

## **Interim Guidance on the Management of Norovirus in Oysters by Shellfish Producers (2025 Revision)**

### **Scope:**

This guidance document has been prepared by the Food Safety Authority of Ireland (FSAI), the Sea-Fisheries Protection Authority (SFPA), the Marine Institute (MI) and Bord Iascaigh Mhara (BIM).

It aims to assist oyster producers to reduce the risk of norovirus contaminated oysters being placed on the market and to reduce the risk 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 generally 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.” However, it is noted that in recent years significant numbers of norovirus infections have occurred in the community outside of the traditional high-risk period.

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 treated discharges and combined stormwater overflow discharges from wastewater treatment plants, as well as from other wastewater treatment systems such as 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 risk of infection 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 receiving shellfish imports from Ireland.

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, nor should they be treated as such.

Oyster 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 and 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 200 cpg 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 (oyster 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 norovirus contamination in originating oyster production areas.
- b. Managing the risk associated with norovirus contaminated oysters.
- c. Maintaining library samples of harvested or dispatched oysters.

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<sup>1</sup> "Risk Management of Norovirus in Oysters" (<https://www.fsai.ie/publications/risk-management-of-norovirus-in-oysters-opinion-by>)

<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.

- d. Developing strategies to reduce norovirus risk or to validate risk profiling.
- e. Non-recommended practices.

Oyster producers are advised to identify norovirus as a “hazard” in their HACCP food safety management system. 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.

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, oyster producers are recommended to develop limits for norovirus that might apply in their operation. These limits can then be used to trigger certain decisions or actions, for example to release or withhold shellfish, to relocate oysters to less contaminated areas or to consider extending purification/depuration.

The question of what constitutes an appropriate limit is one for the shellfish producer to consider and implement.

The higher the limit a shellfish producer wishes to use the greater the probability any shellfish they produce will have norovirus concentrations/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 responding 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 demonstrates that a portion of a production area might be less 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. The relevant number of weeks should be determined and decided upon by the oyster producer.
- While testing for *E. coli* of shellfish growing in a classified production area may indicate that the waters in one part, or subdivision, are of a higher microbiological quality compared to others, this in itself should not automatically determine that the area is suitable for on-growing or finishing in the context of managing norovirus risk. 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 discharges (both treated and untreated) should be considered as part of this assessment. Norovirus testing may be used to support this assessment.

Where such an on-growing or finishing area is identified and is intended to be used, careful stock management should be practiced ensuring 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 elevated temperatures and for an extended period can contribute to norovirus removal and reduction.

However, “enhanced depuration” must be combined with careful other norovirus risk management practices (e.g. restricting initial norovirus virus concentrations) to optimise the risk reduction potential of this approach. The objective should be to start any purification cycle with the lowest possible norovirus concentrations in the shellfish. Purification is not a substitute for good risk management practices elsewhere in the production area and should not be used to compensate for poor practices or as a “shortcut” to placing oyster on the market for human consumption.

Properly and consistently applied, enhanced purification can reduce norovirus concentrations in shellfish, thereby reducing the risk to public health. However, it should be noted that extended depuration may not always successfully reduce norovirus to acceptable levels. Producers should validate their purification operating procedures as one element of their overall risk management process

**Where an operator proposes to use enhanced purification methods then they should ensure they have facilities capable of achieving the required time / temperature regime and that they have sufficient capacity to allow the enhanced purification methods to be applied to the anticipated volumes and throughput. To minimise transfer times, etc, these facilities should be conveniently located to the dispatch centre, where the shellfish will be packed for distribution.**

### **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 currently recommended that this method is used for norovirus testing in all situations.

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. The Marine Institute should be contacted by operators to discuss testing requirements.

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 provides comparable results to the method used in the National Reference Laboratory at the Marine Institute (ISO 15216-1:2017). It is advisable that the laboratory should be accredited to ISO 17025 quality standards.

Further information on selecting an appropriate laboratory for norovirus testing in oysters can be obtained by contacting the Marine Institute.

Laboratory analysis provides results based on two norovirus genogroups (norovirus genogroup I and II). For the purpose of assessing risk it is advisable to combine the values

determined of these two genogroups and consider the total norovirus concentrations present.

