

An Acute Infectious Gastroenteritis Outbreak Linked to Oyster Consumption

Outbreak Report

December 2024

Public Health HSE Dublin and Midlands, HSE National Health Protection Office, HSE National Environmental Health Service, Sea-Fisheries Protection Authority, The Marine Institute, Food Safety Authority of Ireland

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List of Abbreviations

BIM	Bord Iascaigh Mhara
CI	Confidence Interval
ECDC	European Centre for Disease Prevention and Control
NEHS	National Environmental Health Service
EHO	Environmental Health Officer
EPA	Environmental Protection Agency
FBO	Food Business Operator
FSAI	Food Safety Authority of Ireland
GI/GII	Genogroup I/Genogroup II
HPSC	Health Protection Surveillance Centre
HSE	Health Service Executive
LOQ	Limit of Quantification
MI	Marine Institute
MOH	Medical Officer of Health
NoV	Norovirus
NQ	Not Quantifiable
NVRL	National Virus Reference Laboratory
OR	Odds Ratio
RR	Relative Risk
RT-qPCR	Quantitative reverse transcription polymerase chain reaction
SFPA	Sea-Fisheries Protection Authority
WwTP	Wastewater Treatment Plant

Batch A: The batch of Pacific oysters (*Crassostrea gigas*) which were harvested on 28/05/2024 and served at the event associated with a large outbreak of 34 cases of gastrointestinal disease. No samples of batch A were available for microbiological testing.

Batch B: The batch of Pacific oysters (*C. gigas*) which were harvested on 04/06/2024 and subsequently tested positive (post-purification) for norovirus genogroup II at 407 copies per gram.

1. Executive Summary

This report outlines the investigation, control measures, and lessons learned from an outbreak of acute infectious gastroenteritis linked to a congregate social event. In early June 2024, the event attended by 147 people resulted in thirty-four individuals experiencing an acute, non-severe vomiting and diarrheal illness.

Following the event, an investigation was carried out by multiple public health and food safety stakeholders. An inspection by HSE Environmental Health Services deemed the event premises to be satisfactory in terms of their food safety obligations. An external food contractor (providing oysters from a mobile cart) was also inspected and found to be compliant with food safety regulations. Unfortunately, no food or beverage samples from the event, except for kitchen tap water and a blue cheese sample, were available for testing. Both samples complied with microbiological safety standards.

Descriptive epidemiology conducted by the HSE Public Health team indicated that the illness had a short incubation period and a brief, non-severe clinical course. A retrospective cohort study identified a statistically significant association between the consumption of Pacific oysters (*Crassostrea gigas*) at the event and developing gastroenteritis. However, no laboratory confirmation of a causative pathogen was possible, as none of the affected individuals sought medical care. Based on the available epidemiological evidence, it was most likely that oysters contaminated with norovirus (NoV) were the source of the outbreak.

Although oysters from the event (Batch A) were unavailable for testing, a subsequent batch (Batch B) harvested from the same production area one week later was tested by the Marine Institute (MI), and contained detectable levels of NoV genogroup II, at 407 copies per gram. The results of Batch B were recorded at the post-depuration stage. Batch B was voluntarily recalled by the purification and dispatch centre, though some oysters from this batch had already been consumed. Two additional cases of acute gastroenteritis were identified involving individuals who had not attended the event but had become unwell after consuming oysters from Batch B, prior to its recall.

The Sea-Fisheries Protection Authority (SFPA) confirmed that the food business operators (FBOs) - the registered primary oyster producer and the approved oyster purification/dispatch centre - had complied with all legislative requirements, including those for oyster depuration. All customers (including the mobile oyster cart who served the event) for the event batch A and the subsequent batch B were identified. Apart from the event, no other reports of illness were made to the food business operator from individuals who had consumed oysters from batch A.

The levels of NoV detected in batch B were considerably higher than would be expected from farmed oysters in Ireland in summer. A review of human NoV notifications in Ireland was undertaken to compare weekly incidence rates during summer 2024 with previous seasons. It was considered to be relevant that NoV was circulating at an unusually high level in the human population in Ireland in the summer of 2024. It was noted that NoV genotype GII.17 appears to be emerging in Ireland and replacing genotype GII.4 as the dominant strain. A similar pattern has been noted in other European countries in 2024. In addition, an investigation of the oyster production area was undertaken. A temporal correlation was identified between NoV levels in oysters from the production area and preceding heavy rainfall and sewage overflow events, with NoV levels in oysters decreasing over time following these events. This included a heavy rainfall event and a sewage overflow event into the bay where the oyster production area is located which preceded the harvesting of oyster batch A by 7 days.

Recommendations identified in this report include supporting EU legislation to establish upper limits for NoV in oysters, creating an early warning system for contamination in oyster production areas, incorporating human epidemiological data into oyster contamination risk assessments, ensuring official control samples are taken from food sources during suspected foodborne outbreaks, and prioritising the collection of stool samples from human cases.

2. Introduction

An extensive cluster of gastroenteritis was reported to the Department of Public Health Dublin and Midlands on 6th June 2024. This outbreak was notable because of its size, timing, the multi-agency response required and the epidemiological insights and food safety issues that emerged.

The objectives of this investigation were to (1) to confirm the existence and describe the outbreak, (2) to identify the source(s) and any contributing factors, (3) to implement necessary control measures and (4) to provide recommendations for future outbreak prevention and control measures. A retrospective cohort study was undertaken among event attendees to test the hypothesis that people who became unwell after the event did so as a result of consuming a food or beverage item at the event.

A multidisciplinary and multiagency Incident Management Team was established to investigate this outbreak and to prepare this report. Stakeholders included Public Health HSE Dublin and Midlands, HSE Environmental Health Services, the National Health Protection Office, the Food Safety Authority of Ireland, the Sea-Fisheries Protection Authority and the Marine Institute. All of these agencies were involved in the response to the outbreak. A series of meetings were held to facilitate discussions among relevant stakeholders and gather feedback on the draft report.

Table 2.1: Agencies Involved in the report

Agency	Role
Department of Public Health - HSE Dublin and Midlands Health Protection Team	The Health Protection team in the regional Department of Public Health work to protect, support, enable and advise on the health and wellbeing of the population. Under Medical Officer of Health (MOH) legislation, The MOH has the responsibility and authority to investigate and control notifiable infectious diseases and outbreaks.
HSE National Health Protection Office	HSE's National Health Protection Office provides strategic leadership to the delivery of an integrated, evidence-based national health protection service, working with regional, national and international partners.
HSE Environmental Health Services (EHS)	Through the enforcement of food safety legislation, Environmental Health Officers (EHOs) protect the health of the public by controlling and preventing environmental factors which may cause ill health or reduce quality of life.

