Food Safety
AUTHORITY OF IRELAND

Qualitative Risk Assessment on the Development of COVID-19 illness from the Consumption of Bivalve Molluscs

Qualitative Risk Assessment on the Development of COVID-19 illness from the Consumption of Bivalve Molluscs

Table of Contents

Executive summary

Covid-19 is primarily a respiratory illness, but the virus causing the illness (SARS-CoV-2) may also be present in the faeces of infected people and therefore, wastewater. Bivalve molluscs are marine organisms captured or cultivated for food purposes; whose natural feeding behaviour create risks of accumulation of human faecal viruses, present the aquatic environment. The risk assessment question is:

'What is the magnitude of the risk if any, of contracting COVID-19 through consumption of bivalve molluscs produced in Ireland?'

A qualitative assessment was undertaken during May and June 2020 in order to address this question. This work was carried out in the context of the relative novelty of this particular strain of coronavirus, and consequent, poor availability of directly-relevant scientific data. Emergent COVID-19 scientific literature was considered along with extrapolation from existing scientific understanding of related virus biology, mollusc physiology, wastewater treatment and food production and consumption.

A general hazard characterisation considered this specific SARS-CoV-2 viral hazard, including its biology and the epidemiology of the resultant illness, and assessed the likelihood of human infection from food sources to be very low, albeit with medium uncertainty.

The hypothetical exposure pathway for the bivalve mollusc food chain to result in transmission of this illness was defined and a qualitative exposure assessment was carried out on each individual step and then for the exposure pathway as a whole. As individual steps; a medium probability of viable SARS-CoV-2 excretion in faeces, a low probability of viable virus persistence in wastewater, a low probability of viable virus persistence through sewage treatment, and medium probability of viable virus persistence following discharge to an aquatic environment was identified, with these three latter assessments surrounded by high uncertainty. A medium probability of accumulation of the virus in bivalve molluscs was assessed with the probability that the viable virus would persist at any level through to consumption of contaminated molluscs being assessed as very high when the mollusc is consumed live, and generally lower when cooked.

An important consideration in the overall exposure assessment, is the pre-existing recognition of the potential for faecally-shed human viruses to be transmitted through bivalve mollusc consumption. That recognition results in the existence of specific food safety obligations to manage such viral transmission risks. The exposure assessment concluded that, for the exposure pathway as a whole, the probability of the consumption of live bivalve molluscs containing viable SARS-CoV-2 virus accumulated from their aquatic environment, was considered very low and for cooked mollusc tends towards negligible depending on the extent of cooking.

Consequently, the risk characterisation, assessed the risk of contracting this high severity illness through the consumption of live or cooked bivalve molluscs carrying SARS-CoV-2, as negligible. There exists a high degree of uncertainty in that characterisation, arising from the limited extent of available scientific information particularly for faecal-oral transmission. The concentration of SARS-CoV-2 necessary to infect humans via the gastrointestinal route is also unknown as is the role of the gastrointestinal tract, if any, in infection.

Background

Live bivalve molluscs feed by filtering sea water for nutrients. As a result, they can also ingest microorganisms, bacteria and viruses. If they do not excrete these microorganisms as fast as they ingest them, then a concentration effect ensues which increases the microbial load in the bivalve mollusc above that in its environment, potentially to a point where it becomes unsafe to consume without further processing to reduce the load to a safe level e.g. cooking

COVID-19 is a new respiratory infection caused by a coronavirus called SARS-CoV-2. If SARS-CoV-2 finds its way into the aquatic environment it may potentially contaminate bivalve molluscs which could pose a risk to human health.

The risk assessment question is:

'What is the magnitude of the risk if any, of contracting COVID-19 through consumption of bivalve molluscs produced in Ireland?'

This qualitative risk assessment will utilise the multidimensional representation of risks approach adopted by the UK Advisory Committee on Microbiological Safety of Food (ACMSF, 2019). See Appendix 1 for the interpretation of probability categories.

Hazard identification

The hazard is identified as the SARS-CoV-2 coronavirus which causes a communicable respiratory tract disease in humans called COVID-19.

Virus features and spread

The coronavirus genus consists of single stranded RNA viruses between 80nM and 160nM in size that have envelope proteins and crown-shaped glycoprotein peplomers that mediate binding to the host cell through its cell membrane (Sahin *et al.*, 2020). They circulate in animals and man normally in a relatively host-specific manner, however as a relatively 'large' genome RNA virus they exhibit a high mutation rate and occasionally acquire the ability to infect other hosts (Yin and Wunderink, 2018). The Coronaviridae family includes a diverse group of viruses, with individual strains identified as causing different diseases in different species including respiratory diseases of chickens, and gastroenteritis in cattle or pigs. In human hosts, coronaviruses are one of the viruses, along with rhinoviruses implicated in mild upper respiratory tract illness termed the 'common cold'.

In 2002/2003 a highly pathogenic coronavirus SARS-CoV emerged in China and caused severe acute respiratory syndrome (SARS) in humans. This was followed approximately 10 years later by another similar coronavirus called Middle East Respiratory Syndrome Coronavirus (MERS-CoV) (Sahin *et al.*, 2020). In late 2019 another highly pathogenic coronavirus emerged in Wuhan Sate of Hubei province in China causing SARS illness. This was later called SARS-CoV-2 and the illness was called COVID-19 by the World Health Organisation (WHO). This virus circulated throughout the world in 2020, leading to the WHO declaring a pandemic in March 2020.

Viruses are obligate pathogens, meaning they are dependent on the infrastructure of live host cells to facilitate their replication. Viral infection requires a molecular interaction with host cells, and the intricacy of this molecular interaction is generally expressed as a relatively narrow host and tissue range. In the case of SARS-CoV-2 the relevant host cell receptor is the ACE2 molecule, meaning host cells with such receptors are susceptible to infection (Zhang *et al.*, 2020). Viruses may persist in the environment outside of hosts, but they cannot replicate outside of host cells. Environmental persistence outside of a host is best described for non-enveloped viruses, but there is increasing understanding of the same potential for enveloped viruses such as Coronaviridae (Yinyin *et al.*, 2016).

Virus detection

The presence of viruses on surfaces or in tissues may be detected using techniques which recognise the structure or shape of the viral particles such as electron-microscopy (EM); or

techniques which recognise the genetic material, in the case of an RNA virus, reverse-transcriptase polymerase chain reaction (RT-PCR). While concepts of 'survival' and being 'alive' or 'dead' are frequently ascribed to viruses, these organisms comprise a capsid and a genome and it is more correct to consider the presence of viable virus that are potentially infectious. The only true index of the presence of viruses which are infectious is to provide live host cells, usually in tissue culture or animal models, and assess viral replication by lysis of those cells. Additionally, viral particles appearing physically intact on EM can be an indirect indicator of the presence of the viable virus. PCR is a technique with many advantages including speed and bulk scale-ability, as well as high specificity (low likelihood of false positives). However, without a viability screening step, PCR detects both the genetic material of viable intact viral particles, as well as any free/naked RNA from lysed viral particles which poses no infectious risk. The latter consideration is particularly relevant in considering the relevance of PCR positivity in a tissue or secretion that might have been subjected to a virus-lysing scenario e.g. passage through an enteric tract into faeces, environmental stress.

