems

<table>
<thead>
<tr>
<th>Reasons for defective on-site sewage systems</th>
<th>GA 2 Case 1</th>
<th>GA 2 Case 2</th>
<th>GA 3 Case 3</th>
<th>GA 4 Case 1</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inadequate maintenance</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Design not approved/non-compliant with standards</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Installation not compliant with approved design</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>Design meets regulatory standards and guidelines but is not effective in preventing environmental contamination</td>
<td>√</td>
<td>√</td>
<td>√</td>
<td></td>
</tr>
</tbody>
</table>

Table 9.4: Summary of drivers for observed deficiencies in on-site sewage systems based on reports of growing area investigations following norovirus outbreaks.

Several issues impacting on failure to ensure on-site sewage systems do not contaminate waterways were common across cases. One recurring issue was the poor quality of on-site system inspections undertaken by personnel on whom reliance is placed to provide robust observations. This impacted on the ability to detect malfunctioning systems. In several cases the outcome of inspections by Environmental Health Officers, on-site system maintenance service providers or Food Authority personnel were inconsistent with conclusions drawn when premises were re-inspected by more skilled personnel or expert consultants. In GA 4 this was identified as resulting from a combination of lack of systematic inspection protocols, levels of expertise, and differences in environmental conditions at the times of inspection (e.g. ground saturation, occupation of dwelling).

The failure by Councils to inspect on-site sewage systems was also a factor in the undetected installation of systems of unapproved design. On our enquiry, lack of resources was one reason cited by several Councils for this. One Council responded that inspections of existing on-site sewage systems were undertaken only when the Council received a complaint that a system was malfunctioning (usually from neighbours). In GA 4, Council officers also noted logistical difficulties (such as the difficulty in getting a Building Inspector to a site at short notice while all the features of the system were still visible to be checked) were barriers to completing full inspections (particularly with respect to the installation of effluent disposal fields).

The failure of on-site sewage systems that were designed apparently in accordance with approved design standards or guidelines to prevent discharge to waterways arising from effluent break-out during saturated soil conditions in three case studies is of significant concern. In one growing area, (GA 2) the same on-site system was implicated in two cases, and the original and upgraded designs had both been approved by Council. Most cases of design failure investigated by Councils related to lack of sufficient or appropriate consideration of soil type and distance to watercourses or the
coast. However it is clear that even expert opinions can differ significantly in the field of on-site sewage system design: in the case of GA 3 Case 3, we note that two different consulting engineers engaged by the Council at different times to advise on remediation of on-site sewage systems at the Point differed significantly in their opinions with respect to the issue of the adequacy of design of existing systems in relation to the soil type. In this case, regulations by local and regional Councils also differed with respect to the minimum size of section for properties with on-site sewage systems at this site.

In GA 4, a review of Council processes with respect to the design, alteration and installation of on-site sewage systems identified failures at multiple control points, including failure to ensure that sufficient information about the site was provided in the application process, failure to check that all aspects of the system design were appropriate to site conditions, and reliance on the applicant’s site report and design by a “qualified person” without defining what qualifications were required. In addition, it was found that there were no systematic processes of checking that the on-site system had been constructed, installed (or, in the case of alterations, modified) in accordance with the approved design, and that in some cases this was not checked at all.

**Changes in management of on-site sewage systems following outbreaks**

Although defective on-site sewage systems were implicated in the NoV contamination of oysters in five illness outbreaks, in only two cases were substantial changes made by Councils in the way in which on-site sewage systems were managed. In both these cases the Councils were working collaboratively with oyster farmers and the Food Authority in an active investigation of contamination sources, and had hired in expert assistance. Changes included the development of a new on-site sewage system management strategy, and improved management procedures and documentation in GA 4, and the development of a management plan for on-site sewage systems at the Point in GA 3. The Council in the GA 3 region also implemented new by-laws with respect to the maintenance and inspection of on-site sewage systems. However, it appears that improvements in the management of risk of virus contamination introduced following a NoV outbreak investigation are not necessarily rigorously maintained into the future. For example, in the latter case (GA 3), the by-law introduced to regulate the maintenance and inspection of on-site sewage systems was recently amended by Council because of cost and difficulties in its implementation. The amended by-law was less rigorous than the original one, and on-going monitoring of the quality of stormwater from the Point, which acted as a check on run-off from on-site sewage systems, does not appear to have been maintained by the Council at the intensity defined by the management plan. Since the growing area was reclassified as “Conditionally Approved” following remediation of contamination sources, no monitoring results have been reported by the Council to the Food Authority. Lack of continuing vigilance of potential contamination sources on the part of Councils and the Food Authority increases the risk of future NoV contamination events from known potential sources.

**Wastewater Treatment Plants**

The effluent discharged routinely from wastewater treatment plants was identified as a potential source of contamination in two cases. In both cases the WWTP was situated some distance from the growing area, but hydrodynamic studies identified that on occasion effluent from the plant could be transported to the growing area. In each case the level of treatment routinely provided at the plant with respect to viruses was of potential concern, and this issue was exacerbated in both cases by maintenance issues that reduced the level of treatment to below its design specifications. In addition, there was a possibility that a valve failure that allowed partially treated effluent to be discharged during a power cut may have been linked to the NoV outbreak in one event. This malfunction was not communicated to the Food Authority at the time.
Spillage/Exfiltration from Sewerage System
In all cases there was a formal written agreement between the Council and Food Authority to ensure that the Food Authority is notified of any sewage spillages likely to impact on shellfish growing areas. This tends to work effectively in protecting the health of shellfish consumers provided that the spills are detected in a timely manner and the communication of events to the Food Authority is consistently reliable. In two of the three spillage events implicated in NoV outbreaks, breakages were not detected until investigation of potential sources of contamination prompted by the illness outbreaks (i.e. GA 4 and GA 5). In GA 5, intensive shoreline surveys by industry and checks by Council failed to find the source of contamination, but the discharge from the WWTP pond was detected by chance by observant children at a time when the effluent was discoloured by work being undertaken in the pond. It is possible that in this case more rigorous monitoring of the influent and effluent flow rates at the WWTP could have detected the breach in the pipe more rapidly. In case of GA 4, the detection of the broken sewer pipe at a caravan park followed an intensive investigation (dye testing, followed by inspection of the sewer by video camera). Previous less thorough investigations of this site undertaken by the Council at the insistence of the local oyster farmers prior to and after the illness outbreak had failed to identify any problems. This illustrates the practical difficulties in readily detecting some sources of effluent spillage.

In GA 3 Case 1, contamination arising from the broken sewer main at the river was detected well before the illness outbreak as a result of routine monitoring for faecal coliforms in water samples taken by the local Council as a condition of the resource consent associated with the WWTP. Both the local and regional Councils failed to report this contamination event to the Food Authority, even on enquiry after the illness outbreak, and it was not revealed until a review of Council documents undertaken by a consultant after a third NoV outbreak in the same growing area seven years later. Had the Food Authority been notified they would have been able to make an informed choice about whether the growing area should be open for harvest.

Although there was no indication of NoV risk from monitoring of bacterial indicators in the growing areas, in the cases of GA 3 Case 3 and GA 4 the presence of an effluent discharge was apparent from faecal coliform testing of water samples close to the source of discharge (by local Council in the former case, and by oyster farmers in the latter case). In both these cases, sewage spillage could have been prevented by more timely maintenance or replacement of a sewer line.

Discharge from boats
Discharge of effluent from boats was suggested as a possible cause of NoV contamination in three cases all from the same growing area (GA3). Frequently one of the difficulties in attributing NoV contamination to effluent discharge from boats with any certainty is the lack of evidence other than the presence of boats in the general vicinity of the growing area. Officials have no authority to board boats to confirm whether or not they have facilities to contain effluent, and are generally not on hand to observe effluent discharge. In addition, the risk presented by effluent discharge depends on the health status of the people on board. In none of the three cases at Growing Area 3 was NoV contamination definitively linked to boat discharges, although the presence of popular mooring areas, and latterly a marina within a few kilometres made this source a possibility. At the time when the first two cases occurred (1994, 1999) there was no regulatory control preventing the discharge of effluent from boats in shellfish growing areas. By the third outbreak in 2001, regulations had been introduced that prohibited the discharge of untreated effluent from boats in less than 5 m of water and within 500 m of a marine farm. It is likely that this distance would be insufficient to prevent significant NoV contamination of shellfish on an inter-tidal oyster farm if faeces or vomit from a person infected with the virus were discharged from a boat. This suggests
that even if all boats complied with the regulations, this would have been insufficient to prevent NoV contamination of oysters as there were areas within the inlet and the channel leading to it where discharge from boats was permissible because the depth was >5m. By the advent of the second outbreak, a seasonal closure to harvest had been established to manage the risk of discharge from boats, but a subsequent Council report on boat numbers in the area revealed that this did not extend to the time of peak visits to the area from yachts travelling internationally. With the cooperation of the regional Council, the management of the risk of effluent from boats in this growing area has subsequently been significantly reduced by a combination of measures, including extension of the “no discharge” zone through a modification of the Council Coastal Plan, monitored controls preventing discharge at the marina, provision of more on-shore toilet facilities at the wharf and marina, and public education including visits to moored boats during the peak boating season. At the time of writing this report, discussion with the regional Council suggests that these management measures have currently been maintained.

Reliance on other agencies to supply information for Sanitary Surveys
In all cases the Food Authority relied heavily on the cooperation of Councils and their service providers to supply the information required to assess the risk of viral contamination from on-site sewage systems, wastewater treatment plants and reticulation systems. This reliance is necessary because detailed information about the design and maintenance of these systems can impact significantly on risk. The development of microbial source tracking techniques and other techniques that allow the identification of the presence of human sewage contamination in shellfish growing areas is relatively recent, and none of these techniques were reported to have been utilised in the routine Sanitary Surveys undertaken prior to outbreak events.

Testing for Norovirus
Table 9.5 shows the results of NoV testing of oyster samples associated with NoV outbreaks across all cases studies. Although the technology for detection of NoV in human faecal samples was well-established and results were available promptly, fewer oyster samples were tested for NoV in early cases such as GA 3 Cases 1 & 2 because the technology for detection of NoV in shellfish samples was still in the early stages of development. In GA 3 Case 1, it was over 7 months after the outbreak before the results of NoV analysis of an oyster sample were reported to the Food Authority, and in GA3 Case 2 the absence of a validated test method in the local laboratory and consequent requirement to get the results confirmed by a laboratory in England resulted in a five week time lag between the outbreak and the reporting of oyster sample results. In the latter case, these results were required by the Food Authority before an official product recall was initiated. The delay before the oyster sample results became available resulted in the consumption of frozen product remaining in the market and an additional four illness events. This illustrates the importance of having a laboratory with the capability and capacity to provide prompt sample analysis in situations in which time-critical management decisions rely on the results.
<table>
<thead>
<tr>
<th>Growing Area/Case Study ID (Year)</th>
<th>Results of Norovirus Testing of Oyster Samples</th>
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</thead>
<tbody>
<tr>
<td></td>
<td>From Leftover Oysters</td>
</tr>
<tr>
<td>GA 1 Case 1 (2008)</td>
<td>Positive^A</td>
</tr>
<tr>
<td>GA 2 Case 1 (2004)</td>
<td>Positive^B</td>
</tr>
<tr>
<td>GA 3 Case 1 (1994)</td>
<td>Positive^C</td>
</tr>
<tr>
<td>GA 3 Case 2 (1999)</td>
<td>Positive^B (1/2)</td>
</tr>
<tr>
<td>GA 3 Case 3 (2001)</td>
<td>NT</td>
</tr>
<tr>
<td>GA 4 Case 1 (2008)</td>
<td>NT</td>
</tr>
</tbody>
</table>

Table 9.5: Results of norovirus testing of oyster samples associated with norovirus outbreaks across all case studies. NT = Not tested; N/A = Not applicable. Superscript denotes norovirus analysis method as follows: A=Analysis by real-time RT-PCR; B=Analysis by semi-nested RT-PCR; C=Method unavailable. Colour coding: Blue = negative result; Orange = all samples positive; Yellow = some positive, some negative results within same time frame.

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18 Recovery method Jothikumar et al., 2005; Greening & Hewitt, 2008; Detection method: Kageyama et al., 2003.
19 Recovery method Greening et al., 2003; Detection: Greening et al., 2001
In both New Zealand and Australia, detection of NoV in shellfish samples is interpreted as a significant risk, and the management of shellfish quality is undertaken based on an assumption that any level of NoV found in shellfish could cause illness in consumers. However, data from overseas suggest that low levels of NoV can occur in shellfish in the absence of reported illness in consumers (e.g. Lowther et al., 2010). This may arise for a number of reasons: low illness reporting rates; residual NoV retained in shellfish tissue after a contamination event may become inactivated; and the risk of illness reduces significantly at low dose rates. The current NoV detection methods do not distinguish between infective and inactivated viruses. We note however that NoV was observed in oysters held on an inter-tidal oyster farm for over 8 weeks after having been fed with the virus (Greening et al., 2003), yet the management of the risk of viral illness based on 21-day or 28-day closures to harvest after human sewage contamination of growing areas (e.g. after sewage spills) is apparently effective. (Had the NoV outbreak in GA1 been attributable to the sewage spill 46 days prior to the illness event, this might have provided an exception to this). Across the case studies the results of NoV testing appear to generally concur with the presence of illness, in that:

- none of the samples taken after remediation of contamination sources/prior to reopening/reclassification contained detectable NoV (including samples taken from GA 3 in Case 3, which included 5 samples taken at each of 3 sampling events across different seasons/environmental conditions); and

- samples taken in temporal and/or spatial association with oysters implicated in the outbreak tended to contain NoV at detectable levels.

