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Food Safety Authority of Ireland

Report of the Scientific Committee
of the Food Safety Authority of Ireland

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Foodborne Risk to Human Health of Hepatitis E Virus in Pigs and Pigmeat in Ireland

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Contents

List of figures

List of tables

Abbreviations

Term	Text
EFSA	European Food Safety Authority
eHEV	quasi-enveloped hepatitis E virus
ELISA	enzyme-linked immunosorbent assay
EU	European Union
FBO	food business operator
FSAI	Food Safety Authority of Ireland
HACCP	hazard analysis and critical control point
HEV	hepatitis E virus
HEV-1	hepatitis E virus genotype 1
HEV-2	hepatitis E virus genotype 2
HEV-3	hepatitis E virus genotype 3
HEV-4	hepatitis E virus genotype 4
HEV-5	hepatitis E virus genotype 5
HEV-6	hepatitis E virus genotype 6
HEV-7	hepatitis E virus genotype 7
HEV-8	hepatitis E virus genotype 8
HIV	human immunodeficiency virus
nHEV	non-enveloped hepatitis E virus
PCR	polymerase chain reaction
RT-PCR	reverse transcription-polymerase chain reaction
RTE	ready-to-eat
RNA	ribonucleic acid
WvGS	whole virus genome sequencing

Executive summary

Hepatitis E virus (HEV) is a virus that infects the liver, causing an inflammatory condition known as hepatitis. It is considered the most common type of acute viral hepatitis recorded in people worldwide. In Ireland, HEV in humans became a notifiable disease in 2015. This means that there is a legal obligation to inform public health departments when a case is diagnosed. Studies of healthy blood donors in Ireland reported serological evidence of past exposure to HEV in approximately 5% of individuals. A small percentage of donors (0.02%) had detectable viral ribonucleic acid (RNA) in their blood. HEV has also been detected in the liver and blood of several animal species, including pigs. Additionally, HEV RNA has been identified in pigmeat products in several countries, including Ireland. These findings raise concerns about the risk to human health arising from HEV transmission from pigs to humans, particularly through the consumption of contaminated pigmeat.

In order to address these concerns, the Food Safety Authority of Ireland (FSAI) requested further advice from the Scientific Committee (Appendix 1). This paper presents the opinion and considerations of the Scientific Committee on the four questions posed by the FSAI.

Question 1: What is the contribution of the pigmeat food chain to the risk of HEV in Ireland?

There is little Ireland-specific evidence to inform a risk assessment on the contribution of the pigmeat food chain to the risk of human HEV. There is also limited information to partition the source of infection to domestic or imported pigmeat and pigmeat products. It is likely, however, based on the limited data available in Ireland, that the situation is similar to that reported in other countries with similar pig production systems. Similarly, it is recognised that undercooked pigmeat products are a significant contributor to human infection with HEV.

Hepatitis E virus poses a public health concern in Europe, with farmed pigs identified as a principal domestic species reservoir facilitating zoonotic transmission to humans. Evidence from molecular epidemiology, serological studies, surveillance, and outbreak investigations supports the hypothesis that the consumption of undercooked or raw pigmeat products, particularly liver and liver-based sausages, constitutes a transmission route for HEV infection. Environmental contamination through agricultural or sewage run-off and faecal pig waste may also contribute to transmission via fresh produce, bivalve molluscs and surface waters. Lastly, direct contact with pigs and pigmeat can contribute to the risk of infection for pig sector workers.

Quantitative attribution of HEV infection in humans to pigmeat remains limited. However, the qualitative data – such as the high HEV prevalence on pig farms; the detection of HEV RNA in pigmeat; the association of clinical cases with dietary habits; and the genetic similarity between HEV strains in pigs, pigmeat and humans – strongly suggest that pig production and consumption of pigmeat, both locally produced and imported, represent transmission pathways for HEV infection.

Question 2: How do different approaches to pigmeat production influence the risk of HEV infection for people in Ireland?

