Food Safety
AUTHORITY OF IRELAND

Opinion by the Food Safety Authority of Ireland Scientific Committee

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Risk Management of Norovirus in Oysters

OBJECTIVE

The objective of this Opinion by the Food Safety Authority of Ireland (FSAI) Scientific Committee is to crystallise the available information and draw conclusions that would help to inform food business operators and risk managers and allow for proportionate risk-based measures to protect consumers from illness linked to oysters that are contaminated with norovirus.

BACKGROUND

Human norovirus infection is typically associated with acute self-limiting gastroenteritis and accounts for a very high proportion of such infections in Europe. Some bivalve molluscs such as oysters are consumed as entire uncooked animals. This pattern of consumption together with the normal biology and culture methods of bivalve molluscs creates the potential for infection with norovirus[1,5]. Typical shellfish purification practices have limited effectiveness in managing that contamination[6]. While the consumption of contaminated oysters has been associated with a number of conspicuous outbreaks of norovirus infection, most cases of norovirus infection are related to other routes of transmission[2] (direct person to person, indirect person to person through contamination of food by handling). From a public health perspective, any reduction in the risk of norovirus infection from contaminated oysters can be expected at best to achieve a limited reduction in the overall burden of norovirus infection.

At present, EU Regulations require the classification of bivalve mollusc production areas according to *E. coli* contamination levels, and set-down only bacteriological criteria for live bivalve molluscs intended for direct human consumption. Viral standards do not exist for shellfish in EU food legislation. However, oysters in the food chain pose a specific risk of transmitting norovirus, and therefore food business operators are obliged to manage the safety of the food they produce, notably in relation to the general provisions of *Article 14* of Regulation (EC) No178/2002.

DETECTION AND QUANTIFICATION OF NOROVIRUS IN OYSTERS

The paucity of information on the level of norovirus contamination required to cause illness hinders quantitative microbial risk assessment. The 2012 European Food Safety Authority (EFSA) opinion[6] recommended the incorporation of quantitative threshold limits for managing the risk of norovirus contamination in oysters. It is not yet possible to culture norovirus in laboratory systems so its detection and quantification in food are currently based on the application of molecular methods for the detection of nucleic acid. These methods have only recently been standardised (CEN ISO/TS 15216-1:2013 & CEN ISO/TS 15216-2:2013), allowing for valid inter-laboratory comparisons. Quantitative Reverse Transcriptase Polymerase Chain Reaction (RT-qPCR) is the analytical method of choice. Norovirus concentrations are expressed in viral genome copies per gram of oyster digestive tissue (cpg). Current methodology allows for the concentration of norovirus geno-groups I and II to be quantified separately. However, EFSA's 2012 opinion considers it appropriate to add the two values together when considering quantitative threshold limits for risk management purposes. All guide values in this Opinion are based on the summing of norovirus GI and GII levels.

The full extent to which norovirus RNA detected by molecular methods correlates with levels of infectious virus remains uncertain, although a dose response relationship has been demonstrated[3,4]. Current evidence[3] clearly indicates that there is a substantial risk of illness when norovirus concentrations exceed 2,000cpg, and outbreaks have also been associated with values above 1,000cpg. The level of risk associated with the consumption of oysters contaminated with norovirus at concentrations between 1,000cpg and 200cpg is much more uncertain. On the basis of available published evidence[3], the indications are that oysters contaminated with norovirus at a concentration reported as less than 150cpg are unlikely to be associated with outbreaks of human disease.

There are, however, significant technical challenges inherent in the quantification of low levels of norovirus which results in considerable uncertainty of measurement. Current advice* is that 200cpg represents the current limit of consistent reliable quantitative detection. A limit of less than or equal to 200cpg is therefore accepted in this document in preference to the 150cpg quoted in the literature.

RECOMMENDATIONS

- In keeping with the general obligation to produce safe food, food business operators should work with relevant competent authorities to develop guidance on managing norovirus risk in oysters, including practical strategies for reducing norovirus concentrations in oysters, particularly during production periods found to pose the greatest risk of norovirus infection.
- People who are immuno-compromised or otherwise unusually vulnerable to infection should be advised against consuming uncooked oysters.
- Routine monitoring of norovirus levels in oysters before they are placed on the market is not legally required at present. However, the food safety management systems of establishments approved to place live oysters on the market for direct human consumption, including Dispatch Centres and Purification Centres, should incorporate procedures to maintain samples of all batches dispatched. Those samples (at least 10 animals per sample) should be frozen to -18°C or below and stored for the duration of the shelf-life of those oysters plus an additional week, and should be made available to facilitate any investigations in the event of any subsequent outbreaks of illness.

* The Marine Institute is the official laboratory accredited for this test method and has advised that, at present, the reliable limit of quantification is 200cpg.

- In order for oysters from a production area implicated in a norovirus outbreak to re-enter the market, food business operators have two options:

  a) Oysters intended for direct human consumption without post harvest treatment should only be placed on the market when food business operators can demonstrate that norovirus concentrations in oysters from that area have been reduced to 200cpg or less. 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.

  b) Oysters intended for human consumption following post-harvest treatment should only be placed on the market when food business operators demonstrate that post-harvest treatment methods designed to reduce norovirus concentrations, e.g. depuration at increased water temperature, can achieve concentrations of less than 200cpg.

- Given the limitations of current knowledge and analytical methods it is important that this Opinion should be reviewed as new information becomes available.

KEY RECENT REFERENCES

1. UK Centre for Environment, Fisheries & Agriculture Science (2011) Investigation into the prevalence, distribution and levels of norovirus titre in oyster harvesting areas in the UK http://www.foodbase.org.uk/admintools/reportdocuments/728-1-1238_P01009_norovirus_surveillance_FINAL_report.pdf
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5. European Food Safety Authority (2011) Scientific Opinion on an update on the present knowledge on the occurrence and control of foodborne viruses. *EFSA Journal* 2011;9(7):2190 [96 pp.]. http://www.efsa.europa.eu/en/efsajournal/pub/2190.htm
6. European Food Safety Authority (2012) Scientific Opinion on Norovirus (NoV) in oysters: methods, limits and control options. *EFSA Journal* 2012;10(1):2500 [39 pp.]. http://www.efsa.europa.eu/en/efsajournal/pub/2500.htm

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