However the strength of this latter relationship varied between cases even within the context of an increase in the sensitivity of the test for NoV after the change from semi-nested RT-PCR to real-time RT-PCR techniques in 2006. For example, in contrast to the results of testing in GA 2 Case 1 for which most results were positive for NoV, in GA3 Case 3 none of the four samples that were taken temporally and spatially closest to the oysters consumed in the confirmed NoV illness outbreaks contained detectable levels of NoV. Similarly, in GA4 the sample with the closest temporal association with the implicated oysters was also negative for NoV. Ironically, it was in these two latter cases, which theoretically presented the weakest evidence for NoV contamination in the growing area, that two of the most thorough and intensive growing area investigations were undertaken (and consequently the most severe and long-lasting harvest restrictions). This response was influenced in GA3 by the detection of NoV in two oyster samples from the growing area in the previous year (one detected through border testing in an export market, and the other in a research programme, neither associated with illness) and there having been two previous NoV outbreaks associated with this growing area. In GA4 the response was prompted by the detection of further NoV in a significant number of samples taken subsequently to determine whether the contamination had cleared from the area.

In the first three cases shown in Table 9.5 (i.e. GA 1, and GA 2 Cases 1 & 2), the results of testing oyster samples for NoV are consistent with the occurrence of NoV contamination in the growing area. It is interesting to note however, that not all the samples tested from the same population contained NoV i.e. in two instances in which oyster samples were taken from the same population there was a variation between the sample results (e.g. GA 2 Case 1 samples from implicated batches and GA 3 Case 1 samples from left-over oysters both had one sample result that was positive and the other negative). This reconfirms that in instances when it is important to verify the absence of NoV, several replicate samples should be tested, as is currently required to clear an area for reopening to harvest.
9.2 Analysis across Cases within Units (Growing Areas)

Shoreline surveys: Intensity and spatial and temporal issues
Two oyster growing areas in this study were associated with several NoV illness events: GA 2 in 2004 and 2008, and GA 3 in 1994, 1999 and 2001. In both growing areas the scope and depth of growing area investigations increased with successive outbreaks: in GA 2 the investigation process was similar in both instances (i.e. inspection of on-site sewage systems, consideration of boat numbers/movements/live-aboards, and visual inspection by boat to determine whether there were any other likely sources) but the spatial range of the property-by-property inspection of on-site sewage systems was increased from the immediate growing area catchment and 5 km up-river in 2004, to include the shoreline 10 km up-river in 2008. There was a similar increase in the range of intensive investigation in GA 3 through the three outbreaks there – for example, inspections of on-site sewage systems on each property was extended from the immediate catchment on the shores of the Inlet adjacent to the growing area in 1994 and 1999, out to the Point and beyond the port area, and approximately 10 km up-river in the estuary adjacent to the Inlet in 2001. The range of information sources was also extended significantly in the investigation following the third outbreak in GA 3: due to the involvement of the local and regional Councils in the investigation, the Council records and information were reviewed, and this resulted in a more in-depth understanding of the risks presented by many of the potential pollution sources identified in the Sanitary Survey. In both growing areas the more intensive/extended investigations identified potential sources of contamination that were subsequently assessed as risks by the Food Authority, and which required remediation before the area reopened to harvest for direct sale. In both cases the importance of having up-to-date information about the potential risks was highlighted, as was the necessity of having detailed knowledge about potential contamination sources in order to robustly assess their risk to shellfish quality.

In GA 3 a number of the potential sources identified during the collaborative investigation with the Councils after the third outbreak could also have been significant sources of NoV contamination in the second outbreak 20 months earlier (e.g. on-site systems at the Point, WWTP), yet at that time they were not recognised as requiring detailed investigation or remediation. It was clear from correspondence that the Food Authority had concerns about the safety of shellfish in the growing area, but lacked solid evidence to support their concerns as the area was still technically compliant with its classification. We note that Food Authority officers from several growing areas mentioned to us that because of the economic impacts of downgrading the classification of a growing area, this is not a step to be taken lightly and Food Authorities require solid evidence that such an action is necessary. In the case of GA 3, the third NoV event convinced the Food Authority that the potential sources of contamination in the growing area were not predictable or manageable, and the area was reclassified as “Restricted”. The predicted economic impact of that action prompted the Councils to collaborate with the oyster farmers in investigation and then remediation of potential sources of contamination. In this manner the barriers to collecting the depth of sanitary survey information required to more robustly assess the risk of faecal contamination of the growing areas from each potential source were overcome. This high level of cooperation and communication from the Councils continued through to the reclassification of the growing area as “Conditionally Approved” eight years later, but appears to have reduced subsequently.

Reliance on good design
The implication of break-out from the effluent disposal field from same on-site sewage system at the oyster processing factory in two NoV outbreaks associated with GA 2 raises several issues. Firstly, the initial system design was approved by Council when it was first designed and installed,
and the extension to the disposal field following the first NoV outbreak was similarly approved. The volume of effluent processed was in both instances within the design capacity of the system, and the system had been maintained according to the manufacturer’s maintenance plan. This suggests that the design of the system and/or the maintenance programme were not adequate to prevent contamination of the estuary close by.

As discussed earlier with respect to these and other cases, the failure of on-site sewage systems may be related to seasonal rainfall and associated soil saturation (see discussion relating to Table 9.2). It is important that the design of all wastewater systems takes account of this adverse environmental condition with respect to potential viral contamination.

**Management measures to prevent repeat contamination**

The second issue highlighted by the occurrence of two illness outbreaks with the same implicated source in GA 2 relates to ongoing management of implicated sources. The first contamination event arising from the on-site sewage system was associated with management failures by two parties (i.e. the failure of the maintenance provider (who had inspected the on-site sewage system in the week prior to the shellfish contamination) and the system operator to detect the visible evidence of effluent break-out). That this management failure was repeated in the second event suggests in hindsight that after the first outbreak there was insufficient consideration at the factory of how to improve management to ensure that any recurrence of the same issue in the future would be detected in a timely manner. (If the exfiltration from the disposal field only occurred during rainfall and was not readily observable, then this presents a management problem in itself – perhaps a solution would have been occasional dye testing during saturated soil conditions). There was an understandable but untested assumption that changes to the disposal field recommended by an expert had solved the problem. In addition, there was no evidence in the Annual Review reports between 2004 and 2008 (or indeed subsequently) of any ongoing attention from the Food Authority as to how well this potential contamination source was being managed. Total reliance was placed on the adequacy of the on-site system design to prevent contamination of the estuary. In contrast, after the third outbreak in GA 3, where there was less confidence in the design on-site systems at the Point, a management plan was established that included monitoring of stormwater quality to confirm the absence of run-off from on-site systems. As discussed previously, this monitoring has not been sustained. These examples illustrate how failure to sustainably address potential contamination sources can result in repeated NoV illness events.
SECTION 10  DISCUSSION

10.1 Introduction

The case studies have raised a number of significant issues relating to the failure to prevent human enteric virus contamination of shellfish within a Shellfish Quality Assurance Programme. Broadly these included:

- The unreliability of *E. coli* and faecal coliform indicators in predicting the presence of NoV in shellfish and their growing waters, with a consequent strong reliance on the other sanitary survey components of the Shellfish Quality Assurance Programme in managing the risk of virus contamination in growing areas.
- Issues relating to the intensity, extent and timeliness of information required for the shoreline survey component of the Shellfish Quality Assurance Programme to consistently protect shellfish consumers against viral illness.
- Failure to apply hindsight in the ongoing management of growing areas following a NoV event.

Where possible the management issues acting as drivers to raise the risk of virus contamination sources in growing areas were also examined in the case studies, with a view to elucidating how to improve the assessment and management of this risk.

This section discusses the observations made in the case analysis and explores the opportunities and barriers to improving the management of the risk of enteric virus contamination.

10.2 The use of coliform indicators in the regulatory framework

In common with many countries overseas, the current Shellfish Quality Assurance Programmes in New Zealand and Australia use the bacterial indicators *E. coli* and faecal coliforms to assist in the classification of shellfish growing areas, to provide the basis for setting harvest criteria, and to confirm the growing area classification on an ongoing basis. Evidence in the case studies showed that in all growing areas from which harvested oysters were implicated in NoV outbreaks, the monitoring data indicated that the growing area was in compliance with its classification, the implicated shellfish were harvested in compliance with the growing area harvest criteria, and all growing water and implicated shellfish samples tested met the regulatory faecal coliform/*E. coli* standards.

Depuration, which is a process founded on studies of the reduction of bacterial indicators in shellfish placed in clean water, and which is confirmed as effective by testing for coliform indicators (faecal coliforms/*E. coli*), had been applied to oysters implicated in the NoV outbreak in one case study (GA 4). A post-depuration oyster sample met the regulatory coliform standard. The depuration processes applied commercially are known to be ineffective in reducing enteric virus contamination to safe levels (e.g. Canzonier, 1971; Scotti et al., 1983; Power & Collins, 1989; Power & Collins, 1990; de Medici et al., 2001) and depurated shellfish have been previously linked to illness in consumers (e.g. Grohmann et al., 1981; Heller et al., 1986; Lowther et al., 2010).

The case studies unequivocally demonstrate that the manner in which faecal coliform indicators are used in the current Shellfish Quality Assurance Programmes fails to consistently predict the risk of
enteric virus contamination in shellfish harvested for market. This finding is unlikely to be a surprise to anyone in the field of shellfish regulation - the disparity between science and the regulatory framework has been known for many years since it became clear from research studies that bacterial indicators are not reliable indicators of viruses in either shellfish or their growing waters on a sample-by-sample basis (e.g. Metcalf, 1978; Gerba, 1979; Goyal et al., 1979; Gerba et al., 1979; Gerba et al., 1980; Fattal et al., 1983; Dore & Lees, 1995; Burkhardt et al., 2000).

Although the relationship between faecal coliforms/E. coli and human enteric viruses has been investigated in a number of studies, internationally little investigation has been undertaken to investigate how well the regulatory shellfish standards based on E. coli or faecal coliforms predict the presence of significant virus levels. However, the raw data presented in some published papers provides an opportunity for such analysis to be undertaken. The CEFAS study (Lowther, 2011) which included analysis for E. coli, NoV GI and NoV GII in 856 oyster monthly samples over 18 months from 39 sites in the UK, provides one of the most comprehensive datasets currently available. As discussed in Section 2.4.2, the Lowther study demonstrated a moderate positive relationship between the geometric means of E. coli and NoV levels in shellfish. This provides some support for the way in which faecal coliform/E. coli indicators are used in the classification of growing areas, i.e. there is likely to be less risk of significant virus contamination in a growing area classified as “Approved” than one classified as “Restricted”. It also suggests that trends of deteriorating water quality observed by faecal coliform/E. coli indicators (as potentially indicated in many of our case studies by the history of tightening harvest criteria and concerns about intermittently high indicator levels – see Table 9.1) can indicate increasing risk of viral contamination. However, this falls short of confirming that the standards used for classification of areas are sufficiently reliable in predicting the risk of viral contamination. Using the raw data published in Lowther (2011) it is possible to investigate the relationship between the background levels of E. coli in oysters at each site (measured by median or geometric means across the 18 month study within each site) and the percentage of potentially significant NoV levels in oysters that were predicted by E. coli levels in shellfish of >230 MPN/100g (see figure 10.1). Our analysis by Spearmans Rank Correlation indicates a strong positive relationship between the within site oyster E. coli median values and the within-site percentages of NoV levels predicted by oyster E. coli levels >230 MPN/100g. A similar relationship is revealed by analysis of the raw data published in Romalde et al. (2002). These data were derived from a study of E. coli, enteroviruses and hepatitis A levels in 164 shellfish samples collected across 11 zones of the Galician coast of Spain. Analysis of the relationship between within zone median shellfish E. coli levels and the percentages of enterovirus and/or hepatitis A predicted by E. coli levels in shellfish >230 MPN/100g using Spearman’s rank correlation also shows a strong positive relationship between the two factors. In simple terms these observations indicate that the lower the background levels of E. coli in shellfish in a growing area, the lower the percentage of virus “detects” (in the case of the UK study, defined as NoV>100 copies/g) that are predicted by the E. coli standard of >230 MPN/100g.

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20 Spearmans rho = 0.62, df = 36, p = 0.00003. A similar relationship is observed using the geometric mean of E. coli levels within each site instead of the median values (rho = 0.59, p = 0.00009)
21 Spearmans rho = 0.67, df = 9, p = 0.02
Relationship between within site median \( E. coli \) levels and % of NoV >100 gene copies/g predicted by \( E. coli \) standard at each site

<table>
<thead>
<tr>
<th>Median ( E. coli ) levels in oyster samples at each site (MPN/100g)</th>
<th>% of NoV levels &gt;100 gene copies/g predicted by ( E. coli ) &gt;230 MPN at each site</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>0</td>
</tr>
<tr>
<td>200</td>
<td>200</td>
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Figure 10.1: Scatter plot showing the relationship between the within site median \( E. coli \) levels and the percentage of NoV levels >100 gene copies/g that were predicted by \( E. coli \) levels >230 MPN/100 g in oysters sampled from 38 sites over 18 months in the UK. (Source: B. Hay analysis of raw data published in Lowther (2011)).