Current clinical protocols for confirmation of COVID-19 illness rely on the application of RT-PCR to detect genetic material specific to SARS-CoV-2 in pharyngeal swabs.

Qualitative hazard characterisation

Epidemiology of COVID-19

The WHO report the epidemiology of COVID-19 as it develops globally using a dashboard. As of 21 June 2020, 12:54pm CEST there were 8,708,008 confirmed cases of COVID-19 reported globally to WHO with 461,715 corresponding deaths. Europe reported 2,527,618 confirmed cases, 29% of global cases. Ireland reported 25,374 confirmed cases with 1,715 corresponding deaths. For Ireland this represents a reported incidence of 532 cases per 100,000 population based on the last Irish census figure of 4,761,865 (CSO, 2016). The actual incidence for COVID-19 is certainly under-reported with different countries employing different symptom criteria to trigger testing with corresponding variation in testing rates per capita and some countries reporting only hospital-confirmed cases whilst others report both hospital-confirmed cases and community-confirmed cases combined. The magnitude of under-reporting is uncertain and will vary by country. For example, Tuite *et al.*, (2020) estimated that the non-identification of COVID-19 cases in Italy was 72% (61-79%). The true prevalence of the virus in a human population is a more important index of overall faecal viral load than the number of reported cases, when considering the likelihood and extent of faecal SARS-COV-2 contamination of the marine environment.

Clinical outcomes

COVID-19 ranges from a mild illness with 'cold-like' symptoms through more severe respiratory illness and death. The clinical presentation of 41 patients (median age 49; 30 males; 19 females) with confirmed COVID-19 disease in a Wuhan Hospital was reported byChina (Huang *et al.*, 2020). Thirteen had underlying diseases (diabetes *n*8, hypertension *n*6, cardiovascular disease *n*6). At the onset, the most common symptoms were fever (98%), cough (76%) and fatigue (44%). With a median of 8 days from onset, 55% developed laboured breathing (dyspnoea). Complications included acute respiratory distress syndrome (29%), acute cardiac injury (12%) and secondary infection (10%). Thirteen patients (32%) were admitted to an ICU and 6 died (15%). A larger study (*n*191)in a Wuhan hospital, China showed increasing odds of in-hospital death associated with older age (OR 1.1 per year increase), higher sequential organ failure assessment score (OR 5.65) and d-dimer greater than 1μg/mL (OR 18.42) on admission with a median duration of viral shedding of 20 days (Zhou *et al.*, 2020).

Verity *et al.*, (2020) studied data on 24 deaths that occurred in mainland China and 165 recoveries outside of China. They ascertained a best estimate of the case fatality rate in China of 1.38% (1.23-1.58) after adjustment for demography and under-ascertainment. However, for older age

groups the figure was much higher, e.g. 13.4% in those aged 80 or older. They reported similar case fatality rates from international cases.

Mode of infection and transmission

The mode of infection involves firstly the interaction of a membrane receptor on a susceptible human cell with the spike protein (peplomer) of the virus. The virus enters the cell and expresses genes encoding accessory proteins that facilitate host adaption of the virus. The host cell transcription apparatus is utilised by the virus to manufacture multiple copies of itself (virons) which are then released from the cell. These go on to infect other cells in the body, including T-lymphocytes, which can affect the immune system response and respiratory tract cells causing the main SARS symptoms (Sahin *et al.*, 2020).

The predominant mode of transmission of SARS-CoV-2 is human to human, which accelerates the spread locally and ultimately globally. The prevailing understanding of entry of SARS-CoV-2 into the human host is one of entry and initial replication in the tissues of the upper respiratory system, particularly nasal turbinates and nasopharynx (Zou, 2020). Transmission primarily occurs when an infected person sneezes or coughs and the virus from the upper respiratory, carried in the droplets, meets the mucus membranes (eyes, nose, mouth or lungs) of a non-infected person. A secondary route of transmission shown with other coronaviruses, is from hands transferring viable virus from surfaces to the mucus membranes of the face (eyes, nose, mouth) through touch (Otter *et al.*, 2016). Consequently, medical advice is to cover coughs and sneezes and wash hands thoroughly and regularly to prevent the spread of COVID-19.

Food as a mode of infection and transmission

Food is a possible vehicle to introduce SARS-CoV-2 into the human gastrointestinal tract. In the stomach, the virus would be exposed to stomach acid which could facilitate inactivation. Inactivation of SARS-CoV was greater than 3 $\log_{10}$ TCID$_{50}$/ml in wine vinegar after 60s (Rabenau *et al.*, 2005) suggesting low pH has a viricidal effect. However, some foods can raise the pH of the stomach during digestion and transit times are variable. Bile secretion into the dueodenum could pose a further barrier to the viability of an enveloped virus like SARS-CoV-2. Although, these barriers may protect the lower gastrointestinal tract from the passage of viable virus, there is uncertainty associated with this conclusion and no studies are available that have examined the ability of SARS-CoV-2 or similar virus to breach these barriers. However, anatomically there is an obvious overlap between upper enteric tract and upper respiratory tract, with theoretical potential for nasopharyngeal contamination through oral entry of virus. Zhang *et al.*, (2020) suggest such modes of infection may be facilitated by: "*high expressions of ACE2, the cell entry receptor of 2019-nCov [SARS-CoV-2], in the lung AT2 cells, oesophagus upper and stratified epithelial cells*

and absorptive enterocytes from ileum and colon, indicating that not only respiratory system but also digestive system are potential routes of infection".

However, according to the World Health Organisation "There have been no reports of faecal−oral transmission of the COVID-19 virus to date" WHO (2020a), and "There is no evidence to date of viruses that cause respiratory illnesses being transmitted via food or food packaging" WHO (2020b).

Conclusion of the hazard characterisation

Based on current information the severity of detriment is considered **HIGH** following infection with SARS-CoV-2. Older people and those with underlying health conditions (e.g. diabetes, cardiovascular disease and organ damage), are especially at risk, with higher mortality rates. The uncertainty associated with this assessment of the severity of detriment is considered **LOW**.

Current epidemiological information indicates that the probability of food being a vehicle for human infection with SARS-CoV-2 is **VERY LOW.** According to WHO, there have been no reported cases of food causing respiratory illness. Nevertheless, it appears that cells in the upper enteric tract may present the receptors necessary for binding of SARS-CoV-2 virus, which is a necessary step for infection, so this mode of infection cannot be excluded. Additionally, whilst stomach acid and bile represent possible barriers to transit of SARS-CoV-2 through into the lower gastrointestinal tract their effectiveness is uncertain and an *in vitro* study concluded "intestinal epithelium supports SARS-CoV-2 replication" (Lamers *et al*., 2020). A further consideration affecting the likelihood of infection is that virus in food is likely to be at low concentration and may also be less available to host cells when contained within a food matrix in comparison to the virus being carried in respiratory droplets. The uncertainty associated with food as a mode of infection is **MEDIUM**.