Sea-Fisheries Protection Authority (SFPA)	SFPA is the competent authority for the regulation of the seafood sector in Ireland including aquaculture and oversees the implementation and compliance with food safety legislation. The functions of the SFPA in respect of food safety are detailed in a service contract agreement with the FSAI. The SFPA also provide technical advice to Government to help inform policy and to support the sustainable development of Ireland’s marine resources.
The Marine Institute (MI)	The Marine Institute is the National Reference Laboratory in Ireland for marine biotoxins, and for foodborne viruses (shellfish) and <i>Escherichia coli</i> (shellfish). The Marine Institute provides specific laboratory testing services, oversight of official control laboratories and technical advice to competent authorities in the relevant areas.
Food Safety Authority of Ireland (FSAI)	The Food Safety Authority of Ireland is Ireland’s central competent authority for food safety.

3. Background

3.1 Overview and Epidemiology of Norovirus in Humans

Norovirus infection is one of the most common causes of gastroenteritis globally. Norovirus is spread by the faecal oral route, either directly from person to person or indirectly via contaminated food, water, fomites or surfaces. Norovirus is highly contagious with a low infectious dose. In high-income countries, most infections are transmitted from person to person. Young children, the elderly, and people who are immunocompromised are at the highest risk for severe disease.(1)

Table 3.1: Norovirus Overview

Associated food and other exposures	Shellfish, salad ingredients, untreated water, ice-cubes, person-to-person spread and contaminated food handlers
Incubation period	15-50 hours
Duration of Illness	4 – 70 hours
Symptoms of infection	Nausea, vomiting, abdominal cramping, diarrhoea, fever, myalgia, and some headache.

Source: HPSC Infectious Intestinal Disease: Public Health & Clinical Guidance (2)

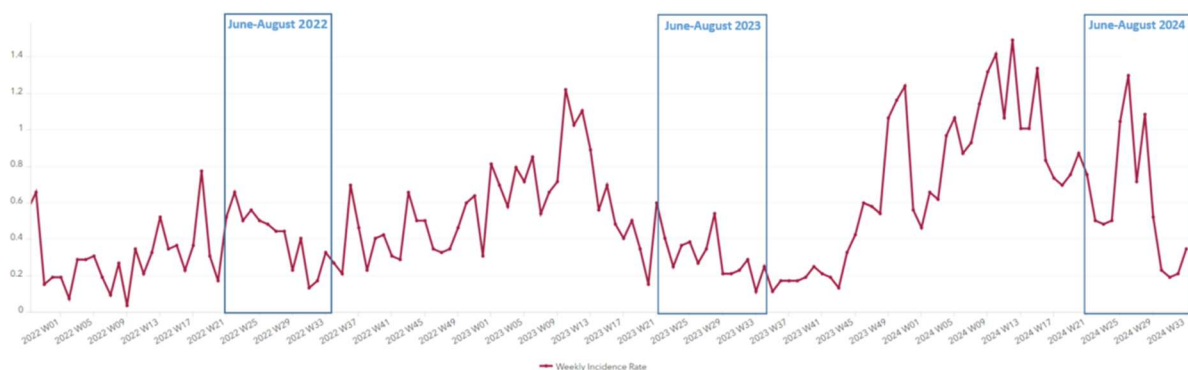
Immunity to NoV following infection is thought to be of limited duration, without evidence of protection across genogroups, and with limited evidence of protection across genotypes in the same group.(1) Interestingly, a subpopulation of individuals are resistant to NoV infection and disease. This susceptibility is NoV genotype-dependent and is largely mediated by the presence or absence of human histo-blood group antigens (HBGAs) on gut epithelial surfaces. The so-called non-secretors, have an inactivated FUT2 (secretor) enzyme, and do not express blood group antigens. Non-secretors appear to be almost completely resistant to the GII.4 genotype. Some data indicate that they are also protected against the GII.17 genotype.(3)

Foodborne transmission of NoV accounts for approximately 14% of NoV outbreaks globally; however, data are predominantly from high-income countries.(1) The link between bivalve molluscs and NoV is well established, and they have been shown to be responsible for a significant proportion of foodborne NoV cases and outbreaks in countries where data is collected.(4)

NoV incidence rates in humans display seasonality and are usually high in Ireland between December and April, but 2024 saw an unusual increase between the months of June to August 2024 (See Figure 3.1, Table 3.2) that has also been seen in Europe and the US.(5)

Figure 3.1 Weekly Incidence Rate of Human Norovirus Infection in Ireland

Week 1 2022 to week 33 2024 (June-August highlighted in blue boxes)



Source: HPSC National Notifiable Disease Hub (6)

Table 3.2 Number of Norovirus Outbreaks and Total Number of Reported Cases for week 1-28 in 2024 compared to week 1-28 in 2023 in Ireland

	2024 week 1-28	2023 week 1-28
Number of outbreaks of noroviral infection	157	72

Total number ill	2,398	1,054
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Source: HPSC Weekly Outbreak Report Week 28, 2024 (7)

3.2 Virology

Noroviruses are divided into 10 genogroups (GI to GX). Genogroups GI, GII, GIV, GVIII, and GIX can all infect humans. Each of these genogroups is further subdivided into genotypes. GI and GII genotypes are by far the most common, accounting for ~90% of all reported cases in humans.(1) According to a review of global and regional NoV circulation trends between the years of 1995-2019, GII.4 was the predominant reported genotype of NoV worldwide.(8)

Many countries in Europe experienced an out-of-season increase in norovirus (NoV) incidence rates in the summer months of 2024, according to the European Centre for Disease Prevention and Control (ECDC). A shift in the predominant NoV genotype from GII.4 to GII.17 or a general increase in genotype GII.17 has been observed in Austria, Finland, France, Germany, the Netherlands and the UK.(9) Epidemiological data from Ireland in 2024 suggests a similar picture. The Health Protection and Surveillance Centre (HPSC) quarter 2 report for 2024 noted that of 23 representative norovirus samples sequenced by the National Virus Reference Laboratory, 17 (74%) were genogroup 2 and of those, 88% (n=15) were GII.17.(10) An increased circulation of this genotype in the population suggests growing relevance of this genotype for future cases and outbreaks.