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

It is a legal requirement to maintain a traceability system on the basis of “one step forward / one step back. In other words, oyster must know who their suppliers are and who their customers are and keep records in relation to them.

Oyster producers are strongly advised to maintain a robust and accurate internal traceability system in place within their operations. This should allow for the rapid identification and linking of the source and destination of any shellfish they purchase, handle or sell. In the event of an outbreak of foodborne disease, such as norovirus, or in the event of an adverse report from a competent authority elsewhere, good internal traceability allows for recalls and withdrawals of products to be carried out in an efficient, targeted and rapid fashion. This not only limits the risk to consumers, but also minimises the disruption to the oyster producers operations.

In this regard, 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 several 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.

For each batch harvested, it is recommended that producers retain a library sample (sample of 10 animals frozen for the shelf-life of the product). Library samples should be representative of the batch harvested (for example, they should not always be taken at the start or end of the harvest). These “library” samples are important for future reference and testing, especially in foodborne outbreak investigations.

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

- [FSAI Guidance Note No.10 Product Recall and Traceability](#)
- [SFPA Depuration Guidance](#)
- [BIM](#) provide periodic training on food safety management systems and HACCP

	<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>3</sup> , to develop a profile of the extent of norovirus contamination in the production area, identifying times of year and locations within areas when/where the norovirus concentrations are highest and lowest. <sup>4</sup> Understand trends over time and within sub-areas of the Classified Production Area. Understand when and where oysters contain lowest and highest norovirus concentrations.	Ensure all oysters taken into establishment for dispatch for human consumption come from areas with an established norovirus risk profile to inform Dispatch centre HACCP.	Ensure all Oysters taken in are from areas with an established norovirus risk profile to inform purification centre HACCP.  Using standardised RT-qPCR method develop understanding of the effectiveness of purification centre procedures in reduction of norovirus.

<sup>3</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

<b>Recommendation to manage risk</b>	<p>Harvest according to knowledge of norovirus profile in area.</p> <ul style="list-style-type: none"> <li>• Determine limit of norovirus concentrations acceptable for harvest to place on the market directly and/or following depuration</li> <li>• Do not harvest during times and/or from sub-areas where profile indicates that acceptable concentrations will be exceeded.</li> <li>• Limit harvest for supply through dispatch centres without purification to times of year 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 of year and sub-areas where profile indicates that acceptable concentrations of norovirus will not exceeded.</li> <li>• Ensure oysters intake from purification centres have been subjected to a purification procedure with adequate duration and temperature aligned to the norovirus risk profile of the classified production area.</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.</p> <ul style="list-style-type: none"> <li>• Avoid intake, purification or dispatch of oysters harvested during times and/or from sub-areas where classified production area profile indicates acceptable concentrations of norovirus may be exceeded.</li> <li>• Ensure intake procedures identify oysters with profile other than lowest risk</li> <li>• Where required to achieve acceptable norovirus concentrations , ensure oysters are subjected to a depuration procedure sufficient to manage norovirus risk.</li> </ul>

<b>Sampling &amp; Analysis strategy<sup>6</sup></b>	Use norovirus analysis of samples from production area to prospectively develop profile over time and across sub areas and assign acceptable norovirus limits (see “ Recommendation to assess risk” above)	Consider the use of norovirus analysis within HACCP procedures to validate risk profiling of intake batches	Consider the use of norovirus testing and analysis within HACCP procedures to validate risk profiling of intake batches.  Use norovirus testing and analysis to validate effectiveness of purification, particularly enhanced purification procedures to achieve acceptable norovirus concentrations in intake batches
<b>Testing &amp; Analysis Strategy that is not recommended</b>	Without prior consideration of acceptable or unacceptable concentration, and resultant actions, analysis of norovirus in individual batches consigned from CPAs, is not recommended.	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.	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.
<b>Library Sample Recommendations</b>	Keep a sample of 10 animals frozen for the shelf-life of the harvested batch	Keep a sample of 10 animals frozen for the shelf-life of the product	Keep a sample of 10 animals frozen for the shelf-life of the product