Qualitative exposure assessment

Hypothetical exposure pathway

```
┌─────────────────┐     ┌─────────────────┐     ┌─────────────────┐     ┌─────────────────────┐
│ Human infection │     │ Human faecal    │     │ SARS-CoV-2      │     │ SARS-CoV-2          │
│ with SARS-CoV-2 │ ──▶ │ shedding of     │ ──▶ │ persistence in  │ ──▶ │ persistence         │
│ virus & COVID-19│     │ SARS-CoV-2      │     │ wastewater      │     │ through sewage      │
│ illness         │     │                 │     │                 │     │ treatment           │
└─────────────────┘     └─────────────────┘     └─────────────────┘     └─────────────────────┘
        ▲                                                                          │
        │                                                                          ▼
┌─────────────────┐     ┌─────────────────┐     ┌──────────────────────────────────────────┐
│ Transmission of │     │ SARS-CoV-2      │     │ SARS-CoV-2 persistence in aquatic          │
│ SARS-CoV-2      │ ◀── │ bioaccumulation │ ◀── │ environment after effluent discharge       │
│ through         │     │ in molluscs     │     │                                            │
│ consumption of  │     │                 │     │                                            │
│ bivalve molluscs│     │                 │     │                                            │
└─────────────────┘     └─────────────────┘     └──────────────────────────────────────────┘
```
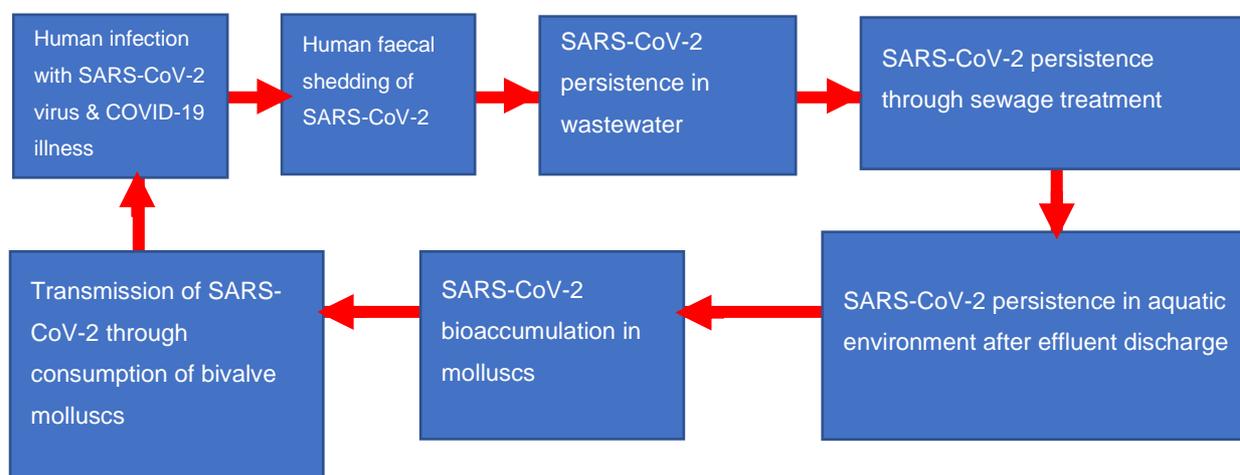
Figure 1 Hypothetical exposure pathway

Human viral shedding in faeces

Human COVID-19 illness will result in contamination of some human excretions with SARS-CoV-2 virus. There are two potential scenarios for virus to end up in human faeces. Firstly, entry of the virus into the lower digestive tract through ingestion of respiratory droplets, although this would require viable virus to transit the acid environment of the stomach and persist through contact with bile in the duodenum; and/or secondly, infection, by some means, of gut epithelial cells containing the ACE2 receptor with the shedding of virions into the gut lumen.

Guan *et al.,* (2020) found 5% of 1099 patients with COVID-19 had enteric symptoms, whilst Pan *et al.,* (2020) reported that 48.5% of 204 COVID-19 patients had digestive symptoms. Xu *et al.,* (2020) found 8 of 10 mildly infected paediatric patients to have persistent faecal PCR-detectable SARS-CoV-2 RNA. Xiao *et al.,* (2020a) found 39 of 73 patients with SARS-CoV-2 RNA-positive faeces, and 17 of those remaining faecal-positive after becoming negative in nasopharyngeal swabs. Wang *et al.,* (2020) found 29% of 153 faecal samples from COVID-19 patients PCR positive with electron-microscopical confirmation of intact viral particles in two of four PCR-positive faeces examined. Although not in faeces, Sun *et al.,* (2020) in a letter, described the detection of SARS-CoV-2 RNA and viable infectious virus from a urine sample of a COVID-19 affected patient in Wuhan using Vero E6 cells. They also observed intact virus using transmission electron microscopy. Viable SARS-CoV-2 virus was cultured from 2 of 3 viral RNA positive faeces samples from hospitalised patients in a Chinese hospital (Xiao *et al.,* 2020b)

Zhang *et al.*, (2020) suggested that a faecal/oral mode of infection could be facilitated by: "high expressions of ACE2, the cell entry receptor of 2019-nCov [early designation for SARS-CoV-2], in the lung AT2 cells, oesophagus upper and stratified epithelial cells and absorptive enterocytes from ileum and colon". Hence, these researchers stated that: "….not only respiratory system but also digestive system are potential routes of infection". A complete review of COVID-19 and the involvement of digestive system based not only on information from studies with SARS-CoV-2 but also SARS-CoV and MERS-CoV provided further evidence to support the theory of faecal shedding of viable SARS-CoV-2 (Wong *et al.*, 2020). Recently an *in vitro* study reported that enterocytes in human small intestine organoids were "readily infected by SARS-CoV and SARS-CoV-2 as demonstrated by confocal- and electron-microscopy" and stated that "intestinal epithelium supports SARS-CoV-2 replication." (Lamers *et al.*, 2020).

The nature and extent of the interaction of SARS-CoV-2 with the human gastrointestinal system remain currently unclear. Based primarily on PCR and bioinformatic evidence of ACE2 receptor location, together with the isolation of viable virus from a small number of critically ill patients, suggests that shedding of viable SARS-CoV-2 is a possibility in some patients.

Therefore, the probability of viable SARS-CoV-2 being excreted in human faeces of infected people is considered **MEDIUM** since there are several reports that show gastroenteric symptoms occur in a significant number of COVID-19 patients, infection of gut enterocytes has been demonstrated *in vitro*, a number of studies show viral RNA in faeces and there is a single report of the isolation of viable virus from two critically ill patients. The uncertainty in this assessment is considered **MEDIUM**.

Persistence in wastewater

There is currently limited data available on the survivability of SARS-CoV-2 in wastewater prior to sewage treatment. However, data available on other coronaviruses with similar morphology and chemical structures to SARS-CoV-2 can be used to estimate its ability to persist in these environments. It is uncertain how applicable data from other coronavirus are to SARS-CoV-2, although as mentioned previously, SARS-CoV and MERS-CoV are likely to be better surrogates than other coronaviruses.