3.3 What is known about the association between oysters and norovirus risk?

Filter feeding bivalve molluscs such as oysters and mussels can accumulate and concentrate pathogens, including norovirus, when grown in shellfish production areas that are impacted by sewage discharges. As a result, sewage-contaminated bivalve molluscs are a recognised risk for consumers. This risk is particularly acute for oysters which are often consumed raw, are grown in intertidal areas most likely to be vulnerable to sewage contamination and because NoV may preferentially bind to receptors found in oysters compared to other species.(11) Overflows of untreated sewage due to high rainfall or other events has been identified as a particular food safety concern.(12)

Despite extensive regulatory food safety controls in use worldwide, gastroenteritis associated with oyster consumption continues to occur. The occurrence of NoV in oyster production areas is common. During a two-year EU wide baseline survey commissioned by the European Food Safety Authority NoV was detected in 38% of all samples analysed.(13) The study also demonstrated that NoV detection

was highly seasonal with both detection frequency and concentrations increasing significantly during the winter months. A similar two-year study in the in the United Kingdom demonstrated that 76% of oyster samples contained NoV.(14)

Following harvesting, depuration is commonly used to reduce food safety risks associated with bivalve molluscs. Depuration is a process of controlled self-purification in tanks of clean seawater over time. However, depuration may be only partially effective at reducing NoV concentrations to safe levels and outbreaks of NoV gastroenteritis have occurred following depuration. Studies demonstrate a variable but often limited NoV reduction during depuration under standard conditions.(11) However, more recently it has been demonstrated that NoV reduction can be maximised by increasing water temperature and extending depuration time (15), which may help to increase the food safety impact of depuration as an element of an overall risk management approach.

Despite the high incidence of NoV detection in oysters, the reported occurrence of outbreaks associated with oyster consumption remains rare in Ireland. The internationally validated method for quantifying NoV (16) does not distinguish between infectious and non-infectious NoV. While, generally, an increasing concentration of NoV in oysters indicates an increasing risk of illness (17) associated with consumption, the presence of NoV does not always lead to illness. This makes risk assessment and setting an acceptable limit for NoV in oysters challenging and an ongoing topic for discussion at the EU level.

3.4 Overview of Bivalve Molluscan Shellfish Regulation - Official Control Activities

Microbiological contamination of bivalve molluscs is a recognised risk for consumers and EU regulations exist to specifically address these risks. In Ireland, bivalve mollusc farming is regulated by a combination of national and EU standards to manage risks to sustainability, food safety, and environmental protection. Key regulatory bodies include the Sea-Fisheries Protection Authority (SFPA), and the Food Safety Authority of Ireland (FSAI). The Marine Institute is the National Reference Laboratory for viruses in bivalve molluscs.

The Sea-Fisheries Protection Authority (SFPA) is responsible for overseeing the implementation of and compliance with food safety legislation for seafood operators. Food business operators responsible for placing bivalve molluscs on the market are required to implement a stringent food safety management system. The SFPA, as the competent authority, carries out risk based official controls including inspections and official control sampling to verify the FBO's food safety management system.

EU shellfish legislation relating to bivalve mollusc production and placing on the market requires a sanitary survey to establish the sampling plan and representative sampling point(s) of *E.coli* contamination in the bay for ongoing routine sampling as part of the bivalve mollusc classification programme. In accordance with Regulation (EU) 2017/625 and the subsequent implementing regulation (EU) 2019/627, the Sea-Fisheries Protection Authority is required to classify bivalve mollusc production areas and to fix the boundaries thereof. The SFPA carries out a monthly bivalve mollusc sampling programme in all active production areas, with the results determining the classification of each area. There are three classifications—A, B, and C—based on *E. coli* levels. Bivalve molluscs from class A areas may go direct for human consumption, while those from class B must be depurated, heat treated or relayed to meet class A requirements. Bivalve molluscs from class C areas must be relayed for 2 months to meet class A or B requirements or may also be heat treated.(18)

3.5 Food safety responsibilities of bivalve molluscan shellfish producers and approved operators

As matters stand, there is no regulatory limit in legislation for NoV relating to bivalve molluscs. Nonetheless the issue of NoV needs to be proactively managed by bivalve mollusc producers, who are required to meet their general obligations in food law, for example, Article 14 of Regulation (EC) No 178/2002 (general principles and requirements of food law) which prohibits placing food on the market if it is unsafe. In terms of the Irish legislation, as per the Food Safety Authority of Ireland Act, 1998 S.12(3), “in respect of any food placed on the market, the primary responsibility for the safety and suitability of the food for human consumption is borne by [FBOs] individually or, as appropriate, collectively, and, as a consequence, each of the parties mentioned shall take all reasonable steps to ensure, in so far as that party is concerned, the safety and hygienic standard of that food.”

A guidance document, jointly prepared by the Food Safety Authority of Ireland (FSAI), the Sea-Fisheries Protection Authority (SFPA), the Marine Institute (MI) and Bord Iascaigh Mhara (BIM) provides recommendations to specifically assist oyster producers to reduce the risk of NoV contaminated oysters being placed on the market and to reduce the risk of outbreaks of illness associated with their consumption. This guidance document outlines risk management strategies, including regulatory obligations, and recommended best practice for oyster producers and purification/dispatch centres.(19) Separately, the FSAI’s Scientific Committee published an opinion piece in 2013 that provides recommendations on market re-entry for any production area implicated in a NoV outbreak.(20) For example, the shellfish operator is recommended to only place oysters on the market following an outbreak when it has been demonstrated that depuration post-harvest can achieve NoV concentrations of less than 200 copies per gram.

Oyster operators work closely with agencies in Ireland to mitigate the risk present from NoV contamination as far as practicable and to implement the recommendations in national guidance. To support these efforts the Marine Institute tests approximately 1,000 samples per year for industry under a programme funded by Bord Iascaigh Mhara (BIM). On the basis of this monitoring, oyster operators take mitigation steps when NoV levels exceed those in the operators own food safety management plan, which can vary by production area depending on historical data. Control steps after an outbreak of NoV include suspending harvest until levels return to acceptable levels and applying increased post-harvest treatments such as extended purification periods at elevated temperatures.

4. Outbreak Investigation and Results

4.1 Public Health Epidemiological Investigation and Results

Public Health HSE Dublin and Midlands devised an anonymous online survey in order to ascertain the clinical aspects of the cases and to investigate the association with all food and beverage exposures (34 possible menu items). The survey was sent to all who attended the event.

Case Definition

A case was defined as a person who attended the event at venue X on date X and developed vomiting and/or diarrhoea within 7 days.