There is no substantial body of evidence that different approaches to pigmeat production influence the risk of HEV infection for people in Ireland. The vast majority of pig production in Ireland is intensive, and accounts for nearly all commercial pigmeat. These are indoor systems with integrated farrow-to-finish operations, with different age groups on one site. Substantially different approaches (such as extensive production) account for only a small proportion of total pig production and are unlikely to have any quantitative influence on the risk of HEV to human health.

While Irish data are sparse, available evidence indicates that HEV is endemic in intensive pig production across Europe. Pigs are typically slaughtered around 6 months of age, which coincides with the time of HEV seroconversion and a decline in both viraemia and faecal shedding of the virus.

Studies suggest that biosecurity practices and herd management significantly influence HEV prevalence. Poor hygiene and high-density housing contribute to its spread among different age groups and its persistence on farms. Although some evidence suggests seasonal variation in HEV shedding on pig farms in some countries, no studies have yet been conducted within Ireland's year-round indoor farming system to assess if there is a seasonal variation in HEV risk.

Question 3: What are the potential risk management strategies to address any identified food chain risk?

Pre-harvest measures to manage HEV focus on minimising infection within pig herds through effective biosecurity, separation of pig groups, inter-cohort hygiene and environmental control. Implementation of these measures on Irish farms can be challenging but should be included on each farm as part of its overall on-farm disease risk reduction strategy. At slaughter, pigs with active HEV infection pose the highest risk. While delaying slaughter to allow for seroconversion

may reduce this risk to human health, practical constraints limit the feasibility of implementing this option. Slaughterhouse hygiene standards, such as hygienic evisceration and removal of the liver and intestines and minimal handling of these organs, play an important role in limiting cross-contamination from faeces and bile to meat, particularly during evisceration and liver removal.

Post-harvest, tissue-specific risk management is a critical component in addressing HEV exposure from pigmeat products, particularly those derived from high-risk tissues such as liver and blood. Identifying HEV as a biological hazard within hazard analysis and critical control point (HACCP) systems is essential, especially for pigmeat products containing raw or minimally processed tissues. Non-thermally treated ready-to-eat (RTE) pigmeat products, such as fermented or cured sausages, present a challenge due to limited viral reduction during their processing and storage. Limited evidence indicates that high-pressure processing does not always completely and reliably inactivate HEV. Therefore, thermal treatment remains the most reliable method for HEV inactivation.

Pig liver and blood products are consumed in Ireland, and in the case of blood products (e.g. black pudding), this is usually done following thermal processing at the production plant. In addition, existing food safety guidance emphasises the importance of good hygiene and thorough cooking in catering, in hospitality settings and at home. When followed, this is effective, but further targeted advice may be warranted for people who are at increased risk of clinical disease from HEV infection, including people with compromised immune systems, organ transplant recipients, older people with comorbidities, and pregnant women.

Question 4: Given any risks identified, would active surveillance programmes on pigs and pigmeat production be beneficial?

The evidence base on HEV transmission to humans via pigmeat in Ireland is very limited and fragmentary, which makes it difficult to determine with confidence the likely veterinary public health benefits of implementing surveillance programmes in pigs and pigmeat production. If surveillance were implemented, it could help to address gaps in understanding of the comparative risks posed by different sources of HEV infection. Systematic monitoring could support early detection of viral presence in pigs, contribute to more robust risk assessment, and inform the development of targeted interventions.

Integrating human, animal and environmental surveillance data, including molecular genotyping, could clarify transmission pathways and strengthen One Health[1] strategies. Environmental sampling, such as testing farm run-off, offers a non-invasive method to track endemic circulation and seasonal dynamics.

The implementation of surveillance faces significant barriers, including methodological inconsistencies, limited diagnostic tools, and challenges in interpreting viral RNA detection. While advanced techniques like whole virus genome sequencing (WvGS) and digital polymerase chain reaction (PCR) and viability assays show potential, they remain largely experimental and resource intensive.

Conclusions and future considerations

In conclusion, there are not enough data for a quantitative attribution of the risk of HEV from pigmeat and pig production in Ireland. However, there is qualitative evidence of their role as contributors to HEV infection. Ireland's pig production system facilitates HEV persistence due to overlapping age cohorts present on farms. Although most pigs clear the virus by slaughter age (5–6 months), some may still be viraemic at slaughter, representing a food safety risk. This risk varies by tissue type, with liver carrying the highest viral loads.