Relationship between within zone median \( E. coli \) levels and percentage of virus "detects" predicted by \( E. coli \) >230 MPN/100g

<table>
<thead>
<tr>
<th>Within zone median ( E. coli ) (MPN/100g) (log scale)</th>
<th>Within zone % of virus &quot;detects&quot; predicted by ( E. coli ) &gt;230MPN/100g</th>
</tr>
</thead>
<tbody>
<tr>
<td>0.0</td>
<td>0.0</td>
</tr>
<tr>
<td>1</td>
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<td>10000</td>
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Figure 10.2: Scatter plot showing the relationship between the within site median \( E. coli \) levels and the percentage of samples in which enteroviruses and/or hepatitis A virus that were predicted by \( E. coli \) levels >230 MPN/100g in shellfish sampled from 11 sites in Galicia, Spain. (Source: B. Hay analysis of raw data published in Romalde et al. (2002)).

One might therefore expect that in an Approved growing area the incidence of virus contamination would be lower than in a Restricted growing area, but that a lower percentage of virus contamination in an Approved area would be predicted by the occurrence of \( E. coli \) levels in shellfish >230 MPN/100g. In the Lowther (2011) data, in Class A sites (n=6) the within site mean percentage of samples that contained a NoV level >100 copies/g was 19.4%, and of these, the within site mean percentage that were predicted by oyster \( E. coli \) levels >230 MPN/100g was 11.3%. For Class B sites (n=31), the figures were 39.5% and 45.1% respectively. In our case
studies, the absence of any faecal coliform/E. coli levels >300 MPN/100g or >230 MPN/100g respectively in shellfish sampled concurrently with those from Conditionally Approved areas implicated in NoV illness is consistent with this observed relationship.

Consideration of the possible factors that drive this relationship are relevant to the classification of growing areas. One significant contributing factor to this relationship may be that higher background levels of faecal coliforms/E. coli reflect closer proximity to the source of faecal (and thus viral) contamination. As discussed in Section 2, viruses persist longer in the environment than faecal coliforms/E. coli and thus can be detected at a greater distance from their source than the bacterial indicators. This is supported by our further analysis of the raw data from Galicia provided in Romalde et al. (2002): In one zone sampled during their study, feral mussels were sampled from close to the shore, and mussels of the same species were sampled from farms off the shore where they were hung from rafts. Our analysis indicates that the percentage of the total samples in which enteroviruses and/or hepatitis A was detected was similar for feral mussels (53.33%, n=15) and raft mussels (57.9%, n=19), but while 62.5% of the virus contamination found in the feral mussels close to the shore was predicted by E. coli levels in mussels >230 MPN/100g, only 9.1% of the virus contaminated samples of the raft mussels was predicted by the E. coli above this level. Romalde et al. (2002) commented that the higher E. coli levels generally observed in shellfish closer to shore were likely to result from closer proximity to the faecal contamination.

In growing areas in which faecal contamination is sporadic (such as might be found in Conditionally Approved areas) but contains a component of human faecal contamination, the longer persistence of viruses than bacteria in shellfish could also contribute to the relationship observed in Figures 10.1 and 10.2.

Within the context of this relationship, the potential benefits of increased frequency of monitoring for faecal coliforms/E. coli (such as increasing sampling events in the growing area, or the voluntary batch testing for E. coli in harvested shellfish undertaken by some processors) has limited value: increasing sample frequency results in a better estimate of the background levels of faecal coliform/E. coli indicators in the growing area, which can provide a very general indication of the overall risk of virus contamination. However it is of minimal benefit in determining whether shellfish are safe for consumption since viral contamination can occur in the absence of the indicators, particularly in Approved growing areas which by definition have low levels of bacterial contamination.

One important point to note in the management of virus contamination is that viruses will not be present in faecal contamination unless the viral illness is present in the population within the growing area catchment. In catchments with few houses present, all served by on-site sewage systems (as is the case in many of the growing areas in our case studies), viruses may not be a common component of faecal contamination impacting the growing area even if there is potential for virus contamination of the growing area when they are present in the population. Thus a negative sample result for virus analysis may not necessarily mean that a potential source does not physically impact on a growing area, but instead that the virus is absent from the population. The zero tolerance for viral illness arising from the consumption of shellfish grown in New Zealand and Australia requires the management of potential sources, whether or not virus is present in the population at the time.

The systemic failure of faecal coliform/E. coli standards to reliably predict the risk of viral contamination in growing waters, particularly in those areas that are apparently less faecally contaminated, places a very high reliance on thorough shoreline surveys to identify potential
contamination sources and understand the distances over which virus contamination from identified sources will impact.

The setting of harvest criteria in Conditionally Approved areas based on the clearance rates of faecal coliforms/E. coli from growing waters and shellfish assumes no prior virus contamination of the shellfish. A similar assumption is made in the application of depuration over 36-48 hours using analysis against faecal coliform/E. coli indicators in the final product to confirm the effectiveness of the process. These aspects of the shellfish programme are therefore also reliant on the sanitary survey component to provide robust information with respect to the presence and impact of sources of viral contamination.

The tenuous link between the derivation of the current coliform-based standards and science is described in Section 2. However, in spite of this, the formulaic quantitative approach to the management of shellfish quality made possible through the use of coliform indicators has provided benefits that have driven its continued use despite the known short-comings. In addition to undoubtedly providing some protection to the health of consumers (for example, with respect to protecting against pathogens such as Salmonella, Shigella, and Campylobacter), these benefits include the advantages to trade in having measurable standards. With respect to bacterial contamination from faecal sources, compliance monitoring based on bacterial indicators complements the other sanitary survey components of the shellfish quality assurance programme in providing objective quantitative feedback on the more subjective assessments of risk made in the sanitary survey, and acting to trigger further investigation in a growing area when necessary. This function is critically impaired with respect to viral contamination by the use of an indicator that is not consistently reliable for human enteric viruses.

10.3 Sanitary Surveys

10.3.1 Introduction

The failure of coliform indicators to reliably predict viral contamination places a very high reliance on the other sanitary survey components of the shellfish quality assurance programme in the management of the risk of enteric virus contamination of shellfish. In this section we will use the term “sanitary survey” to include shoreline surveys and the collection of other information about the growing area, its catchment and actual and potential pollution sources but excluding the monitoring for coliform indicators undertaken for development of harvest criteria, and for classification and confirmation of classification of the growing area.

The case studies suggest that the implementation of the sanitary survey components of the shellfish quality assurance programme failed to adequately protect consumers from illness arising from enteric virus contamination as a result of:

- Insufficient information gathered during the sanitary survey process to allow an adequate assessment of the risk of enteric virus contamination in shellfish in the growing area;

- Lack of currency of information about potential sources of enteric virus contamination in a growing area.
The drivers for these deficiencies potentially result from the interaction of a number of factors discussed in the following sections.

### 10.3.2 Quality and sufficiency of information

One of the barriers to gathering sufficient information to make an informed assessment of the risk of virus contamination in a shellfish growing area is access to adequate reliable information. In their sanitary surveys, Food Authorities gather information from a combination of field work (i.e. personal observation through shoreline surveys), published information and data (for example, information about hydrographics, geology, land use, population etc.) and information about the management of potential pollution sources supplied by Councils and other parties. A visual inspection of potential contamination sources from a road or boat may not provide the depth of information required for robust risk assessment, and in some cases access to undertake a closer inspection may be limited. For example, as discussed in Section 2, in New Zealand sanitary surveys are undertaken by either District Health Boards (DHB) or independent contractors, and although under the Public Health Act 1956 the DHB personnel have wide-ranging powers to investigate potential public health risks impacting on the quality of shellfish in growing areas, this is not the case for independent contractors, who for example, are unable to enter private property to inspect on-site sewage systems, or Ministry of Primary Industries personnel, who have limited powers to interrogate sewage systems. Similarly in New South Wales, under the Food Act 2003 the powers of a NSW Food Authority authorised officer in terms of entry to private property are limited to entering and investigating food premises or food transport vehicles. The NSW Food Authority is reliant on the Environmental Health Officers associated with Councils to undertake inspections of potential contamination sources on private property.

Access to more detailed information can in some cases be problematical because of reliance on the good will of other parties. For example, in a recent exercise by the NSW Food Authority to set Closed Safety Zones for wild shellfish harvest areas around WWTP outfalls along the open coast of NSW, Councils supplied the NSW Food Authority with dilution studies and/or hydrodynamics data associated with outfalls for only 5 out of 47 WWTPs (Hay, 2012).

There is a tension between the cost of intensifying sanitary survey investigations and budgetary constraints. The sanitary survey process has to be affordable for industry. This is particularly an issue in New Zealand, where industry bears the full cost, but is also an issue in New South Wales due to recent budget cuts in State funding.

Budgetary constraints place additional reliance on gaining information from other parties. The quality of the required detailed information that is collected by Councils may also present problems. A Council may ostensibly have good management systems but implement them poorly. For example, in GA 4 the outcome of inspections of on-site sewage systems by Council officers were found to differ significantly from the results of subsequent inspections by the Food Authority and consultants with expertise in the field of on-site sewage systems. In the same case, lack of Council resources in terms of personnel (driven by lack of funding) also limited the scope of the inspections of on-site sewage systems within the growing area catchment, which resulted in an inaccurate assessment of the risk of contamination from this potential source.

In some cases, sources of contamination may be difficult to detect merely by visual observation – for example, although effluent discharge to the surface may be obvious, the short-circuiting of effluent from an on-site sewage systems to groundwater leading to coastal waters through fractured
rock may not be detected unless more intensive investigation is prompted by other cues (e.g. proximate water test results). Funding constraints within Food Authorities may limit the depth of investigation in sanitary surveys, and force greater reliance on external sources of information. Consequent assumptions required to be made by Food Authorities about potential contamination sources may not hold true.

In some growing areas, assessment of the risk presented by virus contamination may be impacted by lack of environmental information – for example, information about the hydrodynamics of the growing area, or the movement of groundwater to the coast. The results from monitoring of bacterial indicators may not signal that these information gaps are significant if the viral contamination sources are not in close proximity to the growing area. Robust studies to fill these sorts of information gaps involve the engagement of specialist scientific/technical expertise to conduct intensive investigations, which places a high financial burden on Shellfish Quality Assurance Programme funds.

### 10.3.3 Currency of Sanitary Surveys

There is an underlying assumption in the design and implementation of the existing shellfish quality assurance programmes that the quality of water in growing areas with respect to viral contamination is sustainable and subject to little fundamental change over time. This is evidenced by the Food Authorities’ reliance on the assessment of the risk of actual or potential pollution sources in the area based on infrequently updated information – i.e. infrequent intensive sanitary surveys, with minimal shoreline investigation undertaken for Annual Reviews in the interim years (e.g. observation from road or boat). In-depth investigation exceeding this is in practice prompted only by illness outbreaks – although the management programme requires some explanation of non-compliant confirm results, resource limitations mean that such events rarely trigger a shoreline survey.

The opportunities for the Food Authority to monitor changes in the growing area catchment on a less formal basis are limited in the current programme. Because of the geographic spread, and in some cases, remote location of oyster growing areas, the Food Authority officers responsible for the Annual Review reports are generally based at a location distant from the growing areas that they manage, and this tends to limit the knowledge gleaned from local sources close to the growing area. This is particularly challenging in NSW, where individual Food Authority officers are responsible for relatively large numbers of growing areas spread over a range of hundreds of kilometres. In New Zealand, the increasing tendency for industry to collect compliance samples themselves has further eroded the opportunity for the trained Food Authority officers to observe changes in growing area catchments. Industry personnel have no formal responsibility within the SQAP in ensuring the currency of sanitary survey information is maintained. Although valuable sources of local information, industry personnel generally have no training in shoreline surveys and have no authority to undertake investigation on private property.

### 10.4 Issues Relating to Maintenance of Water Quality

#### 10.4.1 Introduction

It is clear from the case studies that despite the environmental policies designed to manage environmental quality, changes in water quality in shellfish growing areas occur over several
temporal scales, including changes that occur in short-to-medium time frames that fall between 12-year sanitary surveys.

Sanitary Survey Reports from both New Zealand and New South Wales shellfish growing areas note that there is increasing urbanisation of coastal areas. McCoubrey (2007) found that the environmental pressures are changing in some oyster growing areas in New Zealand. Increased boating activity, and poorly performing septic tanks and WWTPs in areas where settlement was historically seasonal but is now permanent, are increasingly characteristic. She also observed that the current classification indicators (using water monitoring and sanitary surveys) do not provide adequate warning of degradation of the environment impacting on water quality in shellfish growing areas.