Hypothesis

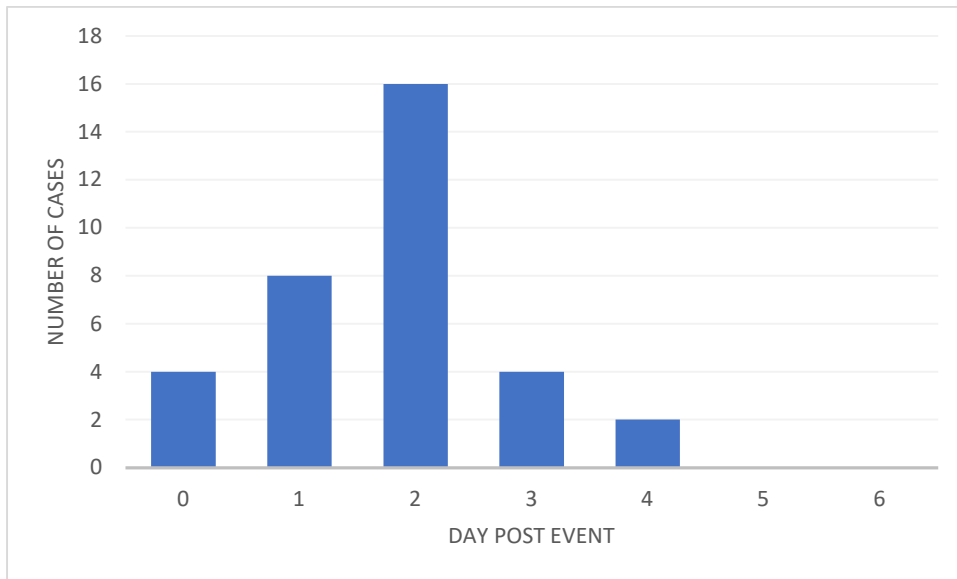
The hypothesis generated by the public health team was that; *people who attended the event on date X, who subsequently became unwell, did so as a result of consuming a food or beverage item served at the event.*

4.2 Results of descriptive study

The event was attended by 147 people. The response rate to the public health survey was 63% (n=92). Of the respondents, 34 had become unwell on or since the date of the event, with clinical features fitting the case definition for this outbreak. None of the cases had sought medical attention for their symptoms at the time of completing the survey. In terms of the incubation period, the distribution of reported onset of illness is as follows: four individuals became unwell on day 0 (date of the event), eight individuals on day 1, sixteen individuals on day 2, four individuals on day 3 and two individuals

on day 4 (Figure 4.1). Additionally, two respondents reported secondary case(s) in their household, in people who did not attend the event.

Figure 4.1 Epicurve (number of cases per day post event)



The symptoms experienced by cases are included in Table 4.1 below. In terms of duration of symptoms, 38% of cases had symptoms for one day. 18% of cases had symptoms for 2 days and 32% of cases had symptoms for 3 days. The median duration of symptoms was 2 days.

Table 4.1. Symptoms and their prevalence in cases

Symptom	n	%
Nausea	27	79
Abdominal pain	26	76.5
Diarrhoea	23	67.6
Chills	21	62
Vomiting	20	59
Muscle aches	20	59
Fever	17	50
Bloody diarrhoea	0	0

Based on the descriptive study results, the most likely pathogen was strongly suspected to be norovirus, given the typical symptoms of vomiting and diarrhoea and the absence of bloody diarrhoea, the short incubation period, the short duration of symptoms and the fact that nobody reported seeking healthcare for their illness, indicating a non-severe illness. The table in Appendix A outlines the differential diagnoses considered by the Public Health team.

4.3 Analytical results - retrospective cohort study:

An analytical retrospective cohort study was carried out based on the information provided by attendees in the survey. All analyses were conducted using SPSS Version 27.

In total 16 out of 34 menu items had a relative risk (RR) for becoming unwell of >1 on univariate analysis (see table: Appendix B). Only oysters [RR 4.67, (95% CI 2.14-10.2, $p < 0.001$)] and bottled water [RR 2.14 (95% CI 1.03-4.22, $p = 0.005$)] had statistically significant associations with becoming unwell. The dessert panna cotta had a high RR of 5.01 (95% CI 0.75-33.3, $p = 0.10$). While the result for panna cotta was not statistically significant at the 5% level, it was decided to proceed to a multivariable model in order to increase accuracy and adjust for the effect of other variables.

A binary logistic regression was performed to evaluate the impact of all 16 menu items shown in appendix B on the likelihood of becoming unwell. The logistic regression analysis indicated that consuming oysters remained significantly associated with becoming unwell [OR 9 (95% CI 2.39-34.12, $p = < 0.001$)]. None of the other menu items included in the model were statistically significant at the 5% or 10% level.

Of note, the survey results indicated that 6 individuals who did not consume oysters had become unwell - meeting the case definition - after the event. This discrepancy might possibly be attributed to person-to-person transmission post-event or to errors in survey responses. It was noted that 6 out of the 34 cases became unwell >48 hours after the event. If the illness was indeed norovirus, these 6 cases could be more likely to have been infected by secondary person-to person transmission. 3 out of these 6 cases with onset >48 hours after the event had not consumed oysters.

4.4 Environmental Health Service Investigation and Results

The local area Environmental Health Service (EHS) conducted an inspection of the event premises. Overall, the premises were clean and sanitary on the inspection date. The Food Business Operator (FBO) who provided the main catering for the event reported that no staff or food handlers had experienced symptoms of gastroenteritis in the two weeks preceding the event. They also provided records demonstrating suitable traceability of ingredients to the premises, as well as records verifying the maintenance of the cold chain during delivery and storage. Additionally, records were maintained for monitoring the cooking processes of foods served on the day of the event.

The water supply to the premises was via the public mains water supply. A water sample from the kitchen tap was tested and was found to be compliant with routine microbiological standards for drinking water safety. The only food sample remaining at the venue from the event was some blue

cheese which was served as an appetiser. The results were satisfactory for routine microbiological parameters (table 4.4).

The event premises informed the EHS that a separately contracted caterer provided oysters at the event. These oysters were served from a stall on the grounds of the premises, before the main dinner. The local EHS inspected the oyster stall after the event and found it to be clean and well maintained. Minor non-compliances were noted which were not considered by the local EHS to be of significance to the outbreak.

An outbreak control team meeting was convened and was attended by representatives from the EHS and Public Health Dublin/Midlands on June 12th, 2024. The National EHS notified the Sea-Fisheries Protection Authority (SFPA) of the possibility of an outbreak attributed to oysters.

4.5 SFPA investigation and Results

A sea-fisheries officer contacted the approved operator regarding the specific batch of oysters (batch A) which were served at the event. These oysters had been harvested on 28/05/2024 by the oyster producer, and originated from a B-class production area, therefore requiring depuration before being placed on the market. All oysters from this harvest were supplied to one approved purification and dispatch centre (hereafter known as the approved operator). The production area was open for harvest with respect to biotoxins based on results from the national monitoring programme.

The SFPA verified the list of customers for batch A, and the quantities sold to each. Batch A consisted of 88 kg and 15 kg had been supplied to the event. All customers of batch A confirmed that the entire stock had been sold, leaving no remaining product available for sampling. The approved operator was not aware of any other additional cases of illness associated with batch A of oysters. The SFPA verified the purification records and noted that the depuration conditions for batch A were 12°C for 46 hours. Batch A had not been selected for routine NoV monitoring under the approved operator's food safety management system. The SFPA noted that the approved operator's food safety management system stipulates an upper limit of 500 copies of NoV per gram, prior to purification.