Lodder and Husman, (2020) in published correspondence reported detection of SARS-CoV-2 RNA by RT-PCR methodology in human wastewater collected at Amsterdam airport and at Tilburg, Netherlands. They reported that this detection in The Netherlands was the first report of SARS-CoV-2 in wastewater. Other reports have begun to emerge on the detection of SARS-CoV-2 in wastewater, for example in Australia (Ahmed *et al.,* 2020), Arizona (Hart *et al.,* 2020) and Paris (Wurtzer *et al.,* Preprint). Real time RT-PCR (RT-qPCR) was used to show the presence of SARS-

CoV-2 RNA in 35 out of 42 untreated wastewater samples at an average of 5.4 +/- 0.2 $\log_{10}$ genome copies/L in Spain (Randazzo *et al.*, 2020). The prevailing theme in these environmental health projects is an examination of the utility of wastewater as a sentinel index of the presence or prevalence of Covid-19 in the catchment population contributing to that wastewater. However, detection of viral RNA is not necessarily indicative of the presence of viable virus especially in environmental situations where virus have encountered stress conditions that affect the integrity of the viral envelope (see section virus detection in hazard identification).

The survivability of SARS-CoV was investigated by Duan *et al.*, 2003. The study investigated the ability of SARS-CoV to persist in human excreta (including urine and faeces) and the environment. The study found that SARS-CoV persisted in urine for up to 72 hours with a low level of infectivity and in faeces for up 96 hours maintaining a relatively high infectivity (Duan *et al.*, 2003). In contrast, Lai *et al.*, (2005) found that with SARS-CoV, an initial virus titre of 10^5 $TCID_{50}$ /mL was undetectable by cell tissue culture after room temperature incubation for 6 hours in normal adult stool at pH 7-8 and 1 day in adult stool pH 8, but could persist for up to 4 days in an adult diarrhoea stool sample pH 9.

Casanova *et al.*, (2009) evaluated the survival of two surrogate coronaviruses in water and sewage, transmissible gastroenteritis virus (TGEV) and mouse hepatitis virus (MHV). The surrogate viruses were shown to remain infectious in water and sewage for up to 8 weeks. At 25°C a 2 $\log_{10}$ reduction in $TCID_{50}$/mL was reported at 9 days for the TGEV and 7 days for MHV in pasteurized settled sewage. The findings suggest that surrogate coronaviruses can remain infectious for long periods in pasteurized settled sewage (Casanova *et al.*, 2009). However, the number of human coronavirus 229E reduced by >2 $\log_{10}$ $TCDI_{50}$/mL in 3 days in unfiltered primary effluent and by >2.9 $\log_{10}$ $TCDI_{50}$/ml in 3 days in unfiltered secondary effluent suggesting that although organic matter may have a protective effect on the virus inactivation is relatively rapid (Gundy *et al.*, 2009). These two studies show variability in survival rates depending on the testing regime and the coronaviruses used.

There are also other factors in wastewater that may negatively affect the viability of an enveloped virus like SARS-CoV-2, depending on their concentration and these include bacteria, detergents and disinfectants.

Given the available information, the probability of viable SARS-CoV-2 persisting in wastewater is considered **LOW** and there are no reports of viable SARS-CoV-2 being found in wastewater. Persistence of viable virus would also depend on the initial virus load, chemical and microbiological composition of the wastewater and the length of time in transit before sewage treatment. However, the uncertainty in this assessment is **HIGH**. Only SARS-CoV-2 viral RNA has been detected in wastewater and that is not a direct measure of viable virus. Peer reviewed reports of SARS-CoV

surviving in human faeces and urine provide contradictory findings whilst reports with other coronavirus surrogates show survival but their applicability to the survival of SARS-CoV-2 is uncertain.

Persistence through sewage treatment

In Ireland, the EPA report that "over a billion litres of wastewater are collected every day in Ireland's public sewers and treated at 1100 treatment plants". In 2018, 2% of wastewater from public sewers received no treatment, 1% received only primary treatment, 67% received secondary treatment and 30% received secondary treatment with nutrient removal (EPA, 2019).

In the treatment of wastewater, during aeration, viruses are inactivated by antagonistic microorganisms and environmental factors (e.g. temperature) (Gerba and Pepper, 2009). The removal of solids in wastewater treatment is also believed to reduce the viral content as viruses tend to be associated with solids. Ye *et al.*, (2016) found that 26% of the enveloped viruses investigated were adsorbed to the solid fraction of wastewater compared to 6% of the two non-enveloped viruses investigated.

Wolf *et al.*, (2005) reported that there were no studies on persistence of SARS-CoV in raw sewage or sewage sludge. They also concluded that based on data for other enveloped virus like HIV it would be unlikely that SARS-CoV and similar virus would persist in sewage waste or through sewage treatment. In Spain, Randazzo *et al.,* (2020) detected SARS-CoV-2 RNA in 2 of 18 effluent samples after secondary treatment and 0 of 12 effluent samples after tertiary treatment.

The enveloped structure of coronaviruses is believed to impact their stability in an environment. Enveloped viruses are generally less stable in the environment than non-enveloped viruses and are more susceptible to oxidants, such as chlorine (WHO, 2020a). In general terms, the large single-stranded RNA (ssRNA) genome (~29.8 kb) of SARS-CoV-2 should theoretically render it relatively susceptible to UVC inactivation and WHO (2020a) recognise general coronavirus sensitivity to such a disinfection approach for wastewater (tertiary treatment). Wastewater and sewage management are designed for more environmentally resistant pathogens, it is believed that conventional effluent disinfection methods would be expected to readily inactivate SARS-CoV-2 (Wigginton and Boehm, 2020; WHO, 2020a). However, tertiary disinfection of wastewater with UV is uncommon in Ireland.

Considering the available evidence, the probability of viable SARS-CoV-2 surviving sewage treatment is considered **LOW** following secondary treatment[1]. This is based on the general finding that enveloped virus is easier to inactivate by the sewage treatment process than non-enveloped virus and the finding that they adhere to the solid sludge fraction more readily than the non-enveloped virus. In addition, a single study showed that the detection rate of SARS-CoV-2 RNA was low in effluent following secondary treatment. However, detection of viral RNA does not equate to the detection of viable virus. The uncertainty in this assessment of risk is **HIGH** since the evidence is based on few reports with surrogate coronavirus and detection of viral RNA only.

Persistence of SARS-CoV-2 in aquatic environments following effluent discharge, with or without sewage treatment

A common outcome following wastewater treatment in sewage plants is effluent discharge into the aquatic environment. A further pathway to be considered is that of raw untreated wastewater reaching such an environment for example through inadequate treatment or in stormwater over-run of treatment plant capacity. Data on volumes of wastewater following this latter pathway are not readily available in Ireland.

There were 64 areas designated as shellfish waters in Ireland. Impact assessment has found no adverse impact from wastewater discharge in 14 of the 64 areas with 29 impact assessments outstanding for those shellfish waters requiring an impact assessment (EPA, 2019).

In Ireland there are currently 103 Classified Production Areas (SFPA, 2019). Some areas are classified for several molluscan species, with a total of 137 classifications. In addition to setting out the geographical area of seawater from which bivalve mollusc may be harvested, classification considers the extent of faecal contamination from either human or animal sources based on *E. coli* bacterial indicator. Class A status indicates the lowest faecal contamination with Class B indicating higher contamination. Of those classifications, 61 are Class A, 19 are Class A reverting to B on a seasonal basis, and 57 are Class B. Whilst the *E. coli* counts informing these classifications may arise from either animal or human faeces, there is reasonable but not absolute correlation with the likelihood of human norovirus presence (EFSA, 2019). A correlation with other virus has not been established. Overall, ongoing classified production area bacterial monitoring, and specific surveys of human viral presence (EFSA, 2019), demonstrate that human faecal contamination of shellfish growing waters, whilst higher in some areas than others, is common.