10.4.2 Environmental policy issues

The maintenance of ongoing water quality in shellfish growing areas relies on environmental policy and its implementation. Although detailed analysis of differences in legislation between New Zealand and New South Wales is beyond the scope of this report, the legislative framework in New South Wales appears to be more explicitly supportive of the maintenance of water quality in oyster growing areas than environmental policy in New Zealand, both in terms of the current situation and in consideration of future development. History has a bearing on this, and provides an example of significant changes made following an enteric illness outbreak associated with oyster consumption. In early 1997 an outbreak of 444 cases of Hepatitis A was associated with the consumption of oysters harvested from Wallis Lakes in New South Wales. This was the most serious oyster-related outbreak ever attributed to Australian shellfish, and resulted in a class action against the regulatory authorities and oyster growers (Ryan vs. Great Lakes Council, FCA 177, 5th March 1999). This event, and ensuing efforts at remediation of virus contamination sources in the growing area, acted as a catalyst for change (See Appendix II). The inquiry that followed the Wallis Lakes event clearly identified the importance of the direct link between catchment and estuary management and oyster quality and resultant human health. To improve its understanding, and to test the relevance of the findings of the Coastal Lakes Inquiry (i.e. the inquiry following Wallis Lakes) to other growing areas, the NSW Healthy Rivers Commission (HRC) engaged a consultant to provide advice on oyster cultivation and river health. The consultant’s report (White, 2001) found that oyster production had been declining over the period 1968-2001, a trend that was attributed to socio-economic and physical factors. The physical factors identified were influence by population growth and agricultural land use, which affect downstream environments and ultimately oyster production in the estuaries. One of the conclusions stressed in the report was the need for a greater acceptance by government of its responsibility for the health of estuaries. In 2003 an independent review of the relationship between healthy oysters and healthy rivers was funded by the NSW Health Rivers Commission. This review identified that there was:

“A critical gap in land and water planning and management processes, in that they often fail to draw together the requirements of oyster cultivation for human consumption with those of other land uses (for example, urban and agricultural development) and water uses (for example, siting of WWTP discharges and management of sewage from boats)”.

22 We note however, that wild shellfisheries, which are generally located on the open exposed coast of NSW, do not received prioritisation in NSW environmental policy.
In NSW, recommendations made by the Health Rivers Commission report (HRC, 2003) resulted in the development of the NSW Oyster Industry Sustainable Aquaculture Strategy (NSW Government, 2003), which among other things, identified priority oyster growing areas, and SEPP 62 (i.e. State Environmental Planning Policy No. 62 – Sustainable Aquaculture) was amended to include consideration of the effects of proposed development on oyster aquaculture. This priority is therefore recognised in local environment plans, and Council strategies etc.

As recognised in the NSW Healthy Rivers Commission report (HRC, 2003), degrading water quality in shellfish growing areas places increasing cost on industry due to increasing harvest closure time, costs associated with relaying (and in New Zealand, the costs of sufficient preliminary investigation to prove to Councils there are contamination problems in order to initiate some action on their part etc.) and ultimately threatens the existence of the industry. In New Zealand the Food Authorities (Ministry for Primary Industries, District Health Boards or private contractors) now play a minimal role as active advocates for the long-term preservation of water quality in growing areas due to tighter funding constraints (government cuts combined with a policy of full cost recovery from an industry facing increasing economic pressure). Those areas in which District Health Boards are involved in the management of growing areas can benefit from the DHBs advocacy in their role of protecting public health. In New South Wales the State government attitude which actively encourages cross-agency cooperation provides a more supportive environment. As manager of the NSW Shellfish Program, Anthony Zammit described the role of the Food Authority in NSW in maintaining water quality in shellfish growing areas:

“A strict interpretation of the role of the NSW Food Authority in the regulation of shellfish safety would be to assess the level of risk of pollution of the shellfish harvest area and close areas when levels are exceeded. This is the limit of the powers granted to the Authority under legislation. However, closure of shellfish harvest areas due to pollution is only treating the symptom. There are other government agencies that have control over sources of pollution/contamination and the NSW government has expressed a strong desire for NSW government departments to take a whole of government approach to problems, in particular problems that impact on businesses. Collaborative efforts between different departments and between local and state government are expected.

In terms of improving shellfish safety, closing harvest areas removes shellfish that are considered too risky from the market, remediation of pollution sources reduces the risk. To limit our activities to closing areas once they have become unsafe is to only manage the risk, it is also closing the gate after the first horse has bolted.”

The absence of a supportive environmental policy can place a very high cost on the shellfish industry to maintain long-term water quality in growing areas in the face of increasing pressure from urbanisation of the coastline. In New Zealand, assessing the risk of each resource consent application, making submissions to Councils on those for which sewage treatment management systems present a risk of viruses in the growing area, and fighting to ensure the protection of water quality through the Environment Court if applicants are unwilling to compromise, all involve very significant costs in terms of legal and technical expertise. (An example of this is the oyster farmers in Orongo Bay who over 3 years had to fight three challenges to water quality in their bay – one involved action in the Environment Court, one had a Court-mediated settlement, and the other was settled prior to a Council hearing). Eventually the required level of vigilance of resource management issues and the financial burden becomes too high for the farmers in a single growing area to bear, and water quality ultimately suffers in the longer term.
One of the key conclusions reached in the study undertaken by McCoubrey (2007) was that if New Zealand wants to protect shellfish growing areas there needs to be a new paradigm to manage the environmental and food safety issues. It was concluded that one of the keys to a new successful paradigm is the need to break down the barriers between policies relating to food safety and environmental pressures, and to apply an overarching vision of pollution control (McCoubrey, 2007). This has not yet been achieved.

### 10.4.3 Implementation of environmental policy

Our case studies illustrate that Councils can experience difficulty in implementation of environmental policy, and that this can significantly impact on the risk of viral contamination in shellfish growing areas. The case studies indicate that this is an important issue in both Australia and New Zealand. Lack of financial resources was identified as one key driver of this and, possibly linked to funding issues, lack of competence and relevant expertise was another. In the one growing area where this was investigated in depth, this covered both technical expertise, and the management expertise required to provide sound management of Council processes.

### 10.4.4 The role of standards and guidelines

While legislation and regulations define the required outcomes, the practical processes by which the outcomes are achieved often rely on adherence to established guidelines or standards (such as the Australian/New Zealand Standard for on-site domestic wastewater management (AS/NZS1547:2000), Auckland Council’s Technical Publication 58 (TP58), and NSW Department of Local Government “Environment & Health Protection Guidelines: On-site Sewage Management for Single Households”). In several case studies unquestioning and uncritical reliance on standards associated with the design of on-site sewage systems resulted in viral contamination of oyster growing areas. This issue was discussed by van de Graaff et al. (2007) at an on-site sewage management conference in 2007. As observed in our case studies, they note “It is not uncommon for consultants advising on on-site wastewater management to assume that either (i) a literal and uncritical adherence to such guidelines and standards ensure their work is sound and ought to be accepted by the responsible authorities without qualms, or (ii) unless they do so, their reports will be rejected.” In at least one of our case studies (GA 4) such an assumption would not have been ill-founded with respect to the design of on-site sewage systems – the Council was relying on the qualifications of the applicants’ consultants (but the required qualifications were not specified) and the requirement to meet design standards in their assessment of applications, but the Officers themselves did not have the technical expertise to assess whether a design was appropriate for site conditions or not. Van de Graaff et al. (2007) comment “During site assessment of land capability for on-site wastewater management one frequently runs up to regulations, standards and guidelines that have so grossly simplified the real physical complexity of the issues that many non-specialists think they can carry out the assessment. It also can happen that government officials merely check these assessments to see if all the boxes have been ticking. Reports may be accepted merely because the writer has genuflected in all the right places, although the report’s recommendations may be erroneous or wholly nonsensical”. Van de Graaff et al. (2007) provide several examples in which adherence to Australian standards and guidelines led to a land capability assessment that would have resulted in the inappropriate design of on-site systems for their site conditions.

On two occasions an inappropriate design for an effluent disposal field for the same on-site sewage system was approved by a Council in GA 2, leading to its implication in two NoV illness events. It
appears questionable whether uncritical implementation of standards and guidelines can be regarded as robust controls for ensuring the maintenance of water quality in shellfish growing areas. Perhaps a review of the standards is required: Van de Graaff (2007) cites the lack of engagement of scientists and technical experts in the development of standards and guidelines as a key problem.

One alternative to the reliance on standards to deliver the required outcomes in sensitive areas with difficult soil conditions is for Councils to utilise expert consultants to recommend the design of a system that would be suitable for the area. This was used successfully in Tiligerry Creek (NSW) where effluent from on-site sewage systems on coastal properties was moving through the sandy soil into the sea in the vicinity of an oyster growing area. The problem was solved by the expert development of a series of recommended on-site disposal field designs for dwellings of different sizes, which householders used as the basis for upgrading their malfunctioning systems. This reduced the design costs to individual households, and ensured that all systems were of an appropriate design.

10.5 Learning from Experience

In the course of epidemiological and growing area investigations following an illness outbreak linked to a shellfish growing area it is rare that information becomes available in an orderly fashion, and decisions are made on the best possible information at the time. However, following an event there is an opportunity to analyse the situation to see how the risk of viral contamination might be better managed in the future.

One of the primary sources of information in the case studies was reports of growing area investigations by the Food Authority following NoV illness outbreaks. We observed that the quality of these reports, including the level of detail provided about identified or possible contamination sources, varied significantly across cases. While in some cases this may reflect the depth of investigation, in discussion with Food Authority personnel associated with the investigations it was apparent that in some instances not all the information gleaned in an investigation had been thoroughly documented and/or collated into the report. This also applied to some reports provided by Councils to Food Authorities. Failure to adequately document investigations potentially limits the transfer of institutional knowledge when personnel change, and inhibits the continued monitoring of potential sources that history has shown may be higher risk than others.

It is apparent from several cases that there is insufficient ongoing vigilance with respect to sources of contamination that have previously been implicated in NoV illness outbreaks. This was particularly significant in GA 2, in which the same on-site sewage system was implicated in two outbreaks. In GA 3 some components of on-site sewage management plans put in place as part of remediation efforts are no longer being implemented. Annual reviews do not appear to include any re-inspection of potential contamination sources formerly implicated in illness outbreaks to ensure that corrections made are sustained.

The slow implementation or lack of implementation of recommendations made for changes to a growing area’s shellfish programme following an illness outbreak was also evident in several cases (e.g. GA 1, GA 3).
Together, these issues result in a failure to optimise the learning that arises from an illness outbreak in which shellfish growing areas are implicated, and inhibit improvement in the management of the risk of viral contamination in shellfish growing areas.

We do note however one example in which an oversight in an inspection of an oyster processing facility, which was discovered in the growing area investigation in GA 2, was used as a teaching example in subsequent training workshops.

10.6 The Use of Complementary Indicators

10.6.1 Introduction

The ineffectiveness of coliform indicators in confirming the conclusions drawn in the sanitary survey regarding the risk of viral contamination, and in confirming that harvest criteria continue to be appropriate, is a critical gap in the current SQAP. This section discusses the use of complementary indicators that could be used to provide additional assurances that the viral risk is low.

10.6.2 Use of viruses as indicators

The limitations of virus test methods remain an issue to be considered in the design and interpretation of virus testing used in the management of the risk of viral contamination in shellfish growing areas. These challenges are outlined in the box below.

The challenges of virus testing in shellfish

Compared to virus concentrations in clinical samples, the levels of viruses in environmental samples can be low. Because low levels of enteric viruses are significant in terms of the initiation of infection, virus detection methods need to be sensitive, and typically involve a step to concentrate the viruses in a sample. Subsequent virus detection is undertaken using cell culture assays or, more recently, using molecular methods such as PCR (polymerase chain reaction).

Cell culture assays, such as those that in the past have been used for the detection of hepatitis A, involve inoculation of the sample onto cells of a kind that will become infected by the type of virus to be detected, followed by observation and quantification of the cytopathogenic effects (i.e. damage to the cells) as evidence of virus infection. The advantages of this method are that it provides a direct measure of virus infectivity, it provides quantitative data, and a relative large sample volume can be used. Disadvantages include the long processing time (4-30 days), toxicity to compounds in the sample can result in false positive results, and not all viruses can grow in cultured cells (Fong & Lipp, 2005; Rodriguez et al., 2009). Results achieved from using different cell lines or cell culture methods can differ very significantly (e.g. Hurst et al., 1988), and it is therefore difficult to draw conclusions across studies in which cell culture detection methods differ. Despite much research effort, NoV remains one of the viruses that cannot be grown in cell cultures (Richards, 2009).

Molecular viral detection assays such as PCR (polymerase chain reaction) are based on the amplification and detection of part of the viral genome (i.e. part of the sequence of nucleic acids in
PCR techniques are used to detect viruses that are not culturable (such as NoV). However, the infectivity of the virus cannot be determined: The standard assays may detect inactivated viruses by amplifying fragments of the viral genome. Otherwise intact viruses with damaged binding sites on the capsid will also result in positive assay results (e.g. Sobsey et al., 1998; Dancer et al., 2009; Dancer et al., 2010), although the virus would not be capable of infection. Thus PCR assays may result in an over-estimation of the risk of viral infection. False negative results may occur as a result of inhibitory substances in the sample, but current techniques incorporate internal standards to measure this impact, and dilution is utilised to overcome the inhibitory effect of the matrix. This can result in decreased sensitivity and increased variability in results. Only a very low sample volume can be tested (i.e. 10-100 µl) (Fong & Lipp, 2005; Rodriguez et al., 2009). Researchers (including scientists at the NZ Institute of Environmental Science & Research) are working to develop PCR techniques that distinguish between infectious and non-infectious noroviruses, but to date no techniques have been developed in which a “false positive” result arising from damage to either the viral capsid or the viral genome is reliably prevented in the same assay.23

The limitations imposed by the test methods and the inability to distinguish between infective and non-viable viruses result in some key information gaps with respect to the assessment of the risk of NoV in shellfish growing waters. These include knowledge of how long noroviruses remain infective in the marine environment and within shellfish, and the effectiveness of wastewater treatment processes in reducing infective NoV levels.