The SFPA was satisfied that both the oyster producer and the approved operator had adhered to their legislative obligations, including depuration requirements. As a precaution, the approved operator voluntarily tested a subsequent batch of oysters, batch B, which was harvested one week after batch A. Batch B was found to contain NoV GII of 407 copies/gram post depuration. Batch B was also sent for testing by the approved operator for *E.coli* and *Salmonella* and results were compliant with EU limits (Table 4.6). Batch B was subsequently recalled. The recalled batch had been supplied to five

customers in Ireland – four restaurants and one online outlet. Varying amounts of stock had been supplied and some had been already consumed at the time of recall.

As part of the SFPA investigation, it emerged that two individuals (a married couple, tourists) had become unwell with gastrointestinal symptoms 24 hours after consuming oysters from batch B which had been served at a restaurant in the West of Ireland. One of the individuals was interviewed by a member of the HSE Public Health Dublin and Midlands Team. A food history was taken. One of the individuals reported having been unwell with nausea, vomiting and diarrhoea, and the other individual reported nausea only. It was noted that neither of these two individuals sought healthcare for their symptoms, and therefore stool samples were not obtained for microbiological analysis to confirm a diagnosis.

4.6 Marine Institute Investigation

The Marine Institute utilises a standardised quantitative reverse transcription polymerase chain reaction (RT-qPCR) to test for NoV GI and GII, measuring the "detectable virus genome copies per gram of digestive tissue." (ISO 15216-1:2017). This testing method includes controls for RT-PCR inhibition and extraction efficiency, with the limit of quantification (LOQ) for both GI and GII NoV assays set at 100 copies per gram. The Marine Institute has been accredited by the Irish National Accreditation Board for use of this method since 2010.

On the 13th May 2024, approximately three weeks prior to the outbreak occurring, a sample was tested by the Marine Institute as part of the operator's food safety management programme. Norovirus results for this sample were below the limit of quantification (<LOQ) for both GI and GII NoV.

Following the outbreak, the producer supplied the Marine Institute with approximately weekly samples of oysters from the implicated production area. Results from this testing (Table 4.5) suggest that intermittent NoV contamination of the production area occurred from early June until the end of July 2024.

Generally, historical data indicates the site is a production area that is at risk of significant levels of NoV during the winter high risk period. There is a general lack of historical NoV data available from the site for the summer months, as the summer months are considered to be lower risk for NoV contamination.

4.7 Investigation results of potential contamination event of the production area

It was felt that there was a strong possibility that the NoV result recorded in batch B was linked to a contamination event, for example human sewage releases close to the oyster beds. Risk factors for NoV contamination in bivalve molluscs include high rainfall (potentially leading to sewage system overflows), and high levels of NoV circulation in the human population. Other risk factors for NoV contamination of bivalve molluscs include low solar radiation which limits sunlight inactivation of NoV particles, low wind speeds which limits dispersal of NoV contamination and low water temperatures which also slow NoV degradation. As shown in section 3.3, NoV illnesses were circulating at unseasonably high levels in Ireland during the summer months of 2024. It should be noted that even advanced wastewater treatment systems may not entirely eliminate NoV from the effluent (21). A secondary hypothesis was developed: contamination of oysters in batch B occurred pre-harvest in the growing area, related to rainfall and sewage overflow events.

According to the Sanitary Survey Report and Sampling Plan produced by the SFPA for the production area in 2020, there is one large town on the coast close to the production area. There are seven wastewater treatment plants (WwTPs) in the catchment. Three WwTPs discharge directly into the production area itself. Of these, one large WwTP in the town is the biggest treatment works within the catchment and is likely the main impacting source of contamination levels in the harvesting area. The other four WwTPs discharge into rivers much higher in the catchment and their impacts will be diluted.

The monthly classification data for the production area were provided by SFPA and reviewed and it was confirmed that Pacific oysters sampled from the area had remained within parameters (<4,600 E.coli) for a B class production area throughout the study period (May-July 2024).

The oyster results for NoV GII were graphed (Figure 4.2) from 13/05/2024 (when NoV GII levels were noted to be <LOQ) until 29/07/2024 to assess for any association with high rainfall events, sewage overflow events and NoV being subsequently recorded in the oysters. Rainfall levels in the area were obtained for the closest climate station to the production area from WOW-IE, the Weather Observations Website of Met Éireann. Data on wastewater treatment plant routine overflows into the bay where the production area is located were obtained from Uisce Éireann.

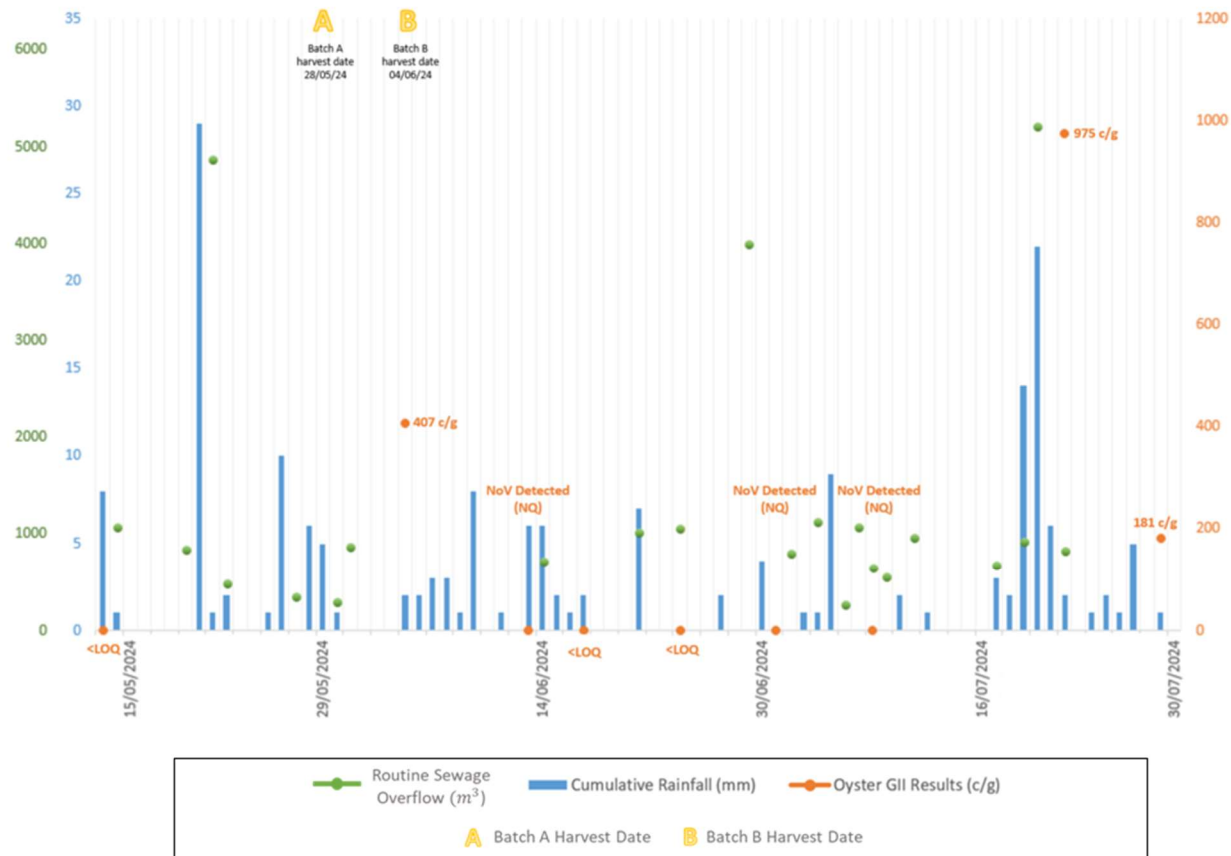
The detected NoV GII levels are of interest as they appear to temporally correlate with preceding heavy rainfall days/sewage overflow events, with NoV GII levels reducing over time and eventually returning to <LOQ after these events. Of particular interest, there was a heavy rainfall event (29mm) on the 20/05/2024, followed by a sewage overflows into the bay of 4878 m³ and 486m³ one and two days later respectively. The event batch of oysters (Batch A) was harvested on the 28/05/2024. While unfortunately there are no NoV results for Batch A, the recorded levels in Batch B on 04/06/2024 of

