

## **Interim Guidance on the Management of Norovirus in Oysters by Shellfish Producers**

### **Scope:**

This guidance document, prepared by the Food Safety Authority of Ireland (FSAI), the Sea-Fisheries Protection Authority (SFPA), the Marine Institute (MI) and Bord Iascaigh Mhara (BIM) aims to assist shellfish producers to reduce the risk of norovirus contaminated oysters being placed on the market and to reduce the risk of outbreaks of illness associated with the consumption of norovirus contaminated Oysters.

This guidance is advisory only. Adoption is recommended but it is not a requirement on any shellfish producer or FBO.

### **Background:**

Norovirus is the most common cause of viral gastroenteritis globally. Infections in Ireland and other countries demonstrate a strong seasonal distribution with illness peaking in the winter months (December through to March). Because of this seasonal distribution, acute gastroenteritis caused by norovirus is often described as “Winter Vomiting Disease.”

Transmission of norovirus is via the faecal-oral route either directly or via contaminated food or water. Person-to-person transmission is most common, especially in closed communities and outbreaks are often associated with highly publicised closures of hospital wards and other care settings. Such outbreaks are simply a reflection of the circulation of the virus in the wider community.

As a result the virus circulates relatively freely in the community and can be present in discharges from waste water treatment systems including systems from single houses. Even the most advanced methods of wastewater treatment (such as UV treatment) are incapable of removing 100 percent of norovirus particles.

Bivalve shellfish can accumulate human pathogenic viruses (including norovirus) when such viruses are present in the growing waters. Such shellfish can represent a significant health risk when consumed raw or lightly cooked.

High risk factors for shellfish-related norovirus include cold weather (low water temperatures), high prevalence of norovirus gastroenteritis in the community, and high rainfall (potentially leading to sewage system overflows).

### **Legislation:**

As matters stand, there is no regulatory limit for Norovirus in legislation relating to shellfish.

The absence of a regulatory limit means the issue of Norovirus needs to be proactively managed, not only to prevent it becoming a consumer issue, but also to prevent or limit the probability that batches of shellfish are rejected by customers or competent authorities in jurisdictions where the shellfish are being imported into.

Until such time as a regulatory limit is introduced, shellfish producers are still 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.

Nominal, suggested limits may be included in guidance published in the EU or elsewhere. These are intended to act as prompts for action; they are not enforceable regulatory requirements and should not be treated as such.

Shellfish producers may wish to consider if such limits are applicable to their operations and, if so, in what circumstances.

For example, the FSAI's Scientific Committee published an opinion<sup>1</sup> that where a production area implicated in a norovirus outbreak seeks to re-enter the market, the shellfish producer should either

1. Seek to demonstrate that norovirus concentrations in oysters from that area have been reduced to **200 copies per gram (cpg)** or less, if the oysters are intended for direct human consumption **without post-harvest treatment**<sup>2</sup>; or,
2. In the case of oysters intended for human consumption **following post-harvest treatment**, the shellfish producer should only place such oysters on the market when it has been demonstrated that post-harvest treatment can achieve concentrations of less than 200cpg.

However, it is worth re-iterating that the figure of 200cpg is not intended to apply generally and only applies if the production area has been implicated in a Norovirus outbreak; where there has been no such outbreak then this figure is not intended to be applied.

### **Management Measures:**

The attached 'Norovirus Management Table' outlines a series of recommended risk management options designed to reduce the potential of norovirus contaminated oysters being either harvested or placed on the market. These risk management options include regulatory obligations, and recommended best practice and are designed for both primary producers and approved dispatch centres.

The obligatory sections for both primary producers, (shellfish growers) and dispatch centres are contained in the first three, highlighted, rows in the table. The remaining sections of the table describe recommendations such as:

- a. Assessing the risk of where norovirus contaminated oysters may originate from.
- b. Recommendations on managing the risk of norovirus contaminated oysters.
- c. Recommendations on maintaining library samples of harvested or dispatched oysters.
- d. Developing strategies to reduce risk or to validate risk profiling.
- e. Non-recommended practices.

Oyster producers are advised to include Norovirus as a "hazard" in their food safety management systems. Where it is decided not to include Norovirus as a hazard, then the reason should be recorded.

They are also recommended to develop and describe measures intended to either prevent the Norovirus hazard being realised or to minimise the risk of it disrupting their business by causing an outbreak or a reported case of gastro-enteritis.

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<sup>1</sup> "Risk Management of Norovirus in Oysters" ([www.fsai.ie/publications\\_norovirus\\_opinion/](http://www.fsai.ie/publications_norovirus_opinion/))

<sup>2</sup> For this purpose, a level of less than or equal to 200cpg in two consecutive samples (at least 10 animals per sample) harvested at least 24 hours apart provides substantial reassurance that such a concentration had been reached.

Furthermore, based on their knowledge of their production area, the requirements of their customers and the efficiency of any on-growing or purification/depuration process at reducing Norovirus, shellfish producers are recommended to develop limits for Norovirus that might apply in their operation. These limits can then be used to trigger certain decisions for example to release or withhold shellfish, to move on from any location or to consider/extend purification/depuration.