In our case studies, testing for NoV was used to confirm the presence of NoV in implicated oysters (with varying results) and to confirm the absence of NoV in a growing area before reopening for harvest (results were consistently negative after remediation). In a recent study which compared the results of testing oysters by real time RT-PCR with self-reported gastroenteric illness in restaurant customers in the UK, illness was reported associated with 23% of oyster batches that were consumed. All these batches tested positive for NoV. However, of the total number of batches that tested positive for NoV, only 49% were associated with reported illness (Lowther et al., 2010). While this latter observation could be impacted by under-reporting of illness, this study suggests that the NoV analysis method does not under-estimate the risk of NoV illness. This raises the question of whether there would be a detectable level of NoV in shellfish that could be considered to be acceptable based on current test methods.

A recent review by the EFSA Panel on Biological Hazards used quantitative data on viral load from areas compliant with current EU legislative requirements in three countries to quantify the number of non-compliant batches that would eventuate over a range of different virus concentration limits. It was concluded that the imposition of virus limits would reduce the risk to consumers, but this could not be quantified. However, McLeod & Kiermeier (2011) developed a predictive model to estimate the probability of illness based on NoV concentration in the shellfish (genome copies/g) using piecewise linear approximations to the dose-response curves presented in Teunis et al (2008) under conditions in which the virus particles were either aggregated or disaggregated. They

23 In this sentence “false positive” is used to denote a positive virus result that is indicative of a virus that does not have the ability to infect a host.
suggested that this may have some value in evaluating the potential risk associated with the results of NoV testing in growing areas when used in context with other data.

Because of the shortcomings of bacterial indicators, in recent years considerable research effort has been directed at identifying a virus that could be a suitable indicator of the presence of human enteric viruses, i.e. a viral rather than bacterial indicator (e.g. Vaughn & Metcalf, 1975; IAWPRC, 1991; Chung et al., 1998; Formiga-Cruz et al., 2003). The use of a viral indicator would obviate the need for testing directly for a range of pathogenic human enteric viruses individually. The absence of a suitable universal viral indicator remains a key information gap. Difficulties in identifying a universal viral indicator include variation in enteric virus levels in the environment (including in wastewater) with varying levels of illness in the human population, differences between viruses in their response to environmental conditions (including wastewater treatment processes) and persistence in the environment, and differences in uptake and persistence in shellfish. Various candidates have been proposed as viral indicators, including enteroviruses, adenoviruses and viruses that infect bacteria that are commonly found in faeces from warm-blooded animals (e.g. F-RNA bacteriophages, somatic coliphages etc.) (see review by Oliveira et al., 2011). Very briefly, the research studies have produced conflicting results, and findings do not appear to be able to be generalised from one location or situation. At this stage it appears that one kind of universal viral indicator is unlikely to be able to be used reliably in all situations. However, there may be specific situations in which one type of virus could be used as a predictor of the risk associated with others provided that any assumptions in the predictive relationships are clearly defined. One example of this is the use of male-specific coliphage as an indicator of the absence of viral contamination in a shellfish growing area following a sewage spill, applied in USA under the NSSP regulations (see Section 2). The safe application of such policies relies on knowing the assumptions made in their establishment (in this case the assumption that the male specific coliphage will always be present in the spilled sewage, and transported, then taken up and retained by the shellfish in a manner that represents the risk of human enteric viruses) and ensuring that these assumptions apply in each situation. The results in a study of the prevalence of viruses at a number of sites in New Zealand showed that the change in levels of viruses in shellfish with increasing distance from a sewage outfall at Dunedin differed between virus types, with levels of adenovirus decreasing less with distance than other viruses (enteric viruses, NoV, bacteriophage) (described in Greening, 2007; Greening & Lewis, 2007).

Overseas there appears to be increasing interest in the use of male-specific bacteriophages as predictors of enteric virus contamination in shellfish growing areas. For example, two studies in Britain using shellfish sampled from commercial growing areas found a significant correlation between bacteriophage levels and the presence and level of NoV (Lowther et al., 2008, Flannery et al., 2009). However, a study of the prevalence of viruses in shellfish from 28 sites in New Zealand (predominantly non-commercial shellfish sites) found no correlation between bacteriophage and NoV except at one site very close to the outfall of a major WWTP (Greening & Lewis, 2007). Similarly a study in Tauranga Harbour (NZ) in which 72 shellfish samples from a non-commercial shellfish site were analysed for NoV, adenovirus and F-RNA bacteriophage, it was found that bacteriophage was not a good predictor for the presence of NoV except after a sewage spill event (Scholes et al., 2009). This suggests the possibility of site-specific differences, possibly related to the nature of the contamination source (e.g. large WWTP vs on-site sewage systems etc.). However, we note that unlike the overseas studies that have prompted the suggested use of bacteriophage as an indicator, the New Zealand studies were undertaken from non-commercial shellfish areas, which might introduce greater variability into the results. Further investigation of the relationship between bacteriophage and NoV in commercial oyster growing areas in New
Zealand and Australia might be useful in the light of increasing international interest in the use of bacteriophages as indicators under specific circumstances.

To date, one of the barriers to investigation directed at improving the management of the risk of NoV in New Zealand and Australia has been the reticence of industry and regulators to test for NoV in commercial growing areas because of the uncertainty about the regulatory response should NoV be detected. This barrier needs to be overcome if progress is to be made. One solution to this would be to adopt a dual trigger system as used by the US FDA during the course of a study of bacterial and viral pathogens in live oysters in a market survey by de Paola et al. (2010). For the purposes of this study, the FDA established a set of triggers to notify states when levels of concern were encountered. In addition to the detection of NoV or hepatitis A, corresponding male-specific bacteriophage level of >50 pfu/100 g were established as a criterion for notifying a state that it had a potential public health issue. Their rationale was that elevated levels of viable male-specific bacteriophage were indicative of possible recent faecal contamination. For NoV, these triggers were reached in only one sample, and during the follow-up investigation it was determined that the oysters had been harvested from an area that was unclassified and potentially subject to human pollution. Alternatively, based on an analysis of available science, McLeod & Kiermeier (2011) suggested a risk matrix approach based on the levels of NoV detected in oyster samples, levels of \textit{E. coli}, and any reported illness. It is suggested that these or similar options be considered.

10.6.3 Microbial source tracking

Norovirus levels vary within the human population through time, and although they may always be present in wastewater in large WWTPs, levels vary significantly in systems treating sewage from small populations. Thus, for example, in an estuary consistently impacted by effluent from a few on-site sewage systems, negative results in sampling shellfish for NoV could occur if there is no illness in those households. This negative result would not be indicative of the absence of contamination by other enteric viruses, or of the absence of risk of NoV contamination if infection were present. The use of viral indicators that are always present in human sewage provides a better indicator of the potential for the presence of human enteric pathogens at any time.

The routine compliance monitoring currently undertaken using bacterial indicators occurs at sites representative of water quality or shellfish quality on farms within in the growing area. The virus contamination sources that are not adequately managed by the current programme are spatially or temporally separated from the compliance samples to the extent that the bacterial indicators are not representative of virus numbers. One solution to this would be to sample closer to the sources of bacterial contamination impacting on the growing area to identify whether they introduce human faecal contamination. This could provide a mechanism to verify conclusions drawn from other components of the shellfish programme such as shoreline surveys and information provided by Councils and other agencies.

The concept that the origin of faecal pollution can be traced using microbiological, genotypic, phenotypic and chemical methods has been termed microbial source tracking (Scott et al., 2002).

The potential value of microbial source tracking in the assessment of risk of viral contamination of shellfish growing areas lies in the ability to identify the presence of human faecal contamination in waters that could impact on the growing area. Microbial source tracking methods involve sampling for indicators that would be consistently associated with human contamination.
There are two major types of microbial source tracking methods described by Stoeckel & Harwood (2007) as follows: Library-dependent methods are culture-based and rely on isolate-by-isolate typing of bacteria cultured from various faecal sources and from water samples. These isolate are matched to their corresponding source categories by direct sub-type matching or by statistical means. In contrast, library-independent methods frequently are based on sample-level detection of a specific, host-associated generic marker in a DNA extract by PCR. Analyses of certain chemicals associated with sewage, including faecal sterols, optical brighteners and host mitochondrial DNA have also been utilised for what can be more broadly termed faecal source tracking.

There is no single faecal source tracking method that provides comprehensive information about potential sources of faecal contamination with a high degree of certainty attached to the result (Scott et al., 2002; Bitton, 2005; ESR Decision Analysis Tree at www.waterquality.org.nz). In New Zealand, ESR therefore recommends the “Toolbox” approach in which several different methods are combined24. In both Australia and New Zealand, there has been much interest in the development of faecal source tracking methods recently, and some have been usefully applied in shellfish growing areas. Following is a brief summary of some of the microbial source tracking methods commercially available in New Zealand and/or Australia.

- **Testing for faecal sterols in water and sediment.** Faecal sterol analysis relies on the analysis of the relative proportions of various sterols and stanols in the environment to gauge the source of faecal contamination, as the profile of sterols and stanols from different animals is different. The interpretation of sterol data is complex. Little is known about the relative persistence of these compounds in the environment, and their low prevalence makes sensitivity of test methods a significant issue. The impact of dilution is a limitation in the detection of faecal sterols in water samples taken at a distance from the source of contamination. ESR in New Zealand considers that only medium certainty can be attributed to the results of their faecal sterol analysis (www.waterquality.org.nz). Analysis of water samples for faecal sterols provides a snapshot of contamination sources impacting on water quality at the time of sampling. Faecal sterols can also be analysed in sediments in which they become concentrated. However analysis of sediment requires careful sampling to ensure that the results represent recent contamination. ESR is trialling the use of “sediment bags” as a means of concentrating *E. coli* and faecal sterols out of water (B. Gilpin, ESR, Christchurch, pers. comm.). The potential advantage of this method is that it provides a temporal component to the information gleaned from the test results, in that any contamination observed from the bags must have occurred during the time between their deployment and retrieval. (This differs from the interpretation of results from *in situ* sediment sampling, from which the timing of contamination is not able to be deduced because *E. coli* and faecal sterols can persist in sediment for some time). However, this technique is still in the very preliminary stages of development, and although positive results could be regarded as significant, negative results cannot be regarded as reliable.

- **Testing water for fluorescent whiteners.** Fluorescent whiteners are used in washing powders etc. and can provide an indication contamination from domestic or industrial effluent. Their presence is not directly linked to human faecal contamination. Dilution with distance from source and the rapid degradation of fluorescent whiteners by sunlight can reduce the sensitivity of this test, but the test is relatively cheap and it can be very useful when investigating a specific potential source. Generally analysis of fluorescent whiteners

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24 [www.waterquality.org.nz](http://www.waterquality.org.nz)
is undertaken on water samples. However, the presence of fluorescent whiteners over a longer time period can be detected by the deployment of chemical-free cotton pads in the environment (e.g. in a stormwater drain) and subsequent viewing under UV light in comparison to a control cotton sample.

- **Detection of bacterial markers by PCR (polymerase chain reaction) methods.** PCR techniques can be utilised to detect genetic markers associated with host-specific bacteria, such as *Bacteroidales* bacteria, which are very prevalent in faeces of many warm-blooded animals. Techniques currently in use in New Zealand include quantitative PCR for *Bacteroidales* markers (including a universal marker, human, dog and ruminant markers) a marker for human contamination based on the bacteria *Bifidobacterium adolescentis* and a duck marker. End-point PCR techniques are used to detect human markers for *Bacteroidales* and *Methanobrevibacter* bacteria, and markers for ducks and gulls. Different markers have different sensitivity and cross-reactivity between hosts may be an issue (Cornelisen et al., 2012). Based on test results from duplicate samples, there may also be differences in test sensitivity or test results between laboratories (Cornelisen et al., 2012; Northland Regional Council (NRC), unpublished data, 2012). These techniques may be used with both water and shellfish samples (Kirs & Cornelisen, 2011). However recent investigations these techniques with oyster samples suggests that further work is required to develop and validate this methodology in oyster samples (NRC, unpublished data).

- **RT-PCR assays for human/animal noroviruses and adenoviruses in water and shellfish samples.** Multiplex real-time RT-PCR assays for enteric viruses in water and shellfish samples can distinguish between human, pig, sheep and cattle faecal contamination (e.g. Wolf et al., 2007; Wolf et al., 2009). The ESR “Virus Toolbox” of host-specific virus assays includes: human adenovirus species F, NoV GI and GII (and human polyomavirus (see below)); plus markers for animal faecal contamination including: porcine adenovirus type 3 (pigs), ovine adenovirus (sheep), NoV GIII (sheep & cows) (and bovine polyomavirus (cows) – see below). These assays rely on the presence of illness in the source population. Human noroviruses and adenoviruses tend to be prevalent in effluent from large wastewater treatment plants, but may only be sporadically present if the source of contamination is on-site sewage systems (such as septic tanks). This technique is thus more reliable in detecting human contamination from sources emanating from communities rather than from individual households.