407copies/gram post depuration are likely related to those rainfall and sewage overflow events, with NoV GII levels finally reducing to <LOQ on oyster samples taken on 17/06/2024. The results are presented graphically in Figure 4.2 and in tabular format in Appendix C.

Finally, in terms of other possible contributory factors to oyster contamination with NoV, it was noted that solar radiation was unseasonably low for May 2024 in the region (about 85% of expected), which would have limited the potential for sunlight inactivation of NoV virus particles. Wind speeds were also low in May, which may have limited dispersal of sewage contamination and increased the likelihood of oysters becoming contaminated.

Figure 4.2

Daily Cumulative Rainfall (mm), Daily Routine Sewage Overflows (m^3) and Oyster NoV GII Levels (c/g) 13/05/2024 – 01/08/2024



<LOQ = below the limit of quantification, NQ = Not quantifiable due to PCR inhibition

All NoV GII results are pre depuration **except** the result of 407 copies/gram which was post depuration.

Sewage overflows excluded from graph if <200m³ for clarity, however they are included in the table in appendix C

4.8 Microbiological/Toxicological investigations and results

Table 4.4 Result of EHS microbiological investigations

Environmental Health Service – results of microbiological analysis		
Sample Type	Tested for	Result
Public mains water supply from event venue	Routine microbiological parameters	Satisfactory
Blue cheese	Routine microbiological parameters	Satisfactory

Table 4.5 Results of MI microbiological investigations

The Marine Institute – results of microbiological analysis				
Sample Type	Depuration status at time of test	NoV GI (copies/g)	NoV GII (copies/g)	Laboratory Quality Control QC comment
Harvest area sample 13/05/2024	Pre	<LOQ	<LOQ	All QC passed
Oysters batch B - Date harvested 04/06/2024	Post	<LOQ	407	All QC passed
Harvest area sample 13/06/2024	Pre	Virus detected (NQ)	Virus detected (NQ)	Sample failed RT-PCR inhibition quality assurance criteria, however NoV GI and NoV GII genome was detected but cannot be quantified.
Harvest area sample 17/06/2024	Pre	<LOQ	<LOQ	All QC passed
Harvest area sample 24/06/2024	Pre	Virus detected (NQ)	Virus detected (NQ)	[Title]
Harvest area sample 01/07/2024	Pre	Not detected	<LOQ	The undiluted sample failed RT-PCR inhibition criteria. This sample was re-tested diluted 1 in 10. Therefore, the LOD and LOQ is 200 and 1000 genome copies/g, respectively. RT-PCR inhibition in neat RNA; virus detected in diluted RNA (10-1)
Harvest area sample 08/07/2024	Pre	<LOQ	<LOQ	All QC passed
Harvest area sample	Pre	<LOQ	975	All QC passed

22/07/2024				
Harvest area sample 29/07/2024	Pre	<LOQ	181	All QC passed

NQ = Not quantifiable, LOQ = Limit of quantification, 100 copies/g (neat RNA); 1000 copies/g (10^{-1} RNA), RT-PCR = Real Time Polymerase Chain Reaction

Table 4.6 Results of further laboratory investigations for oysters batch B

Pathogen	Result	Comment
<i>E.coli</i>	All <18/100g	Compliant with Regulation EC 2073/2005.
Salmonella	Not detected in 25g	Compliant with Regulation EC 2073/2005.

5. Risk Management/Control Measures

5.1 Care of cases and management of contacts

A diarrhoea and vomiting factsheet was provided to all those who attended the event by the HSE Public Health team. This included advice on how to avoid onward spread of infection. In addition, event attendees were advised to attend their GP if symptomatic and to contact HSE Public Health if a stool sample was taken. Contact details for HSE Public Health Dublin and Midlands were provided.

5.2 Prevention of further exposure

A list of customers for batch A (the event batch) were verified by SFPA. All customers reported that all stock had been sold – therefore no product was remaining to sample. The oyster producer had received no other reports of illness from batch A. Oyster purification records were verified by SFPA.

Given batch B, a subsequent batch from the supplier who had supplied the event, had recorded NoV GII at 407 copies per gram post-depuration, a recall of all remaining oysters from batch B was initiated by the FBO as a precaution. After batch B had been recalled, the oyster supplier implemented an extended depuration period at increased temperature until 17/06/2024. Ultimately none of the oysters harvested between the recall and 17/06/2024 were released for consumption as the FBO did not have conclusive NoV testing results on them.

6. Discussion and Conclusions

This outbreak of thirty-four cases of gastrointestinal illness was shown in a retrospective cohort study to be statistically significantly associated with oyster consumption. Norovirus was the suspected pathogen, however this was not laboratory confirmed in any of the cases or in the event batch of oysters. The investigation revealed that the event batch of oysters (batch A) was harvested 8 days after a heavy rainfall event and 7 days after a significant sewage overflow into the bay where the production area is located. The event Batch A was plausibly contaminated with NoV as a result of this sewage overflow event, especially given a subsequent batch of oysters (batch B) harvested one week after the event batch from the same production area contained NoV GII levels of 407 copies/gram post depuration. Batch B was also linked with two further cases of gastrointestinal illness. This outbreak provides further evidence of the risk of large foodborne outbreaks of illness associated with NoV contaminated oysters, especially under certain combinations of epidemiological and climatic conditions.

It was noted that the levels of NoV that were detected in batch B are considered to be unusual in the summer season. However it would appear that heavy rainfall events led to increased NoV concentrations in the oyster production area. Unusually for the time of year, these rainfall events coincided with high circulation of NoV infections in the community which likely compounded the NoV contamination levels.