---

[1] This probability could be considered **VERY LOW** if tertiary disinfection treatment is employed. However, tertiary treatment is uncommon in Ireland and therefore is not accounted for in this risk assessment.

Research into the persistence of coronaviruses in water found that the inactivation of coronaviruses in the test water was highly dependent on temperature, level of organic matter, and presence of antagonistic bacteria. Gundy *et al.*, (2009) described the persistence of representative coronaviruses in water. The concentrations of human coronavirus 229E was determined in filtered and unfiltered tap water (4 and 23°C). Viruses were enumerated on cell cultures using $TCID_{50}$ technique. A 3 log_{10} reduction in $TCID_{50}$/mL was achieved within 10.1 and 12.1 days in filtered and unfiltered tap water respectively at 23°C whereas in filtered tap water at 4°C the same reduction took 588 days.

There appear to be no studies of persistence of coronavirus in salt-water environments such as those in which live marine bivalve molluscs grow.

Based in these limited data, the probability of viable SARS-CoV-2 persisting in a fresh or salt-water environment is considered **MEDIUM** and will be affected by temperature, sunlight and particulate levels including bacteria. A significant dilution factor should also be recognised in the marine environment albeit variable by location, which would reduce the concentration of any viable SARS-CoV-2 reaching shellfish growing areas. The uncertainty in this assessment of risk is **HIGH** since there are no reports of studies looking for SARS-CoV-2 in aquatic environments and a single experimental study showing survival of a surrogate human coronavirus in tap water.

Bioaccumulation in live bivalve molluscs

The potential for human enteric viruses to bioaccumulate in live bivalve molluscs filtering sewage-contaminated water is well described, with a substantial scientific literature pertaining to enteric viruses such as norovirus (EFSA, 2019) and Hepatitis A virus (Suffredini *et al.*, 2017). Such accumulation is not an infection of the mollusc cells followed by viral replication, but merely a magnification of environmental contamination by the normal physiology of the mollusc where accumulation of virus through filtration is faster than the rate of excretion. The mollusc role within the epidemiology of the human viral disease, remains one of a biologically inert fomite, albeit one with a higher concentration in the virus than the surrounding environment.

Considering molluscan filtration in purely mechanical terms of physical entrapment of particles suspended in seawater, it is worth noting that Coronoviridae (80-160nm) are physically larger than norovirus as a member of Caliciviridae (23-40nm), and HAV as a member of Picornaviridae (27-32nM). However, the potential for accumulation of human enteric viruses in molluscs appears to be more than mechanical with some component of a molecular interaction between the virus and the molluscan enteric tract, which facilitates adhesion and thereby retention and ultimately accumulation. In the case of GI-norovirus the mechanism appears to be relatively non-specific interaction of the virus surface with ligand molecules on the cells of the mollusc gut (Le Guyader,

2012), including mollusc cell molecules not dissimilar to MHC antigen receptors found in human blood cells with which norovirus is known to interact. (Almand *et al.*, 2017). Dancer *et al.* (2010) showed the propensity for the accumulation of environmental intact norovirus virons, to be much greater than the accumulation of free RNA. However, no such molecular interactions, nor preferential accumulation have been described for coronavirus and there are significant differences between the surface structure of these Cornaviridae (enveloped and crown-shaped protruding proteins) and Caliciviridae (non-enveloped and icosahedral). Nevertheless, bivalve molluscs have evolved to extract small molecules from water as demonstrated with several bacteria and enteric viruses. In most of these cases there is no described involvement of ligands, so the absence of a described ligand mediated concentration for SARS-CoV-2 does not rule out bioaccumulation of this virus. However, concentration by infection is unlikely due to the absence of ACE2 receptors in bivalve molluscs with sufficient homology to human ACE2 receptors.

Therefore, the probability of viable SARS-CoV-2 accumulating in live bivalve molluscs is considered **MEDIUM.** The uncertainty in this assessment of risk is **MEDIUM**. Whilst there is no data on the accumulation of enveloped virus in live bivalve molluscs there is a wealth of published data about shellfish bioaccumulation of bacteria and virus in the same size range.

Ingestion of SARS-CoV-2 through consumption of bivalve molluscs containing viable virus

Consumption of live bivalve molluscs

Bivalve molluscs are animals where their soft tissues may be consumed entirely (without removal of bioaccumulating tissues). Consumption of live bivalve molluscs is recurrently implicated in the epidemiology of human illness arising from enteric viruses, particularly norovirus and Hepatitis A, which are non-enveloped viruses. However, they have not been associated with human respiratory illness.

Whilst not designed to manage SARS-CoV-2 risks, there exists a regulatory risk management system to address the risk of human enteric viruses transmitting to man through this route. This includes a microbial classification and the monitoring of shellfish production areas as outlined above. Only the lowest microbial contaminated Class A molluscs are allowed for consumption without purification or cooking, subject to compliance with bacterial microbiological criteria as indices of faecal contamination.

Consumption of cooked bivalve molluscs

Some bivalve molluscs are cooked before consumption either due to consumer preference or where EU legislation specifically requires more contaminated molluscs to be cooked to specified

time/temperatures, if not purified to reach Class A standards. Overall, cooking can range from commercial processing including canning to mild cooking at home or in food service. Viruses are inactivated by heat over time, but the extent of inactivation depends of the thermal stability of the virus and the time/temperature combination it is subjected to. Obligatory cooking regimens for non-purified non-Class A molluscs have been shown to have a useful virus reduction impact and significant reduction of foodborne risks (EFSA 2015)

Reliable data on the thermal inactivation of SARS-CoV-2 that are applicable to food treatment are lacking. Darnell $et\ al.,$ (2004) showed an approximate 4.5 $\log_{10}$ $TCID_{50}$/mL reduction in numbers of SARS-CoV after 20 min at 56°C and an approximate 5 $\log_{10}$ $TCID_{50}$/mL reduction in numbers of SARS-CoV after 4 minutes at 65°C. However, they noted that infectious virus was present near the limit of detection of the assay long after these times. Chan $et\ al.,$ (2011) also studied the thermal inactivation of SARS-CoV and showed that 15 min at 56°C would result in loss of infectivity. The presence of protein or other organic material can affect the heat reduction of numbers of SARS-CoV. Rabenau $et\ al.,$ (2005) showed heating at 56°C for 30 minutes resulted in a 5-6 $\log_{10}$ $TCID_{50}$/mL reduction in numbers of SARS-CoV. (However, only approximately a 2 $\log_{10}$ reduction was achieved under the same conditions when protein (20% FCS) was present. SARS-CoV is likely the closest surrogate to SARS-CoV-2.

However, in a more detailed study, Tuladhar $et\ al.,$ (2012) investigated the thermal resistance of respiratory influenza A virus (H1N1) in Dulbecco's Modified Eagle Medium (DMEM). An initial inoculum of 1.3*10^6 $TCID_{50}$ was used and infectivity reductions were determined by cell culture assay. Reductions were modelled and used to calculate the time to first $\log_{10}$ reduction (TFL). Inactivation of H1N1 was reported to be monophasic (straight line first order) and at 56°C the TFL was mean 13.1 min with a 95% CI 11.6-15.4 min and at 73°C the TFL was mean 0.53 min with a 95% CI 0.43-0.74 min. The researchers also looked at detection of the virus nucleic acid material and reported "virus infectivity loss occurs much more rapidly than does loss of amplified viral RNA or DNA…….with viral RNA persisting even after complete loss of infectivity". A heat treatment of 73°C of 3 min was sufficient to result in a >4 $\log_{10}$ reduction in viable H1N1 virus.