- **End-point or q-PCR for human and bovine polyomavirus.** The use of bovine polyomavirus markers is under development in New Zealand but currently requires further validation. Human polyomaviruses, which are excreted with urine, are more prevalent in the human population than noroviruses and adenoviruses, and reliably detected in most human effluent. Concentrations of human polyomavirus in estuarine water were found to be comparable with human adenovirus species F and NoV GII (ESR presentation to Industry Advisory Group, March 2012). One study found that the end-point PCR for the human polyomavirus in shellfish is less sensitive than the end-point PCR for the human *Bacteroidales* or *Methanobrevibacter* markers (Kirs & Cornelisen, 2011). Kirs & Cornelisen (2011) suggested that in the absence of improved recovery methods (i.e. the method of extraction of virus from shellfish tissue), the human polyomavirus marker is not very useful in shellfish samples due to its low abundance (high dilution) in the marine environment and the possible increased likelihood of a false negative result.
**Dye Tracing**

The use of tracing dyes such as fluorescein and rhodamine WT can provide information about potential sources of contamination impacting on a growing area. Activated charcoal packets take up and retain dye that they come into contact with, and can be used as “shellfish surrogates” when dye testing reticulated or on-site sewage systems (Aley, 2011). This overcomes the problem of having to allocate significant time to observe any dye discharged from tested sources into the environment, and improves the sensitivity of detection. Dye tracing is a cost-effective, low technology method that can be easily implemented provided there is access to an analytical laboratory that can elute and analyse the dye from the charcoal packets. Dye studies can also be used to assess the dilution factor from a given pollution source which can assist in determining the size of a closure zone. The use of dye to determine dilution factors requires field staff with significantly greater technical expertise than required for the use of dye in leak detection with charcoal packets.

New technology, including the potential to monitor water quality continuously from buoys anchored in a growing area, and the use of next generation gene sequencing (which analyses and identifies all the genetic material in one sample) present exciting opportunities for the future.

**Laboratory Capability and Capacity**

Source tracking techniques have been used effectively in Australian shellfish growing areas (e.g. Geary & Kable, 2013; Baker, 2013). However, currently in New Zealand the functionality of the methods using bacterial markers are limited by laboratory capability and capacity. In employing several different microbial source tracking methods utilising two laboratories for analysis of concurrent samples for bacterial markers in a current study in Northland, New Zealand, a local council is experiencing long delays before receiving results (3-6 weeks) and there appear to be problems with the reliability of results. These problems hinder the effective identification of potential contamination sources. In addition, recent efforts to find an analytical laboratory to elute and analyse dye samples from charcoal packets in New Zealand were unsuccessful, and the samples had to be sent to NSW for analysis. Development of the capability and capacity of New Zealand analytical laboratories is required to support microbial source tracking work in shellfish growing areas.
SECTION 11 CONCLUSIONS AND RECOMMENDATIONS

11.1 Conclusions

Following is a summary of the conclusions drawn from the study:

- The study demonstrates that the manner in which faecal coliform indicators are used in the current shellfish quality assurance programme fails to consistently predict the risk of enteric virus contamination in shellfish harvested for market. This places a high reliance on the other components of the Shellfish Quality Assurance Programme in managing the risk of enteric viruses.

- The case studies suggest that the implementation of the sanitary survey components of the programme failed to adequately protect consumers from illness arising from NoV contamination as a result of:
  o Insufficient reliable information gathered during the sanitary survey process to allow an adequate assessment of the risk of virus contamination of shellfish in the growing area, driven by
    - Reliance on other agencies such as Councils to provide key information about growing areas and their catchments, and difficulties in obtaining sufficient reliable, high quality information;
    - Assumptions made by the Food Authorities about the quality of management of potential contamination sources by Councils and other parties without detailed information to support these assumptions;
    - Barriers to accessing private properties in some cases prevent Food Authority officers inspecting potential contamination sources themselves;
    - In some cases there is a lack of environmental information – particularly regarding the hydrodynamics of the growing area, movement of groundwater into coastal waters etc.
  o The design of the Shellfish Quality Assurance Programme, which incorporates infrequent detailed sanitary surveys and minimal field observation by the Food Authority in the catchment annually, assumes little change will occur in the risk of viral contamination in the growing area through time. The case studies suggest that this assumption is not correct, and that change may be impacted by the following:
    - There are increasing pressures from competing resource uses, including urbanisation of coastal areas. Particularly in New Zealand, there is little cross-agency planning and environmental policy is not well-designed to protect water quality in shellfish growing areas, especially with respect to the cumulative impact of many small changes. In New Zealand industry faces high costs in protecting their water quality through the processes available through the Resource Management Act.
The implementation of existing environmental policies by Councils (including both in New Zealand and Australia) can be very poor, driven by lack of resources (a key factor), poor management (resulting in inadequate management systems), and lack of technical competence and expertise.

Lack of expertise and uncritical reliance on standards and guidelines in the design of wastewater management systems by consultants and Council officers can result in systems that are inadequately designed to prevent viral contamination of growing areas.

- Failure to continue to manage the risk of sources of viral contamination that have previously been implicated in NoV illness events increases the risk of recurrence of viral contamination. In some cases this was evident in:
  - Inadequately detailed documentation of investigations (which potentially limits the transfer of institutional knowledge when personnel change, and inhibits the continued monitoring of potential sources that history showed may be higher risk than others);
  - Failure to institute and sustain management plans to ensure that issues that caused virus contamination are not repeated.

- Because of the ineffectiveness of coliform indicators, there is a need for a feedback mechanism within the shellfish programme to confirm the validity of the conclusions drawn in the sanitary survey component of the programme with respect to the risk of viruses.
  - The absence of a universal indicator of the risk of virus contamination is a key information gap that acts as a significant barrier to this.

- In the absence of a universal viral indicator, feedback mechanisms may be able to be designed using a combination of techniques:
  - Viral indicators such as male-specific bacteriophage that could be used as predictors of risk within a defined set of circumstances.
  - Microbial source tracking applied close to the potential sources of contamination that might impact on growing areas, to determine whether human faecal contamination sources are present.
  - Testing for specific viruses of concern under specific circumstances (e.g. to identify whether shellfish are implicated in an illness outbreak, or to confirm that known contamination has cleared from shellfish in a growing area).

Key information gaps relevant to this include:

- A NoV test method that distinguishes between infective and non-viable viruses;
- Lack of knowledge about the effectiveness of male-specific bacteriophage as an indicator of risk of viral contamination in oyster growing areas in New Zealand and Australian conditions.
• Sensitive and specific markers for human faecal contamination able to be reliably
detected in a medium that captures information about water quality over a period of
time (e.g. in shellfish, adsorbent media).

• The reluctance to sample shellfish for viruses in commercial shellfish growing areas means
that it is difficult to place the results from testing that is occasionally undertaken into
context. This reluctance arises from an uncertainty as to the regulatory response if the
results are positive. (Anonymised harvest and product surveillance would not provide the
area-specific data require to improve risk management in individual growing areas). The
interpretation of virus test results within the context of other concurrent factors (such as
other indicators) could overcome this problem.

• Other information gaps relevant to improving the management of risk of virus
contamination of growing areas include:
  o The length of time noroviruses remain infective within the marine environment;
  o The length of time noroviruses remain infective in shellfish;
  o The effectiveness of various wastewater treatment processes in reducing the level of
    infective NoV.

11.2 Recommendations

As a result of this study we recommend the following:

Growing Area Management
• A review of the management of sources of contamination that were implicated in previous
  NoV outbreaks in each impacted growing area to ensure that appropriate management of
  risk is on-going – the ongoing use of microbial source tracking techniques could be useful in
  confirming the absence of human contamination close to the source.
• A review designed to identify cost-effective ways of ensuring that the assessment of the risk
  of virus contamination in growing areas stays current.
• An initiative to improve linkages between Councils and Food Authorities, perhaps through
  joint training initiatives, Memoranda of Understanding etc.
• Development of detailed procedures and training initiatives for Food Authority and Council
  officers to follow in the event of suspected viral illness outbreaks implicating shellfish
  growing areas – including templates on what should be documented.
• Introduction of a peer review process of the shellfish quality management in each growing
  area (possibly across states, Australia/New Zealand?).
• An initiative to increase the technical competence of Council and Food Authority officers in
  assessing the suitability and efficacy of WWTPs and on-site sewage systems, through
  targeted training initiatives.
• Use of faecal coliform/E. coli testing, then the best available appropriate microbial source
  tracking tools to detect human sewage contamination close to source in the wider catchment
  of growing areas to provide confirmation of observations made in the shoreline survey, and
  in investigation following non-compliant sample results.
• The development of a science-based policy for determining the actions to be taken in the
  event that enteric viruses are detected in a growing area in the absence of illness (for
example, during research studies), using other indicators to support decision-making processes.

**Science/Technical Issues**
- Continued development of NoV test method that distinguishes between infective and non-viable viruses.
- A study of the effectiveness of male-specific bacteriophage as an indicator of risk of viral contamination in oyster growing areas in New Zealand and Australian conditions, taking into account different potential sources of contamination.
- Continued development of improved reliable, validated faecal/microbial source tracking methods to detect human sewage contamination over an extended time period, including the “viral toolbox” and quick, cheap methods of confirming the absence of human faecal contamination close to source.
- Development of laboratory capability and capacity to undertake analysis of samples using existing and new microbial source tracking tools to provide reliable results in a timely manner.
- A science-based review of standards and guidelines for on-site sewage systems.
- A review of the commonly used on-site sewage systems in Australia and New Zealand to assess their performance in preventing viral contamination of waterways under a variety of environmental conditions, including saturated soil conditions, and the development of new technology if required.
- Development of science-based guidelines to assist Councils in identifying the minimum quality of effluent after treatment in a WWTP to ensure protection of shellfish growing areas from viral contamination (i.e. guidelines to determine how much is enough in any situation).

**Environmental Policy Issues:**
- In New Zealand particularly, the development of public policy that protects water quality in shellfish growing areas in both short and long term. Consideration of:
  - Policy linking environmental quality to commercial shellfish harvest areas;
  - Increased cross-agency planning and cooperation;
  - Improved protection against water quality degradation arising from the cumulative impact of many small changes in the catchment of shellfish growing areas;
  - Development of science-based marine pollution regulations with respect to shellfish growing areas.
- The introduction of mandatory audited quality management programmes for Councils with respect to all aspects of their operations with the potential to impact on water quality in shellfish growing areas.
- A review of the use of standards and guidelines in on-site wastewater management, and the alternatives in sensitive areas in shellfish growing catchments.
- Inclusion of science-based State of the Environment monitoring of water quality in shellfish harvesting areas (commercial & recreational), designed to detect degradation in water quality over time – possible information-sharing of industry data.
- A Government review of the funding of wastewater management systems.
- Regulation to allow Food Authority officers to gain access to private properties for the purposes of investigation of potential sources of growing area contamination.
- The introduction of policy to facilitate the transfer of information relevant to assessment of the risk of contamination of shellfish growing areas, from Councils to Food Authorities.
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APPENDIX I  OUTLINE OF RELEVANT NSW ENVIRONMENTAL POLICIES

1. Protection of the Environmental Operations Act 1997

The Protection of the Environment Operations Act 1997 (POEO Act) is a key piece of environmental legislation in New South Wales. The POEO Act commenced operation on 1st July 1999. It was amended in 2005 (Protection of the Environment Operations Amendment Act 2005) and again in 2011 (Protection of the Environment Legislation Amendment Act 2011). The POEO Act enables the Government to set out explicit protection of the environment policies (PEPs). PEPs are instruments for setting environmental standards, goals, protocols and guidelines. They provide both the framework for Government decisions that affect the environment, and are the means of adopting Australia-wide environment protection measures set by the National Environment Protection Council. Before a PEP can be made, the POEO Act requires public consultation of the draft PEP, and an analysis of the economic and social impact of the PEP. The Act integrates environment protection licensing relating to air pollution, water pollution, noise pollution and waste management.

The Environment Protection Authority (EPA) is the appropriate regulatory authority for the activities specified in Schedule 1 of the POEO Act (scheduled activities) (e.g. wastewater treatment plants). In most cases, local councils are the regulatory authorities for non-scheduled activities (such as on-site sewage management systems), except activities undertaken by a public authority which the EPA will regulate or where a public authority has been declared the appropriate regulatory authority. The EPA licences scheduled activities. In general, Local councils can regulate non-scheduled activities through notice and enforcement powers in their local government area. However the EPA can issue a licence to regulate water pollution from a non-scheduled activity. If it does, the EPA becomes the regulator for all environmental impacts from the activity under the POEO Act instead of the local council.

Factors to be considered when deciding if a licence is to be granted include (Section 45 of the Act):

- Any PEPs
- The objectives of the EPA in section 6 of the Protection of the Environment Administration Act 1991, including ecologically sustainable development principles
- The impact on the environment of any pollution likely to be caused by an activity or work
- Any relevant environmental impact statement or other statement of environmental effects prepared or obtained by the applicant under the Environmental Planning and Assessment Act 1979.