In this report, we demonstrate that sewage overflowed into the bay where oysters are cultivated, following days of heavy rainfall. According to the Environmental Protection Agency (22) an increase in extreme rainfall events is predicted in Ireland as a consequence of climate change. Other climate-change related factors may also be important and their impacts on NoV in seawater should be explored further, such as changes in sea temperatures or solar radiation levels. Recognising and understanding environmental and epidemiological patterns is crucial for developing effective preventive measures and improving the overall safety of oyster consumption. Currently NoV monitoring and associated management practices are targeted to the higher-risk winter period. However, this outbreak occurred outside of the identified risk period. The reduced monitoring frequency in place during the summer months may have contributed to the occurrence of the outbreak, as a potential opportunity to mitigate the risk may have been missed. This highlights the need for a more informed risk assessment process, and consideration should be given to develop an event-driven early warning system for prevention of outbreaks associated with microbial contamination of oysters. Such a system could include predictors such as rainfall (and or national

hydrometric monitoring programme data), sewage overflows and human epidemiological information, and could trigger preventative measures such as delaying harvests, increasing NoV monitoring and increasing depuration times and temperatures.

This outbreak occurred in the context of an unseasonal increase in human NoV cases in Ireland. Many countries in Europe, and the US, have reported an increase in the proportion of NoV samples characterised as GII.17. As per the ECDC, this genotype is growing in relevance for outbreaks in Europe. Gaining insights into the characteristics of this genotype in future could enhance our understanding and management of NoV outbreaks. However, unfortunately it could not be confirmed if this outbreak was indeed associated with a GII.17 NoV strain, as no cases provided stool samples for microbiological analysis. Genotyping from the food source (oysters) is not straightforward. As contamination would be due to sewage presence in the growing waters, multiple genotypes may be present. Cloning is required and sensitivity is an issue. There is no guarantee that genotyping from batch B will be successful, and in any case this was not the batch consumed at the event.

Extensive regulations (as detailed in section 3.5) exist to control the risks associated with microbiologically contaminated oysters. The oysters implicated in this outbreak were fully compliant with the existing regulation. However, it is clear from this outbreak and others throughout Europe that these regulations do not fully protect consumers from the risk associated with NoV contaminated bivalve molluscs. In addition to the regulations, guidance exists to help oyster producers and approved operators fulfil their responsibility to produce safe food. There is currently no legislative upper limit on NoV levels in oysters produced for human consumption in Ireland. The European Food Safety Authority (EFSA) recommends establishing acceptable limits for the presence of NoV in oysters that are harvested and placed on the market in the European Union.⁽²³⁾ This limit if implemented is likely to increase food safety, and any introduction of an upper limit for NoV in oysters should maximise the public health benefits while still remaining feasible for oyster producers.

It should be noted that despite the lack of legal obligations to do so, oyster producers in Ireland conduct regular, structured NoV monitoring to inform their food safety management plans (FSMP). They actively collaborate with national agencies to mitigate NoV risks and endeavour to adhere to all national guidelines. Integration of best practice as outlined in the guidance is paramount to their ability to place food on the market which is safe for human consumption. However, a gap in implementation of recommended best practice was identified as part of this investigation - existing guidance documents recommend that relevant food business operators should maintain frozen samples of all dispatched batches of oysters for a specified period ⁽²⁰⁾. Unfortunately, a frozen sample

from batch A was not retained for investigation. Operators should be encouraged to audit their practice against the national guidance. In addition, the investigation was limited by a reliance on operator provided samples. Official control samples taken by a competent authority would be more reliable in the setting of an outbreak.

Limitations of this study include the lack of a confirmed pathogen from any of the cases. This could have been alleviated by timely posting of stool pots to cases for return to a laboratory. The exact time of onset of symptoms was elucidated by date, not by time in hours after the event which would have increased precision. We did not have information of the dose (number) of oysters consumed by any individual at the event, which would have increased the precision of our study. We also did not have information on the attendees' genetic predisposition (secretor status) to NoV infection, which has been documented in previous outbreaks.(3) We are confident that the full menu for the event was obtained, but there is a small chance some menu items were not identified.

In conclusion, while the outbreak can be attributed to NoV-contaminated oysters with only moderate certainty, the available evidence strongly supports the hypothesis that contamination of the event batch of oysters occurred, most likely pre-harvest due to human sewage in the growing areas. It is clear that existing EU regulations on oyster food safety in Ireland would benefit from the inclusion of explicit legislative limits to fully protect consumers from related foodborne illnesses, particularly given the evolving challenges posed by changing climatic and epidemiological conditions. This legislation will not diminish the need for operators to integrate best practices into their food safety management systems to effectively manage this risk. Moreover, the growing impact of climate change and related events must be factored into broader risk assessments to ensure that monitoring programs and operator mitigation efforts are conducted at the appropriate times to effectively manage these risks. Based on this investigation, the following recommendations have been developed to help reduce the likelihood of future NoV outbreaks linked to oysters.

7. Recommendations

1. Risk Management and Early Warning Systems to prevent outbreaks:

- a. Risk management efforts for NoV contaminated oysters currently focus on the high-risk winter period. However, the results of this outbreak investigation underscore the importance of adopting a proactive event-driven risk management approach throughout the year. An early warning system should be developed and implemented to inform industry and regulatory agencies when conditions occur that may impact oyster production areas. Human epidemiological information (such as NoV incidence rates), sewage overflow information and rainfall information could be incorporated into such a predictive system, which would trigger control measures such as increasing the frequency of monitoring samples for microbial analysis, deploying enhanced depuration or delaying harvesting of oysters for a time period.

2. Reinforcing the importance of FBOs following existing guidance

- a. Food Business Operators (FBOs) have a legal obligation not to place unsafe food on the market. FBOs involved in the production, or depuration and dispatching of oysters should classify NoV as a hazard and be encouraged to integrate existing guidelines for managing NoV risks into their food safety management systems. Food business operators should be encouraged and supported to audit their food safety management system against the current guidance on the management of NoV in oysters.

3. Legislation at EU level to protect consumers:

- a. Given that increasing concentrations of NoV in oysters are associated with increased risk of NoV illness in the consumer, Ireland should continue to support efforts at the EU level to establish an acceptable upper limit for NoV in oysters which adequately balances the public health benefits and industry impacts.

4. Outbreak response and investigation

- a. The results available for analysis in the investigation were voluntary samples submitted by the purification and dispatch centre. Official control samples should be taken by the competent authority when there is an outbreak associated with a particular batch of oysters.
- b. Where possible stool samples should be collected as a priority following suspected outbreaks of foodborne NoV to support epidemiological investigation. Posting of stool pots to cases for return to a laboratory could make this more convenient for cases who

do not require healthcare. The lack of a confirmed pathogen in human cases or from the event batch of oysters was a limitation to this investigation.