Given these results, the mild cooking process applied to bivalve molluscs would reduce the numbers of SARS-CoV-2 if present but may not deal with high numbers of virus particles which would require temperatures around normal pasteurisation times and temperatures e.g. 70°C for 2 min.

Conclusion on consumption risk

If present in live bivalve molluscs, the probability of viable SARS-CoV-2 being ingested from their consumption whole and uncooked is considered **VERY HIGH** since there is no intervention step to

kill the virus. However, the risk for cooked bivalve molluscs is lower due to inactivation of the virus through cooking. This would depend on the time and temperature combination so would lie between **HIGH** for mild cooking and **NEGLIGIBLE** for bivalve molluscs subjected to pasteurisation time/temperature combinations. The uncertainty is **LOW** for consumption of live bivalve molluscs but is **MEDIUM** for cooked bivalve molluscs due to the available inactivation data being based on surrogate coronavirus.

Exposure assessment conclusion

Up to this point in the exposure assessment, the qualitative probability has been evaluated for each step independently of preceding steps; assuming that viable virus is present entering the step and looking only at the chance of these virus passing on to the next step. However, if the whole pathway is examined as a series of sequential steps with linked probability of viable virus transmission throughout, an overall qualitative probability of viable SARS-CoV-2 entering the human body through consumption of bivalve molluscs contaminated by faeces containing viable virus, can be considered.

Evaluation of the combined evidence throughout the exposure pathway leads to the conclusion that the probability of consumption of live bivalve molluscs containing viable SARS-CoV-2 virus accumulated from their aquatic environment, is considered **VERY LOW** especially when effective sewage treatment is involved but also accounting for the fact that live bivalve molluscs can only be consumed as such if they are come from Class A areas subject to careful oversight by the Competent Authorities or are purified to Class A standard. If bivalve molluscs are cooked at temperature/time combinations sufficient to inactivate SARS-CoV-2, the probability of consumption of viable SARS-CoV-2 virus is considered **NEGLIGIBLE**.

The uncertainty in this exposure assessment is **HIGH** because there is an absence of data relating to the presence of the viable virus in wastewater or its potential to persist through sewage treatment and effluent discharge[2]. This uncertainty also accounts for the fact that in 2018 there were no effluent discharge impact assessments for 29 of the 64 designated shellfish waters.

---

[2] As this risk assessment goes to publication the French institute Ifremer has reported early results showing no detection of SARS-CoV-2 RNA in bivalve molluscs despite the finding or norovirus which indicates the presence of faecal contamination. https://wwz.ifremer.fr/en/Latest-news/No-traces-of-SARS-CoV-2-detected-in-the-first-samples-of-sea-water-and-shellfish-analyzed

Qualitative risk characterisation

COVID-19 is a serious illness resulting from infection with the SARS-CoV-2 coronavirus. Based on current information the severity of detriment is considered **HIGH** (severe illness: causing life threatening or substantial sequelae or illness of long duration). Older people and those with underlying health conditions (e.g. diabetes, cardiovascular disease and organ damage) are especially at risk with higher crude mortality rates.

This exposure assessment concludes that the probability of consumption of live bivalve molluscs containing viable SARS-CoV-2 virus accumulated from their aquatic environment, is considered **VERY LOW** and is **NEGLIGIBLE** if bivalve molluscs are cooked at time/temperature combinations sufficient to inactivate SARS-CoV-2.

The hazard characterisation concludes that the probability of food being a vehicle for human infection with SARS-CoV-2 is **VERY LOW.** According to WHO, there have been no reported cases of food causing respiratory illness. Nevertheless, it appears that cells in the upper enteric tract may present the receptors necessary for binding of SARS-CoV-2 virus, which is a necessary step for infection, so this mode of infection cannot be excluded. A similar conclusion was reached by the French risk assessment agency ANSES that concluded: "To date, there is no evidence to suggest that consumption of contaminated food can lead to infection of the digestive tract; however, the possibility of the respiratory tract becoming infected during chewing cannot be completely ruled out." (ANSES, 2020). Additionally, whilst stomach acid and bile represent possible barriers to transit of SARS-CoV-2 through into the lower gastrointestinal tract their effectiveness is uncertain and an *in vitro* study concluded "intestinal epithelium supports SARS-CoV-2 replication".

Evaluation of the totality of the available evidence outlined in the hazard characterisation and exposure assessment, suggests that overall, the risk of contracting COVID-19 from the consumption of live or cooked bivalve molluscs is considered **NEGLIGIBLE**. However, the uncertainty in this conclusion is **HIGH** since there is a lack of data on the persistence of SARS-CoV-2 through the various complex elements of the exposure pathway and a lack of information on infection through the ingestion of infected food, other than the absence of reported cases from this source. The concentration of SARS-CoV-2 necessary to infect humans via the gastrointestinal route is also unknown as is the role of the gastrointestinal tract, if any, in infection. Caution with respect to the risk characterisation is appropriate due to this uncertainty and the rapidly emerging details of the biology for this novel virus.

References

ACMSF UK (2019) Fixed term group on multidimensional representation of risks. https://acmsf.food.gov.uk/sites/default/files/acm-1309-risk-representation.pdf accessed 17th April 2020.

Ahmed W, Angel N, *et al* (2020) First confirmed detection of SARS-CoV-2 in untreated wastewater in Australia: A proof of concept for the wastewater surveillance of COVID-19 in the community. Science of the Total Environment 728: https://doi.org/10.1016/j.scitotenv.2020.138764

Almand EA, Moore M, Jaykus LA. (2017) Norovirus Binding to Ligands. Beyond Histo-Blood Group Antigens. Frontiers in Microbiology 8: 2549

ANSES (2020) OPINION of the French Agency for Food, Environmental and Occupational Health & Safety on an urgent request to assess certain risks associated with COVID-19. https://www.anses.fr/en/system/files/SABA2020SA0037-1EN.pdf Accessed 1st May 2020

Chan KH, Malik Peiris JS, Lan SY, Poon LLM, Yuen KY, Seto WH (2011) The effect of temperature and relative humidity on the viability of SARS Coronavirus. Advances in Virology. Article ID 734690: 7 pages.

CSO (Central Statistics Office). 2016. Population change and historical perspective. https://www.cso.ie/en/media/csoie/releasespublications/documents/population/2017/Chapter_1_Population_change_and_historical_perspective.pdf accessed 17th April 2020

Dancer D, Rangdale RE, Lowther JA, Lees DN, (2010) Human norovirus RNA persists in seawater under simulated winter conditions but does not bioaccumulate efficiently in Pacific oysters (*Crassostrea gigas*), Journal of Food Protection, 73(11): 2123-2127.

Darnell MER, Subbarao K, Feinstone SM, Taylor DR. (2004). Inactivation of the coronavirus that induces severe acute respiratory syndrome, SARS-CoV. Journal of Virological Methods. 121: 85–91.