Licences are usually issued with conditions. Examples of conditions that can be attached to a licence are provided in the Act, and include requirements to monitor, to provide certification of compliance with a licence, to undertake and comply with a mandatory environmental audit programme and pollution studies, reduction programmes and financial assurances. The EPA must review a licence once every 5 years, but a licence remains in force until suspended, revoked or surrendered.

Integration of EPA licensing with the development approval procedures under the Environmental Planning and Assessment Act 1979 provides for public participation in the environmental assessment of activities that may be licensed by the EPA.

Clean-up notices, prevention notices and prohibition notices are the environmental protection notices which are provided for under the legislation, and environmental protection offences and penalties are classified under the Act.

There is a duty to notify “relevant authorities” as specified in section 148(8) of the Act (the EPA, local authority, Ministry of Health, WorkCover Authority and Fire & Rescue NSW) of pollution incidents where material harm to the environment is caused or threatened. Material harm includes actual or potential harm to the health or safety of human beings or to ecosystems that is not trivial or that results in actual or potential loss or property damage of an amount over $10,000. Failure to do this is an offence. Under the POEO Amendment Act 2011, licensees under the POEO Act and anyone carrying on an activity or occupying a premises who becomes aware of a pollution incident is required to report pollution incidents immediately. We note that all licence-holders for wastewater treatment plants are now required to report incidents of pollution to waterways that might impact on oyster growing areas to the NSW Food Authority as a condition of their licences. Under the POEO Amendment Act 2011, licence holders have a duty to prepare and implement pollution incident response management plans for each licensed activity. The content of these plans has been specified in a regulation and the EPA has prepared guidelines to assist licensees in preparing plans. New associated offences have been introduced for not preparing a plan or keeping it at the premises to which it relates, not testing a plan in accordance with the Regulation, and not implementing a plan when an incident occurs.

The POEO Act provides that mandatory audits may be required as a condition of a licence if the EPA reasonably expects that:

- The holder of the licence has on one or more occasions contravened the POEO Act, the regulations or the conditions of the licence, and the contravention has caused or is likely to cause harm to the environment, or
- An activity is being carried out in an environmentally unsatisfactory manner as defined in section 95 of the Act.

Under the POEO Amendment Act 2011, licensees are required to publish the pollution monitoring data that have been collected as a result of a licence condition, in accordance with section 66(6) of the POEO Act and written requirements issued by the EPA. The same amendment introduced new associated offences for failure to publish monitoring data and for publishing false or misleading data.

The POEO Amendment Act 2011 also expanded the powers of the EPA to place a condition on a licence requiring a mandatory environmental audit. The EPA and the Ministry of Health have new explicit powers to require the occupier of a premises and any person they reasonably suspect of causing a pollution incident to pay for an analysis of the human health and environmental risks arising from the incident.
2. Environmental Planning Instruments

2.1 Environmental Planning and Assessment Act 1979 No. 203

The Environmental Planning and Assessment Act 1979 is administered by the NSW Department of Planning.

Under the Environmental Planning and Assessment Act 1979 No. 203 section 37 the Governor may make environmental planning instruments for the purposes for environmental planning by the State. Such an instrument is called a State Environmental Planning Policy (SEPP).

Under section 53 of the same Act, the Minister may make environmental planning instruments for the purpose of environmental planning in each local government area, and in such other areas of the State (including the coastal waters of the State) as the Minister determines. Any such instrument may be called a Local Environmental Plan (LEP).

2.2 State Environmental Planning Policy No. 62 – Sustainable Aquaculture

The aims and objectives of the State Environmental Planning Policy No. 62 – Sustainable Aquaculture (SEPP 62), which commenced on 1st October 2000, include:

a) to encourage sustainable aquaculture in the State, namely, aquaculture development which uses, conserves and enhances the community’s resources so that the total quality of life now and in the future can be preserved and enhanced, and

b) to make aquaculture a permissible use in certain areas for which a comprehensive and integrated regional aquaculture strategy has been developed (being a strategy that incorporates the relevant Aquaculture Industry Development Plan under the Fisheries Management Act 1994 and the assessment regime for integrated aquaculture development), and

c) to set out the minimum site location and operational requirements for permissible aquaculture development (the “minimum performance criteria”), and

d) to establish a graduated environmental assessment regime for aquaculture development based on the applicable level of environmental risk associated with site and operational factors...

Part 3A of SEPP 62 specifically provides for consideration of effects of proposed development on oyster aquaculture and applies to all development and all land (clause 15A).

Clause 15B outlines the consultation required with the Director-General of Primary Industries. Consultation is required in cases where the consent authority considers that because of its nature and location the development may have an adverse effect on oyster aquaculture development or a priority oyster aquaculture area. Clause 15B outlines the consultation with the Director-General of Primary Industries as follows:

1) Before determining a development application for any development, a consent authority:
   a) must consider whether, because of its nature and location, the development may have an adverse effect on oyster aquaculture development or a priority oyster aquaculture area, and
   b) if it suspects that the development may have that effect, must give notice of the application to the Director-General of the Department of Primary Industries.
(2) In determining a development application for any development, a consent authority must consider any comments received from the Director-General of the Department of Primary Industries pursuant to subclause (1), including, in particular, such comments as identify:

a) any adverse effect that the development may have on, or ways in which the development may impede or be incompatible with, any oyster aquaculture development or priority oyster aquaculture area, and

b) any measures to avoid or minimise any such adverse effect, impediment or incompatibility.

Development may be incompatible with or impede oyster aquaculture if, for example, the development will limit access to oyster leases or have an impact on water quality and, consequently, on the health of oysters and of consumers of those oysters.

Clause 15C outlines that consent may be refused if development adversely affects oyster aquaculture, as follows:

A consent authority may refuse to grant consent to development:

a) if it is satisfied that the development will have an adverse effect on, or impede or be incompatible with:

i) any oyster aquaculture development that is being carried out (whether or not within a priority oyster aquaculture area), or

ii) any oyster aquaculture development that may in the future be carried out within a priority oyster aquaculture area, or

b) if it is not satisfied that appropriate measures will be taken to avoid or minimise any such adverse effect, impediment or incompatibility.

3. NSW Oyster Industry Sustainable Aquaculture Strategy

Under the Fisheries Management Act 1994 a sustainable aquaculture strategy for the NSW oyster industry was developed in 2006 (NSW Government, 2006). Under the aims and objectives of SEPP 62 this has the effect of making oyster farming a permissible use in those areas specified in the strategy.

The NSW Oyster Industry Sustainable Aquaculture Strategy (OISAS):

- Identifies those areas within NSW estuaries where oyster aquaculture is a suitable and priority outcome;
- Secures resource access rights for present and future oyster farmers throughout NSW;
- Documents and promotes environmental, social and economic best practice for NSW oyster farming and ensures that the principles of ecological sustainable development, community expectations and the needs of other user groups are integrated into the management and operation of the NSW oyster industry;
- Formalises industry’s commitment to environmental sustainable practices and a duty of care for the environment in which the industry is located;
- Provides a framework for the operation and development of a viable and sustainable NSW oyster aquaculture industry with a clear approval regime and up-front certainty for existing industry participants, new industry entrants, the community and decision makers;
- Identifies the key water quality parameters necessary for sustainable oyster aquaculture and establishes a mechanism to maintain and where possible improve the environmental conditions required for sustainable oyster production; and,
• Ensures that the water quality requirements for oyster growing are considered in the State’s land and water management and strategic planning framework.

Amongst the planning and approval issues addressed in the strategy, the issue of the impact of other resources on oyster farming is considered in section 8 as follows:

8.3 Making Local Environmental Plans that may affect oyster aquaculture

As a result of the impacts of development of estuarine catchments (e.g. stormwater, septic seepage, sewerage outfalls), there has been a deterioration in the environmental conditions required for oyster cultivation in some estuaries.

To address this issue the priority oyster aquaculture areas will be shown on Local Environmental Plans and Council must have regard for these areas in preparing a new LEP. The Director-General of DPI may object to the terms of a draft local environmental plan on the grounds of deleterious effects on an oyster aquaculture area.

8.4 Determining development applications that may affect oyster aquaculture

When considering an application for development that, because of its proposed location, may affect a priority oyster aquaculture area or oyster aquaculture outside such an area, the consent authority must:

1. Give the Director-General of the Department of Primary Industries written notice of the development application and take into consideration any written submissions made in response to the notice within 14 days after notice was given, and
2. Take into consideration the provisions of the NSW Oyster Industry Sustainable Aquaculture Strategy.
3. Consider any issues that are likely to make the development incompatible with oyster aquaculture and evaluate any measures that the applicant has proposed to address those issues. Examples of potential land use incompatibility issues include access to oyster leases being limited by the development or the risk of adverse impacts of the development on water quality and, consequently, on the health of oysters and on the health of consumers of those oysters.

The consent authority may refuse to grant consent to development if, in the opinion of the consent authority, the development is likely to have an unreasonable impact on a priority oyster aquaculture area or on oyster aquaculture outside such an area.

4. NSW Local Government Act 1993

The NSW Local Government Act 1993 Section 68 specifies what activities require the approval of Council. Amongst others these include:

• To install, construct or alter a waste treatment device or human waste storage facility or a drain connected to any such device or facility; and
• To operate a system of sewage management.

The operation of an on-site sewage system (e.g. septic tank) is encompassed by the definitions of “operate a system of sewage management” provided in Section 68A.
5. NSW Local Government (General) Regulation 2005

Clause 29 of the Local Government (General) Regulation 2005 sets out the matters to be taken into consideration by the Council in determining an application for approval to install, construct or alter a sewage management facility. The Council must consider whether the proposed sewage management facility (or the proposed sewage management facility as altered) and any related effluent application field will make appropriate provision for:

(a) preventing the spread of disease by microorganisms,
(b) preventing the spread of foul odours,
(c) preventing the contamination of water,
(d) preventing the degradation of soil and vegetation,
(e) discouraging insects and vermin,
(f) ensuring that persons do not come into contact with untreated sewage or effluent (whether treated or not) in their ordinary activities on the premises concerned,
(g) the re-use of resources (including nutrients, organic matter and water),
(h) the minimisation of any adverse impacts on the amenity of the land on which it is installed or constructed and other land in the vicinity of that land.

The Council must consider any matter specified in guidelines or directions issued by the Director-General in relation to the matters referred to above.

Local Government (General) Regulation 2005 clause 26 specifies matters to accompany application for approval to install or construct sewage management facilities, including plans, specifications, site assessment (including details of the climate, geology, hydrogeology, topography, soil composition and vegetation of any related effluent application areas together with an assessment of the site in the light of these details), a statement relating to the number of residents and other factors relevant to the capacity of the proposed system, and details of the proposed operation and maintenance and servicing arrangements of the system. The information to be provided with an application for approval to alter an on-site sewage system is not prescribed by regulation. A note to Clause 26 of Local Government (General) Regulation 2005 states that the information that is to accompany such applications is to be determined by the council in each particular case. Section 81 of the Local Government Act 1993 requires that such applications must be accompanied by “…such matters as may be prescribed by regulations and such matters specified by the council as may be necessary to provide sufficient information to enable the council to determine the application”.

The performance standards for operation of a sewage management system are set out in clause 44 of the NSW Local Government (General) Regulation 2005, which includes the following outcomes (clause 44(1)):

With some exceptions (e.g. model and test systems, unique systems), the sewage management facility must be installed or constructed to a design or plan that is the subject of a certificate of accreditation from the Director-General of the Department of Health (Clause 41).

A system of sewage management must be operated in a manner that achieves the following performance standards:

(a) the prevention of the spread of disease by microorganisms,
(b) the prevention of the spread of foul odours,
(c) the prevention of the contamination of water,
(d) the prevention of degradation of soil and vegetation,
(e) the discouragement of insects and vermin,
(f) ensuring that persons do not come into contact with untreated sewage or effluent (whether treated or not) in their ordinary activities on the premises concerned,
(g) the minimisation of any adverse impacts on the amenity of the premises and surrounding lands,
(h) if appropriate, provision for the re-use of resources (including nutrients, organic matter and water).

When a property with an on-site sewage system changes hands, the new owner must get approval to operate the system. A temporary exemption is granted for a period of three months after the transfer of the property, and if application for approval is made within two months of the property transfer the person may continue to operate the on-site sewage system without approval until the application is finally determined (Local Government (General) Regulation 2005, clause 47).

Section 26 of the Local Government (General) Regulations 2005 notes that the information that is to accompany applications for approval to operate on-site sewage system is not prescribed by regulation, and that under Section 81 of the Local Government Act 1993 such applications must be accompanied by “such matters as may be prescribed by the regulations and such matters specified by the council as may be necessary to provide sufficient information to enable the council to determine the application”.

6. Standards and Guidelines

Standards and guidelines have been developed to ensure that environmental quality is maintained. These include for example, the ANZECC Guidelines and the Australian Standard/New Zealand Standard for on-site domestic wastewater management (AS/NZS 1547:2000) (see Section 2.7.13 previously).