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9. Appendices

Appendix A. Common acute infectious gastroenteritis pathogens

Pathogen	Food/Other Associations	Incubation Period	Duration of Symptoms	Associated Symptoms
Norovirus	Shellfish, salad ingredients, untreated water, ice cubes, person to person.	15-50 hours	4 – 70 hours	Nausea, vomiting, abdominal cramping, diarrhoea, fever, myalgia, and some headache.
Salmonella	Raw meats, poultry, eggs, dairy products, fish, shrimp, salad dressings.	12-72 hours	3-7 days	Diarrhoea, fever, abdominal cramps, vomiting, occasionally muscle cramps and headache.
Verotoxigenic <i>E. coli</i> (VTEC)	Beef, pork, fast foods, salad vegetables, beansprouts, untreated water, milk, processed meats, person-person	1-8 days (3-4 typical)	5-10 days	Varies – from mild illness to moderate or severe bloody diarrhoea, with abdominal pain. Vomiting/fever uncommon.
Campylobacter	Undercooked poultry, person to person, milk, cheese, untreated water	1-10 days (2-5 typical)	2-10 days	Diarrhoea, abdominal pain, fever, vomiting, bloody diarrhoea in half of cases
Staphylococcus aureus	Contaminated food handlers, unpasteurised dairy products	2-4 hours	1-2 days	abrupt onset, severe cramping pain, nausea, vomiting, diarrhoea, hypotension and prostration
Cryptosporidium	Contaminated water (possibly raw vegetables), person to person	1-28 days (2-10 typical)	2-4 weeks	Diarrhoea (usually watery, with mucus), stomach cramps, upset stomach, slight fever.

Source: HPSC Infectious Intestinal Disease: Public Health & Clinical Guidance

Appendix B: Univariate analysis: Relative Risk (RR) of menu items (included if RR>1)

Food Item	Exposed (Item Consumed)			Unexposed (Item Not Consumed)			Relative Risk	95%CI	P value
	Cases	Non-Cases	Attack Rate	Cases	Non-Cases	Attack Rate			
Oysters	28	18	61%	6	40	13%	4.67	2.14 - 10.2	<0.001
Panna cotta	33	46	42%	1	11	8%	5.01	0.75 to 33.3	0.10
Bottled Water	9	5	64%	21	49	30%	2.14	1.26 to 3.64	0.005
Ice in drinks	28	39	42%	4	18	18%	2.30	0.91 to 5.83	0.08
Side dish: Green Vegetables	32	47	41%	2	9	18%	2.23	0.62 to 8.03	0.22
Sorbet	32	49	40%	2	7	22%	1.78	0.51 to 6.22	0.37
Red Wine	21	25	46%	13	33	28%	1.62	0.92 to 2.82	0.09
Soup	28	38	42%	6	16	27%	1.56	0.74 to 3.25	0.24
Seafood Medley	17	21	45%	17	36	32%	1.39	0.82 to 2.36	0.21
Breakfast Morning	18	24	43%	16	33	33%	1.31	0.77 to 2.24	0.31
Drinks reception: Pimms	21	30	41%	13	28	32%	1.30	0.74 to 2.27	0.35
Coffee	20	30	40%	14	28	33%	1.20	0.69 to 2.07	0.51
Mixed leaf salad	5	7	42%	29	51	36%	1.15	0.55 to 2.38	0.70
Fish main course	14	21	40%	20	37	35%	1.14	0.67 to 1.95	0.63
Table Water	31	55	36%	1	2	33%	1.08	0.21 to 5.49	0.92
Poultry main course	20	34	37%	14	24	37%	1.01	0.58 to 1.73	0.98

Appendix C: Table of Cumulative Daily Rainfall, Sewage Overflow, Oyster NoV GII results by date

Date	Cumulative Daily Rainfall (mm)	Sewage overflow (m3 per day)	Oyster NoV GII Results (c/g)
13/05/2024	8	0	Below the Limit of Quantification
14/05/2024	1	1068	-
15/05/2024	0	0	-
16/05/2024	0	0	-
17/05/2024	0	0	-
18/05/2024	0	0	-
19/05/2024	0	843	-
20/05/2024	29	0	-
21/05/2024	1	4878	-
22/05/2024	2	486	-
23/05/2024	0	0	-
24/05/2024	0	0	-
25/05/2024	1	0	-
26/05/2024	10	0	-
27/05/2024	0	348	-
28/05/2024 Batch A Harvested	6	0	-
29/05/2024	5	0	-
30/05/2024	1	300	-
31/05/2024	0	873	-
01/06/2024	0	0	-
02/06/2024	0	0	-
03/06/2024	0	0	-
04/06/2024 Batch B Harvested	2	0	407 (post depuration)
05/06/2024	2	0	-
06/06/2024	3	0	-
07/06/2024	3	0	-
08/06/2024	1	0	-
09/06/2024	8	0	-
10/06/2024	0	0	-
11/06/2024	1	0	-
12/06/2024	0	0	-
13/06/2024	6	0	Detected - Not Quantifiable
14/06/2024	6	726	-
15/06/2024	2	0	-

16/06/2024	1	0	-
17/06/2024	2	0	Below the Limit of Quantification
18/06/2024	0	0	-
19/06/2024	0	0	-
20/06/2024	0	0	-
21/06/2024	7	1017	-
22/06/2024	0	0	-
23/06/2024	0	0	-
24/06/2024	0	1059	Detected - Not Quantifiable
25/06/2024	0	0	-
26/06/2024	0	165	-
27/06/2024	2	0	-
28/06/2024	0	0	-
29/06/2024	0	4002	-
30/06/2024	4	24	-
01/07/2024	0	111	Detected - Not Quantifiable
02/07/2024	0	795	-
03/07/2024	1	33	-
04/07/2024	1	1128	-
05/07/2024	9	27	-
06/07/2024	0	273	-
07/07/2024	0	1068	-
08/07/2024	0	651	Below the Limit of Quantification
09/07/2024	0	561	-
10/07/2024	2	42	-
11/07/2024	0	960	-
12/07/2024	1	0	-
13/07/2024	0	0	-
14/07/2024	0	0	-
15/07/2024	0	0	-
16/07/2024	0	0	-
17/07/2024	3	678	-
18/07/2024	2	105	-
19/07/2024	14	921	-
20/07/2024	22	5212	-
21/07/2024	6		-
22/07/2024	2	834	975 (pre-depuration)
23/07/2024	0	0	-
24/07/2024	1	0	-
25/07/2024	2	0	-
26/07/2024	1	0	-
27/07/2024	5	0	-

28/07/2024	0	0	-
29/07/2024	1	0	181 (pre-depuration)
30/07/2024	0	0	-