Duan SM, Zhao XS, Wen RF, Huang JJ, Pi GH, Zhang SX, Han J, Bi SL, Ruan L, Dong XP. (2003) Stability of SARS coronavirus in human specimens and environment and its sensitivity to heating and UV irradiation. Biomedical and Environmental Sciences. 16(3): 246-255.

Duizer E, Bijkerk P, Rockx B, de Groot A, Twisk F, Koopmans, M. (2004). Inactivation of caliciviruses. Applied and Environmental Microbiology. 70: 4538–4543.

EFSA (2015) Evaluation of heat treatments, different from those currently established in the EU legislation, that could be applied to live bivalve molluscs from B and C production areas, that have

not been submitted to purification or relaying, in order to eliminate pathogenic microorganisms. EFSA Journal 13: 12. https://doi.org/10.2903/j.efsa.2015.4332

EFSA (2019) Analysis of the European baseline survey of norovirus in oysters . EFSA Journal 17:7 doi: 10.2903/j.efsa.2019.5762

EPA (2019) Urban waste Water Treatment in 2018
https://www.epa.ie/pubs/reports/water/wastewater/Urban%20Waste%20Water%20Treatment%20in%202018_Web.pdf

Gerba CP, Pepper IL. (2009) Wastewater treatment and biosolids reuse. Environmental Microbiology: Academic Press, pp. 503-530.

Guan, W. Ni, Z., Hu, Y. et al.(2020) Clinical Characteristics of Coronavirus Disease 2019 in China. New England Journal of Medicine DOI: 10.1056/NEJMoa2002032

Gundy PM, Gerba CP, Pepper IL. (2009) Survival of coronaviruses in water and wastewater. Food and Environmental Virology, 1(1): pp10.

Hart O, Halden R. (2020) Computational analysis of SARS-CoV-2/COVID-19 surveillance by wastewater-based epidemiology locally and globally: Feasibility, economy, opportunities and challenges. Science of total Environment 730: https://doi.org/10.1016/j.scitotenv.2020.138875

Huang C, Wang Y, Li X, Ren L, Zhao J, Hu Y, Zhang L, Fan G, Xu J, Gu X, Cheng Z.], Yu T, Xia J, Wei Y, Wu W, Xie X, Yin W, Li H, Liu M, Xiao Y, Gao H, Guo L, Xie J, Wang G, Jiang R, Gao Z, Jin Q, Wang J, Cao B. (2020) Clinical features of patients infected with 2019 novel coronavirus in Wuhan, China. The Lancet. 395(10223):497-506

Kampf G, Todt D, Pfaender S, Steinmann E. (2020) Persistence of coronaviruses on inanimate surfaces and their inactivation with biocidal agents. J. Hospit. Infec. 104: 246-251.

Lai MYY, Cheng PKC, Lim WWL. (2005) Survival of severe acute respiratory syndrome coronavirus. CID. 41: 67-71.

Lamers MM, Beumer J, van der Vart J, et al. (2020) SARS-CoV-2 productively infects human gut enterocytes. Science 10.1126/science.abc1669. (1st May).

Le Guyader, F.S., Atmar R.L., Le Pendu, J. (2012) Transmission of viruses through shellfish : when specific ligands come into play. Current Opinions in Virology 2: 1

Lodder W, De Roda Husman AM. (2020) SARS-CoV-2 in wastewater: potential health risk, but also data source. The Lancet (Gastroenterology & Hepatology) Published: April 01, 2020 DOI: https://doi.org/10.1016/S2468-1253(20)30087-X

Otter JA, Donskey C, Yezli S, Douthwaite S, Goldenberg SD, Wevber DJ. (2016) Transmission of SARS and MERS coronaviruses and influenza virus in healthcare settings: the possible role of dry surface contamination. J. Hosp. Inf. 92: 235-250.

Pan, L., Mu, M., Pengcheng, Y.(2020) American Journal of Gastroenterology. Pre-print accessed 03 April 2020
https://journals.lww.com/ajg/Documents/COVID_Digestive_Symptoms_AJG_Preproof.pdf

Rabenau HF, Cinatl J, Morgenstern B, Bauer G, Preiser W, Doerr HW. (2005) Stability and inactivation of SARS coronavirus. Medical Microbiology and Immunology. 194 (1-2):1-6

Randazzo W, Truchado P, Cuevas-Ferrando E, Simon P, Allende A, Sanchez G. (2020) SARS-CoV-2 RNA in wastewater anticipated COVID-19 occurance in a low prevalence area. Water Research. 181, 115942.

Sahin AR, Erdogan A, Agaoglu PM, Dineri Y, Cakirci AY, Senel ME, Okyay RA, Tasdogan AM. (2020) 2019 novel coronavirus (COVID-19) outbreak: A review of the current literature. EJMO; 4 (1): 1-7

SFPA (Sea Fisheries Protection Authority) 2019 List of Classified LBM Production Areas in Ireland

https://www.sfpa.ie/LinkClick.aspx?fileticket=heojKb8zM9Q%3d&portalid=0&resourceView=1

Suffredini, E., Proroga, Y.T.R., Di Pasquale, S. et al. Occurrence and Trend of Hepatitis A Virus in Bivalve Molluscs Production Areas Following a Contamination Event. Food Environ Virol 9, 423–433 (2017). https://doi.org/10.1007/s12560-017-9302-8

Sun J, Zhu A, Li H, *et al* (2020) Isolation of infectious SARS-CoV-2 from urine of a COVID-19 patient. Emerging Microbes and Infections. VOL. 9.
https://doi.org/10.1080/22221751.2020.1760144

Tuite AR, Ng V, Rees E, Fisman D. (2020) Estimation of COVID-19 outbreak size in Italy. The Lancet (Infectious Diseases). Published: March 19, 2020 DOI: https://doi.org/10.1016/S1473-3099(20)30227-9

Tuladhar E, Bouwknegt M, Zwietering MH, Koopmans M, Duizer E. (2012) Thermal stability of structurally different viruses with proven or potential relevance to food safety. J.Appl.Micro. 112: 1050-1057.

Van Doremalen N, Bushmaker T, Morris DH, Holbrook MG, Gamble A, Williamson BN, Tamin A, Harcourt JL, Thornburg NJ, Gerber SI, Lloyd-Smith JO, de Wit E, Munster VJ. (2020) Aerosol and surface stability pf HCoV-19 (SARS-CoV-2) compared to SARS-CoV-1. medRxiv preprint doi: https://doi.org/10.1101/2020.03.09.20033217 (accessed 20th March 2020)

Vasickova P, Pavlik I, Verani M. (2010) Issues concerning survival of viruses on surfaces. Food Environ Virol 2:24-34.