The question of what constitutes an appropriate limit is one for the shellfish producer to consider. The higher the limit a shellfish producer wishes to use the greater the probability any shellfish they produce will have Norovirus present at levels which present as an issue of consumer concern or lead to batches being rejected by customers or competent authorities in countries receiving their shellfish.

Proactively addressing Norovirus in a food safety management system limits the potential for it becoming a food safety issue and helps in any response to any incidents or cases. It can also greatly assist shellfish producers return to normal operations in the wake of a confirmed incident.

#### On-growing/Re-location within a production area

Where testing indicates that a portion of a production area might be less prone or vulnerable to contamination by Norovirus, consideration can be given to using this part of the production area as an on-growing or finishing area. Oysters can be moved into this area for a number of weeks before being harvested.

While testing may indicate that the waters are of a higher microbiological quality in one part of a production area compared to other parts, this in itself should not automatically determine that the area is suitable for on-growing or finishing. Oyster producers are advised to assess the relevant part of the production area to see how resilient it is against Norovirus contamination. Water and tidal flows within the production area, as well as the location of waste-water outfalls (both treated and untreated) should be considered as part of this assessment.

Where such an on-growing or finishing area is identified and is intended to be used, careful stock management should be practiced to ensure that shellfish moved into the area can be tracked to ensure they remain in the area for the prescribed time.

#### Enhanced Purification methods<sup>3</sup>:

Trials conducted by the Marine Institute have demonstrated that **correctly operated Depuration Systems** operated at higher temperatures and for a prolonged period combined with careful norovirus risk management practices can significantly reduce Norovirus concentrations in shellfish, thereby reducing the risk to public health.

#### Laboratory testing for norovirus:

Norovirus detection in bivalve shellfish is based on the use of reverse transcription quantitative real-time PCR (RT-qPCR). An internationally recognised standard method exists for the quantitative determination of norovirus (ISO 15216-1:2017) and it is recommended that this method is used for norovirus testing in the situations highlighted above.

As it stands the only laboratory in Ireland currently undertaking norovirus testing in shellfish is the Marine Institute. Due to resource and scheduling requirements the Marine Institute is

currently restricted to the number of samples that can be tested for risk management and quality assurance purposes. It is expected that given demand, private commercial laboratories will begin to provide norovirus testing in the near future.

Private laboratories in the UK and elsewhere are currently providing norovirus testing services. If using private laboratories for norovirus testing careful consideration should be taken in selecting the laboratory. It is advisable to ensure that the method used in any laboratory is the same or comparable to the method used in the National Reference Laboratory at the Marine Institute (ISO 15216-1:2017).

Further information on selecting laboratories can be found in the “Guidance note on assessment of virus testing laboratories for Food Business Operators and Competent Authorities” published by the European Union Reference Laboratory (EURL) for monitoring bacteriological and viral contamination of bivalve molluscs (<https://eur1cefas.org/media/14109/comprehensive-guidance-note-on-assessment-of-virus-testing-laboratories.pdf>)<sup>3</sup>.

### **Traceability, Withdrawal and Recall:**

It is a legal requirement to maintain a traceability system. Shellfish producers are strongly advised to maintain a robust and accurate traceability system in place that allows them to rapidly identify the source and destination of any shellfish they purchase, handle or sell.

Consideration needs to be given to how batches are made up before being placed on the market. Large batches, while they may involve less documentation, generate fewer records and be easier to handle, can lead to broader recalls or withdrawals than would otherwise be the case if the shellfish were placed on the market as a series of smaller batches. This can be further complicated if a large batch is comprised of shellfish from a number of different sources.

Associated with the requirement for traceability, shellfish producers are recommended to develop withdrawal and recall procedures and to review them regularly. They are also recommended to keep records that might be required in such an eventuality (for example, traceability information, customer lists, shipping records etc) in a form and place that is easily accessible.

### **Where to go for further advice**

- [FSAI Guidance Note No.10 Product Recall and Traceability](#)
- [SFPA Depuration Guidance](#)

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<sup>3</sup> A summary is also available (<https://eur1cefas.org/media/14110/summary-guidance-note-on-norovirus-testing.pdf>).

	<b>Primary Producer</b>	<b>Dispatch Centre without Purification</b>	<b>Combined Purification Centre and Dispatch Centre</b>
<b>Legal Status</b>	Registered to grow and harvest oysters.	Approved to dispatch oysters for direct human consumption	Approved to dispatch oysters for direct human consumption following purification
<b>Obligatory Documentary requirements for oysters produced</b>	Shellfish Registration Document showing Classification and Biotoxin status of production area.	Label and Commercial documentation with Identification Mark showing approval number.	Label and Commercial documentation with Identification Mark showing approval number.
<b>Some Obligatory Food Safety Requirements</b>	General Hygiene, Annex I of 852/2004. Only Harvest from Classified Production Areas (CPAs). Only harvest from biotoxin-open areas. Registration as FBO	General Hygiene Annex II 852/2004. Structures and systems to comply with specifics of Annex III Section VII 853/2004. Food Safety Procedures based on HACCP principles. Approval of establishment.	General Hygiene Annex II 852/2004. Structures and systems Annex III Section VII 853/2004. Food Safety Procedures based on HACCP principles. Approval of establishment.
<b>Recommendation to assess risk</b>	Use standardised RT-qPCR method <sup>4</sup> , to develop a profile of the extent of norovirus contamination in the production area, identifying times and parts of areas when/where the concentrations are highest and lowest. <sup>5</sup>  Understand trends over time and within sub-areas of the Classified Production Area. Understand when and where oysters contain lowest and highest norovirus	Ensure all Oysters taken in to establishment for dispatch to human consumption come from areas with understanding of profile of norovirus available to inform Dispatch Centre HACCP.	Ensure all Oysters taken in are from areas with understanding of profile of norovirus available to inform purification Centre HACCP.  Using standardised RT-qPCR method develop profile of effectiveness of purification centre procedures in reduction of Norovirus.