The NSW Department of Local Government (DLG) has also developed guidelines relating to the management of on-site sewage systems (“Environment and Health Protection Guidelines: On-Site Sewage Management for Single Households”) (DLG, 1998). These guidelines were developed to help local councils assess, regulate and manage the selection, design, installation, operation and maintenance of single household on-site sewage management systems. They provide advice on planning, site evaluation, system selection, systems operation and maintenance, and ongoing system management. The guidelines consist of two parts: the first sections are modelled on a typical cyclical management model of continuous improvement, covering the definition of the factors and issues affecting on-site sewage management, the development and implementation of strategies and plans for on-site sewage management, the periodic monitoring of installed on-site sewage systems and the review of management strategies. The latter sections provide guidance on site evaluation, treatment and application systems, and the selection of an on-site sewage system for a specific site. We note that these guidelines specifically address the risk of viral contamination of waterways by human sewage by providing for the calculation of set-back distances of on-site sewage systems from watercourses based on a formula proposed in a paper by Beavers & Gardener (1993).

7. Marine Pollution Regulations 2006 – Reg 27

Amongst other issues the Marine Pollution Regulations 2006 regulate the discharge of sewage into the marine environment from vessels.
Sections 26 and 27 of the regulations relate to discharge of untreated sewage and treated sewage from vessels as follows:

26  **No discharge of untreated sewage**

1. A person must not discharge or deposit untreated sewage from a vessel into any navigable waters or onto the bank or bed of any navigable waters unless the sewage is discharged or deposited
   a) into a waste collection facility, or
   b) in accordance with an environment protection licence under the POEO Act 1997

2. The owner and master of a vessel are each guilty of an offence if untreated sewage is discharged or deposited from the vessel by any person in contravention of subclause (1)

3. It is a defence to a prosecution for an offence under subclause (2) if the defendant shows that all reasonable measures were taken to prevent the discharge or deposit from the vessel.

27  **No discharge zones for treated sewage**

1. This clause applies to the following waters:
   a) all inland waters,
   b) all intermittent closing and opening lagoons,
   c) waters in, and waters within 500 meters of any of the following:
      1. an area in which aquaculture occurs
      2. an area normally used for swimming
      3. a beach
      4. a marine park (within the meaning of the Marine Parks Act 1997)
      5. an area declared to be an aquatic reserve under the Fisheries Management Act 1994
   d) Waters in which, and waters within 500 metres of waters in which there is any of the following:
      i) a person
      ii) a moored or anchored vessel
      iii) a marina.

2. A person must not discharge or deposit treated sewage from a vessel into any navigable waters or onto the bank or bed of any navigable waters unless the sewage is discharged or deposited
   a) into a waste collection facility, or
   b) in accordance with an environment protection licence under the POEO Act 1997

3. The owner and master of a vessel are each guilty of an offence if treated sewage is discharged or deposited from the vessel by any person in contravention of subclause (2)

4. It is a defence to a prosecution for an offence under subclause (3) if the defendant shows that all reasonable measures were taken to prevent the discharge or deposit from the vessel.
APPENDIX II: WALLIS LAKES HEPATITIS A EVENT

General Description of the Growing Area

Wallis Lake is situated on the mid-north coast of NSW, approximately 300 km north of Sydney. The Wallis Lake catchment is large covering approximately 1,420 km$^2$, and stretches from the coast inland for a distance of approximately 50 km. The catchment includes the subcatchments of Wallamba, Coolongolook and its two main tributaries the Wallingat and Wang Wauk Rivers, in addition to Forster and Tuncurry townships and a number of smaller residential and semi-rural settlements including Nabiac, Failford, Pacific Palms and Coomba Park (Map 1). The Wallamba River subcatchment is the largest draining 41% of the total catchment area, followed by the subcatchment of the Coolongolook River and its tributaries which drain 44%, with main lake and estuary foreshores comprising the remaining 15% of the catchment.

Wallis Lake estuary covers an area of approximately 100 km$^2$. Water depth can range up to 5 m but generally waters are relatively shallow with an average depth of 1.8 m. The oyster harvest areas of Wallis Lake and its catchment fall within the municipal boundary of Great Lakes Council.

Wallis Lake estuary is the largest and most significant oyster-producing estuary in NSW, accounting for over 25% of New South Wales' farmed oysters. In 2010/11, Wallis Lake oysters had a farm gate value of ~ AU$10 million. The harvest period usually extends from September to April, with peak harvest occurring in December and January. Occasionally when environmental factors remain favourable and food supplies abundant, oysters hold their condition and remain marketable up until May, however usually by this time the majority of farmers have sold their entire crop.
Oyster farms are concentrated 1.5 km from the entrance of the estuary and extend to the northwest along the Wallamba River to its junction with Bungwhal Creek. Oyster farms are also located to the west of the outer estuary in the Coolongolook River and extend to the junction of the Coolongolook and Wallingat Rivers.

**Epidemiology**

The 1997 Wallis Lake Hepatitis A Outbreak is the most serious oyster-related outbreak ever attributed to Australian shellfish. In February 1997, the NSW Health Department noted a spike in the incidence of reported hepatitis A. Follow up investigations of recent cases revealed a strong association with travel to the NSW mid-north coast and/or consumption of Wallis Lake oysters. On the 14th February 1997 the decision was made to order an immediate withdrawal from sale and recall of Wallis Lake oysters. Surveillance for linked cases continue for 7 weeks until 4 April 1997 with 444 cases linked to the consumption of Wallis Lake oysters during this period.

The cases linked to consumption of Wallis Lake oysters indicated that contaminated oysters were available for sale over at least an 8 week period.

**Investigation**

At the time of the outbreak there was no management plan that provided for the closure of the oyster growing after significant amounts of rainfall - indeed what constituted a significant rainfall event for the area in terms of shellfish safety had not been determined. Additionally, there were no notification procedures in place with the local water utility to provide for the notification of sewage spills.

Immediately following the identification of an outbreak of hepatitis A linked to oysters from Wallis Lake an interagency working group, which included officers of Great Lakes Council (GLC), NSW Health and the NSW Environmental Protection Authority, was formed. This group pooled their resources to undertake a systematic sanitary survey of the Wallis Lake catchment. They identified a number of potential pollution sources that could have been discharging human effluent to the lake including domestic on-site sewage systems, the reticulated sewerage system and associated WWTP servicing the twin towns of Forster & Tuncurry, commercial on-site sewage systems servicing un-sewered tourist parks, pit toilets on public reserves, toilets at oyster depuration facilities and watercraft on Wallis Lake.

**Domestic on-site sewage systems**

The investigation of domestic on-site sewage systems covered 319 un-sewered domestic premises including the village of Nabiac on the Wallamba River. Investigations identified that out of the 319 systems inspected, 154 required remedial work to ensure that they did not pose a threat to water quality in Wallis Lake, with 7 systems found to be discharging directly into the waterway. Orders were immediately issued by the local government authority on the 67 highest risk premises to undertake remedial work by 1 June 1997. The 7 properties discharging directly to the water were ordered to cease this practice immediately.

**Reticulated Sewerage System and the WWTP**

Investigation of the WWTP outfall and sewerage system overflow points did not find any evidence of significant overflows during the outbreak period. However, early warning systems were not as well developed as they are today (i.e. telemetry, etc) and it is uncertain
whether an intermittent overflow (e.g. during a rainfall event) would have been detected. Also there was no legislative requirement for the sewerage system operator to report sewage overflows to the oyster industry.

Investigations into the Tuncurry WWTP outfall revealed that it discharges into sand aquifers near the lake. Studies of the groundwater quality and movement in the aquifer around the discharge point concluded that contamination of the lake via this route was unlikely.

**Commercial On-site Sewage Systems Servicing Tourist Parks**

Four major tourist developments utilising package sewage treatment plants with on-site effluent disposal were identified. Investigations concluded that these systems posed a high risk of contaminating Wallis Lake. The operators of these systems were ordered to immediately convert to pump out. While this imposed considerable cost onto the operators it was deemed necessary to ensure a prompt resolution to the contamination issues affected the local oyster industry.

**Public Toilets on Recreational Reserves (pit toilets)**

**Toilets at Oyster Depuration Facilities**

Of the 27 oyster depuration facilities identified on Wallis Lake 22 were found to have poor or no toilet facilities in place. This was particularly concerning given the sensitivity of the oyster industry to sewage contamination. The oyster industry resolved to correct this issue working cooperatively with the local council to identify and install appropriate toileting facilities given the site limitations at each facility.

**Commercial and Recreational Watercraft**

A survey of private watercraft on the lake found that only 50% had effluent holding tanks installed. While all commercial watercraft had holding tanks and the area was well serviced by pump-out facilities, an audit of pump-out usage showed that these facilities were being under-utilised. An education campaign was undertaken to remind boat owners of their responsibility to have holding tanks installed where toilets were being used in the lake. Boat owners were also reminded of the need to utilise pump-out facilities.

**Quality Assurance Program**

At the time of the outbreak there was no monitoring program for faecal pollution operating in Wallis Lake. Great Lakes Council (GLC) previously had a water quality monitoring program covering 12 sites around the lake, but this program had been suspended in 1994. Consequently there were no water quality data to assist in determining a possible source of the pollution.

Following the outbreak GLC recommenced its water monitoring program. The Wallis Lake oyster industry also fast tracked the implementation of the Wallis Lake Shellfish Quality Assurance Program.

**Remediation Efforts**

Following the Wallis Lake hepatitis A outbreak the immediate priority was to identify and remediate any urgent sources of human faecal pollution impacting on water quality of the lake to allow the area to be re-opened to the harvest of oysters as soon as possible. These action were
completed extremely promptly allowing Wallis Lake to be re-opened for the harvest of shellfish on 18th April 1997.

The re-opening of the harvest area did not end the impact of the outbreak on the Wallis Lake oyster industry or the local economy. Oyster sales took many years to fully recover due to the severe reputational damage done to Wallis Lake oyster brand. Even other local seafood commodities such as finfish that were not implicated suffered reputational damage and reduced markets prices. The Wallis Lake hepatitis A outbreak had a significant negative impact on local tourism, with 40,000 fewer guest nights in the second and third quarters of 1997 than the corresponding period in 1996.

This helped to galvanise the local community into action and facilitate a mindset shift in terms of the local community’s attitude to water quality. Businesses and residents throughout the region actively supported the protection of water quality in the lake. GLC took up the challenge and prioritised a series of programs to improve and secure water quality in the lake. Incredibly this drive still exists today almost 15 years after the outbreak.

Specific actions to improve water quality in Wallis Lake included:

- Extension of the reticulated sewerage system to cover un-sewered townships and tourist parks in the area.
- The implementation of a stringent, risk based, on-site sewage systems inspection programme.
- The installation of artificial wetlands to filter stormwater flows prior to reaching the lake. These wetlands also defray the impact of sewage spills from the reticulated sewerage system.
- The installation of 6 pump-out toilets around the lake to service the oyster industry and waterway users. These facilities are popular with tourism boosting this important industry.
- The installation of riverbank fencing to exclude stock and control erosion.
- The protection of 135.5 ha of wetland.
- The creation of an additional 304 ha of wetlands to replace wetlands lost by urban and agricultural development.

The efforts of GSC and the local community to restore water quality in Wallis Lake led to their winning the 2004 National Theiss River Prize which recognises best practice in environmental management and repair for river environments.

These improvements have also accrued significant on-going benefits to the Wallis Lake oyster industry. Figure 2 shows the reduction in clearance time for the lake following rainfall closures. In particular the constructed wetlands are thought to have played a major role in this change.
Figure 2: Average Closure Length for Wallis Lake Harvest areas 1999-2006.
APPENDIX III: GLOSSARY AND LIST OF ABBREVIATIONS

AEP Annual Exceedence Probability: the probability that a particular flood peak flow will be exceeded in any one year.

ANZECC Australian and New Zealand Environment and Conservation Council

ASQAAC Australian Shellfish Quality Assurance Advisory Committee

ASQAP Australian Shellfish Quality Assurance Program

BOD Biological oxygen demand. The amount of oxygen required by aerobic microorganisms to decompose the organic matter in a sample of water,

Depuration A process using a controlled environment to reduce the level of certain pathogenic organisms that may be present in live shellfish and crustaceans.

E. coli Escherichia coli

FSANZ Food Standards Australia New Zealand, a bi-national statutory authority that works in partnership with the Australian government, state and territory governments and the New Zealand government. FSANZ engages industry, consumers and public health professionals in the development of food regulatory measures.

IMO International Maritime Organisation, a specialised agency of United Nations with responsibility for the safety and security of shipping and the prevention of marine pollution by ships.

LEP Local Environment Plan (New South Wales)

MARPOL The International Convention for the Prevention of Pollution from Ships (abbreviated to MARPOL), established by the United Nations agency International Maritime Organisation, is the main international convention covering prevention of pollution of the marine environment by ships from operational or accidental causes.

MfE Ministry for the Environment (in New Zealand).

NSW New South Wales

OISAS New South Wales Oyster Industry Sustainable Aquaculture Strategy

Pacific oyster A species of rock oyster with the scientific name Crassostrea gigas.

PEP Protection of the Environment Policy (New South Wales)

Pipi The common name in New Zealand and Australia for selected bivalve species of surf clam that dwell in sandy sediments. The species name for pipi found in New
Zealand is *Paphies australis*. The species known as pipi is south-eastern Australia is *Donax deltoides* (also known as the Goolwa cockle in South Australia).

**POEO Act:** Protection of the Environment Operations Act 1997 (in New South Wales)

**RT-PCR:** Reverse transcription polymerase chain reaction

**SEPP** State Environment Planning Policy (New South Wales)

**SQAP:** Shellfish Quality Assurance Programme

**WWTP:** Wastewater Treatment Plant