Verity R, Okell LC, Dorigatti I, Winskill P, Wittaker C, Imai N, Cuomo-Dannenburg G, Thompson H, Walker PGT, Fu H, Dighe A, Griffin JT, Baguelin M, Bhatia S, Boonyasiri A, Cori A, Cucunaba Z, FitzJohn R, Gaythorp K, Green W, Hamlet A, Hinsley W, Laydon D, Nedjati-Gilani G, Riley S, van Elsland S, Volz E, Wang H, Wang Y, Xi X, Donnelly CA, Ghani AC, Fergason NM. (2020) Estimates of the severity of coronavirus disease 2019: a model-based analysis. The Lancet (Infectious Diseases) https://doi.org/10.1016/S1473-3099(20)30257-7

Wang W, Xu Y, Gao R, et al. Detection of SARS-CoV-2 in Different Types of Clinical Specimens. Jounal of the American Medical Association. Published online March 11, 2020. doi:10.1001/jama.2020.3786

WHO (2020a) Water, sanitation, hygiene and waste management for the COVID-19 virus. Technical brief 3 March 2020. https://apps.who.int/iris/bitstream/handle/10665/331305/WHO-2019-NcOV-IPC_WASH-2020.1-eng.pdf accessed 30th March 2020

WHO (2020b) COVID-19 and food safety: guidance for food businesses. https://www.who.int/publications-detail/covid-19-and-food-safety-guidance-for-food-businesses

Wigginton KR, Boehm AB. (2020) Environmental Engineers and Scientists Have Important Roles to Play in Stemming Outbreaks and Pandemics Caused by Enveloped Viruses. Environmental Science & Technology. Published online 2020 Mar 24. doi: 10.1021/acs.est.0c01476

Wolff MH, Sattar SA, Adegbunrin O, Tetro J (2005) Environmental survival and microbicide inactivation of coronavirus. In Coronaviruses with Special Emphasis on First Insights Concerning SARS ed. A Schmidt, MH Wolff and O Weber. Basal Switzerland p202-212.

Wong SH, Lui RNS, Sung JJY. (2020) Covid-19 and the digestive system. Journal of Gastroenterology and hepatology. 35: 744-748 doi:10.1111/jgh.15047

Wurtzer S, Marechal V, Mouchel JM, Maday Y, Teyssou R, Richard E, Almayrac JL, Moulin L. (Preprint) Evaluation of lockdown impact on SARS-CoV-2 dynamics through viral genome quantification in Paris wastewaters.
medRxiv 2020.04.12.20062679; doi:https://doi.org/10.1101/2020.04.12.20062679

Xiao F, Tang M, Zheng X, Liu Y, Li X, Shan H, Evidence for gastrointestinal infection of SARS-CoV-2, Gastroenterology (2020a), doi: https://doi.org/10.1053/j.gastro.2020.02.055.

Xiao F, Sun J, Xu Y, Huang X, Li F,Huang X, Li H, Zhao J, Huang J, Zhao J. (2020b) Infectious SARS-CoV-2 in feces of patient with severe COVID-19. Emerg. Infect. Dis. 2020 Aug [cited 17th June]. https://doi.org/10.3201/eid2608.200681

Xu, Y., Li, X., Zhu, B. et al. (2020) Characteristics of pediatric SARS-CoV-2 infection and potential evidence for persistent fecal viral shedding. Nat Med (2020). https://doi.org/10.1038/s41591-020-0817-4

Ye Y, Ellenberg RM, Graham KE, Wigginton KR. (2016) Survivability, partitioning, and recovery of enveloped viruses in untreated municipal wastewater. Environmental science & technology, 50(10): 5077-5085.

Yépiz-Gomez MS, Gerba P, Bright KR (2013) Survival of respiratory viruses on fresh produce. Food Environ Virol 5:150-156.

Yin Y, Wunderink RG. (2018) MERS, SARS and other coronaviruses as causes of pneumonia. Repirology; 23 (2): 130-137

Yinyin Y, Ellenburg, R.M., Graham, K.E., Wigginton, K.R. (2016) Environmental Science and Technology 50: 5077-5085

Zhang H, Kang Z, Gong H, Xu D, Wang J, Li Z, Cui X, Xiao J, Meng T, Zhou W, Lui J, Xu H. (2020) The digestive system is a potential route of 2019-nCov infection: a bioinformatics analysis based on single-cell transcriptomes. Pre-publication https://doi.org/10.1101/2020.01.30.927806. Not Peer Reviewed Accessed 20th April 2020.

Zhou F, Yu T, Du R, Fan G, Liu Y, Liu Z, Xiang J, Wang Y, Song B, Gu X, Guan L, Wei Y, Li H, Wu X, Xu J, Tu S, Zhang Y, Chen H, Cao B. (2020) Clinical course and risk factors for mortality of adult inpatients with COVID-19 in Wuhan, China: a retrospective cohort study. The Lancet 2020. 395: 1054–62.

Zou, L., Ruan, F., MingXing H., et al, (2020) SARS-CoV-2 Viral Load in Upper Respiratory Specimens of Infected Patients. New England Journal of Medicine; 382:1177-1179

Appendix 1 Interpretation of probability categories reproduced from ACMSF UK (2020)

A qualitative scale for the frequency of occurrence of foodborne risks (EFSA 2006):

Frequency category	Interpretation
Negligible	So rare that it does not merit to be considered
Very Low	Very rare but cannot be excluded
Low	Rare but does occur
Medium	Occurs regularly
High	Occurs very often
Very High	Events occur almost certainly

A qualitative scale for the severity of detriments of foodborne risks (ICMSF 2002):

Severity category	Interpretation
Negligible	No effects, or so mild they do not merit to be considered
Low	Mild illness: not usually life-threatening, usually no sequelae, normally of short duration, symptoms are self-limiting (e.g. transient diarrhoea)
Medium	Moderate illness: incapacitating but not usually life-threatening, sequelae rare, moderate duration (e.g. diarrhoea requiring hospitalisation)
High	Severe illness: causing life-threatening or substantial sequelae or illness of long duration (e.g. chronic hepatitis)

A qualitative scale for the level of uncertainty in food risk assessment:

Uncertainty category	Interpretation
Low	There are solid and complete data available; strong evidence is provided in multiple references; authors report similar conclusions
Medium	There are some but no complete data available; evidence is provided in small number of references; authors report conclusions that vary from one another
High	There are scarce or no data; evidence is not provided in references but rather in unpublished reports or based on observations, or personal communication; authors report conclusions that vary considerably between them

Authors

Dr. Wayne Anderson, Director Food Science and Standards, FSAI

Dr. Micheál O'Mahony, Chief Scientific Adviser, SFPA and member of the FSAI Biological Safety sub-committee

Ms Faye Clarke, Technical Executive, FSAI

Peer reviewers

Dr. Geraldine Duffy, Head of Food Safety, Teagasc and member of the FSAI Scientific Committee and Chair of the FSAI Biological Safety sub-committee.

Dr. Declan Bolton, Research Officer, Teagasc and member of the FSAI Biological Safety sub-committee.

Dr. Helen O'Shea, Senior Lecturer, CIT and member of the FSAI Biological Safety sub-committee.

Dr. Joanne O'Gorman, Consultant Clinical Microbiologist, HPSC and member of the FSAI Biological Safety sub-committee.

Mr. Ray Parle, Principal Environmental Health Officer, HSE and member of the FSAI Scientific Committee and FSAI Biological Safety sub-committee

Food Safety Authority of Ireland
The Exchange, George's Dock, IFSC,
Dublin 1, D01 P2V6

T +353 1 817 1300
E info@fsai.ie

Join us on LinkedIn

Follow us on Twitter @FSAIinfo

Say hi on Facebook

Visit us on Instagram

Subscribe to our YouTube channel

www.fsai.ie