<sup>4</sup> RT-qPCR, Reverse transcriptase real time quantitative PCR, method for the detection of norovirus in bivalve shellfish should be based on ISO 15216-1:2017

<sup>5</sup> Given the potential resource and scheduling requirements, producers are recommended to discuss their intentions with the Marine Institute **before** any sampling takes place to develop such a profile.

<p><b>Recommendation to manage risk</b></p>	<p>Harvest according to understanding of Norovirus profile in area.</p> <ul style="list-style-type: none"> <li>• Do not harvest during times and/or from sub- areas where profile indicates highest concentration.</li> <li>• Limit harvest for supply though dispatch centres without purification to times and sub-areas where profile indicates baseline lowest risk.</li> <li>• Limit supply routes to those that include effective depuration, for harvest during times and from areas where profile indicates risk above baseline but not at highest.</li> </ul>	<p>Identify norovirus as a hazard within HACCP, and include explicit procedures to manage that risk.</p> <p>Inform decisions to take in oysters according to understanding of norovirus profile in area in area.</p> <ul style="list-style-type: none"> <li>• Avoid intake and dispatch of oysters harvested during times and/or from sub-areas where CPA profile indicates highest concentration, regardless of purification.</li> <li>• Limit intake of oysters without purification to times and sub-areas where profile indicates lowest risk.</li> <li>• Ensure oysters intake from purification centres have been subjected to a purification procedure with adequate duration and temperature aligned with to the Norovirus risk profile of the CPA</li> </ul>	<p>Identify norovirus as a hazard within HACCP, and include explicit procedures to manage that risk.</p> <p>If oysters other than lowest risk profile are to be purified then 'norovirus-enhanced' depuration procedures with elongated times and/or raised temperatures should be developed.</p> <p>Inform decisions to take in oysters and according to understanding of norovirus profile in area in area.</p> <ul style="list-style-type: none"> <li>• Avoid intake, purification or dispatch of oysters harvested during times and/or from sub- areas where CPA profile indicates highest concentration</li> <li>• Ensure intake procedures identify oysters with profile other than lowest risk</li> <li>• For oysters with profile other than lowest risk, ensure that they are subjected to a depuration procedure sufficient to manage norovirus risk</li> </ul>
<p><b>Library Sample Recommendations</b></p>	<p>Consider a sample of 10 animals frozen for the shelf-life</p>	<p>Keep a sample of 10 animals frozen for the shelf-life of the product</p>	<p>Keep a sample of 10 animals frozen for the shelf-life of the product</p>

<p><b>Sampling &amp; Analysis strategy<sup>6</sup></b></p>	<p>Use norovirus analysis of samples from production area to prospectively develop profile over time and across sub areas (see note #2 above)</p>	<p>Consider the use of norovirus analysis within HACCP procedures to validate risk profiling of intake batches</p>	<p>Consider the use of norovirus analysis within HACCP procedures to validate risk profiling of intake batches.</p> <p>Use norovirus analysis to validate risk profiling of intake batches</p> <p>Use norovirus analysis to validate effectiveness of purification, particularly enhanced purification procedures to manage risk from oysters with profile other than lowest risk</p>
<p><b>Testing &amp; Analysis Strategy that is not recommended</b></p>	<p>Without prior consideration of acceptable or unacceptable concentration, and resultant actions, analysis of norovirus in individual batches consigned from CPAs, is not recommended.</p>	<p>Without prior definition of acceptable or unacceptable concentration in HACCP of approved establishment, and resultant actions, norovirus analysis in individual batches dispatched, is not recommended.</p>	<p>Without prior definition of acceptable or unacceptable concentration in HACCP of approved establishment, and resultant actions, norovirus analysis in individual batches dispatched, is not recommended.</p>

<sup>6</sup> Further information on selecting laboratories can be found in the “Guidance note on assessment of virus testing laboratories for Food Business Operators and Competent Authorities” published by the European Union Reference Laboratory (EURL) for monitoring bacteriological and viral contamination of bivalve molluscs. The full document is available at <https://eurlcefas.org/media/14109/comprehensive-guidance-note-on-assessment-of-virus-testing-laboratories.pdf>.

A summary is also available (<https://eurlcefas.org/media/14110/summary-guidance-note-on-norovirus-testing.pdf>).