

Policy Response to Norovirus Strategic Risk Assessment

Policy response to the conclusions of the strategic risk assessment into norovirus in oysters and next steps to be taken.

Why the strategic risk assessment was commissioned

As with all food business operators (FBOs), harvesters of live bivalve molluscs are required to meet their general obligations in Article 14 of European Union (EU) and Retained EU Law 178/2002 in Northern Ireland and Great Britain which prohibits FBOs from placing food on the market if it is unsafe.

Thorough cooking will ensure that [norovirus](#) if present in oysters is eliminated prior to consumption. However, oysters tend to be served raw therefore control options for norovirus are limited and depuration treatment at conditions [set out in Food Standards Agency \(FSA\)](#) and [Food Standards Scotland \(FSS\) guidance](#) have limited effectiveness at eliminating norovirus.

Some harvesters across the United Kingdom (UK) are known to operate a positive release system, using norovirus testing as part of their food safety management system. Under EU and retained EU Law, there is no regulatory limit for norovirus (or any other foodborne virus) laid down in legislation and currently no test to determine whether norovirus present in food is infectious or not.

Norovirus outbreaks attributed to consumption of raw oysters are assessed and managed on a case-by-case basis. Risk management options developed are based on epidemiological evidence linking cases with the implicated batch, microbiological evidence, case food chain histories and traceability information which can identify the production area.

FSA and FSS may take into account any FBO test results carried out as part of a positive release system. Where traceability information implicates a specific batch and production area, a pause in harvesting of the affected area may be recommended to prevent further products, which are potentially contaminated, from being placed on the market.

The FSA and FSS commissioned a microbiological risk assessment to support the development of advice and guidance to strengthen management of outbreaks of norovirus associated with consumption of raw oysters.

The aim was to develop risk management advice in relation to norovirus testing of oysters during outbreak situations, taking into account the amount of norovirus contamination detected by the quantitative reverse-transcription polymerase chain reaction (qRT-PCR) method in ISO 15216, and how this may inform the resumption of harvesting from oyster production areas implicated in an outbreak.

Conclusions of the strategic risk assessment

When oysters are eaten raw and there is potential human wastewater contamination from sewage spills or if the oyster batch is epidemiologically linked to outbreaks, there is a risk of illness from norovirus.

If oysters implicated in an outbreak are tested and norovirus levels (in genome copies per gram) are detected, the likelihood of illness is assessed to vary from low-medium risk at 1-200 copies/g; medium risk at 201-500 copies/g; high risk at 501–1000 copies/g and very high risk at >1000 copies/g. However, the level of uncertainty in all cases remains high - see next steps.

In the absence of risk factors such as sewage spills or epidemiological linkage to outbreaks, the risk of illness associated with quantitative norovirus levels is unknown.

Response to strategic risk assessment

The typical risk appetite for incident/outbreak risk management in the FSA and FSS would normally be acceptance of a very low likelihood of illness with low associated uncertainty.

The many uncertainties in the strategic risk assessment makes it very challenging to recommend a quantitative norovirus limit for FBOs to demonstrate before resuming harvesting in a production area after being linked to a norovirus outbreak.

The FSA and FSS cannot recommend such a limit at this time. Risk management during norovirus outbreaks in the UK will continue to be undertaken on a case-by-case basis and take into account all available evidence.

Next steps

It is necessary to reduce uncertainties in the strategic risk assessment associated with assigning public health risk to specific norovirus levels. This can be addressed by gathering more data through testing of oysters from batches epidemiologically linked to outbreaks.

Obtaining oysters from implicated batches to test is challenging; by the time reports of illness are made the implicated product tends to have been consumed or stored in a way which does not facilitate testing.

FSA and FSS are committed to improving the evidence base and as such will consult industry throughout the supply chain to explore ways in which to increase available material for testing in the event of a norovirus outbreak.