Good hygiene practices at slaughter and at processing plants, together with heat treatment of pigmeat and pigmeat products to recommended internal temperatures, are essential in order to mitigate the risk from HEV. Alternative non-thermal technologies applied during processing, such as high-pressure processing, are also reported to support the control of HEV.

Active HEV surveillance on pig farms is rare and not legislated for as certain other zoonotic diseases are, resulting in monitoring that remains fragmented and largely exploratory.

Future considerations include focused monitoring on high-risk pigmeat products in order to build an evidence base for a better understanding of its contribution to human HEV infection in Ireland. This could include qualitative and quantitative epidemiological studies and WvGS. Thus, there is an important role for research to assess the value of surveillance approaches and test methodologies in order to inform decisions on implementing formal surveillance systems.

[1] One Health is an integrated, unifying approach that aims to sustainably balance and optimize the health of people, animals and ecosystems (Word Health Organisations, n.d.)

In order to mitigate the risk, HEV could be identified as a hazard in HACCP and food safety management systems at pig abattoirs and at pigmeat processing plants where high-risk products are manufactured.

Communication to consumers (especially people who are at increased risk from HEV infection due to underlying health conditions) and providing advice on the cooking and safe handling of high-risk products in relation to HEV could complement existing general advice on food safety.

1. Introduction: Hepatitis E virus

1.1 Overview

Hepatitis E virus (HEV) is the leading cause of acute viral hepatitis worldwide (Debing *et al.*, 2016; Kamar *et al.*, 2014). Between 2016 and 2022, the number of notified cases per year was in the range of 42–99. Cases include those diagnosed after they present to the healthcare system with illness, as well as those detected as a consequence of routine testing of blood donors. Cases detected by routine blood donor testing account for a high proportion of cases notified each year and for more than one-half of all notified cases in some years (Health Service Executive, 2023).

A recent report of the Scientific Committee of the Food Safety Authority of Ireland (FSAI) ranked HEV seventh in a list of microbiological hazards in food based on the total disease burden they cause. HEV accounted for 1.25 (95% uncertainty range: 0.49, 1.88) foodborne disability-adjusted life years (DALYs) annually.

HEV is a single-stranded positive-sense ribonucleic acid (RNA) containing virus in the *Paslahepevirus* genus, within the *Hepeviridae* family (Cook *et al.*, 2016). HEV consists of eight genotypes, with genotypes 1–4 being the major causes of infections in humans. Figure 1 shows the worldwide distribution of HEV genotypes.

Hepatitis E virus genotype 1 (HEV-1) and **hepatitis E virus genotype 2 (HEV-2)** are transmitted via contaminated water in regions with poor sanitation. They exclusively infect humans and primates (Carratalà and Joost, 2019; Harrison and DiCaprio, 2018).

Hepatitis E virus genotype 3 (HEV-3) and **hepatitis E virus genotype 4 (HEV-4)** are zoonotic (animal to human transmission), with HEV-3 being the major zoonotic genotype circulating in the United States of America (USA), Europe, China and Japan (Carratalà and Joost, 2019). Transmission is mainly linked to the consumption of contaminated pigmeat and direct contact with infected animals (Bennett *et al.*, 2024). Other routes of infection include contamination of watercourses and fresh produce with effluent and slurry from piggeries, abattoirs and human sewage (Grierson *et al.*, 2015).

Hepatitis E virus genotype 5 (HEV-5) and **hepatitis E virus genotype 6 (HEV-6)** have been found in wild boars, and **hepatitis E virus genotype 7 (HEV-7)** and **hepatitis E virus genotype 8 (HEV-8)** have been found in camels. As of the time this report was prepared in early 2026, there are no confirmed cases of human infection with HEV-5 or HEV-6. A human case of HEV-7 infection has been linked to zoonotic transmission from camels (Lee *et al.*, 2016) and HEV-8 has been successfully inoculated from camels to macaques (Wang *et al.*, 2019), indicating the zoonotic

transmission potential of these genotypes from infected camel meat and milk (Doceul *et al.*, 2016; Kardena *et al.*, 2025).

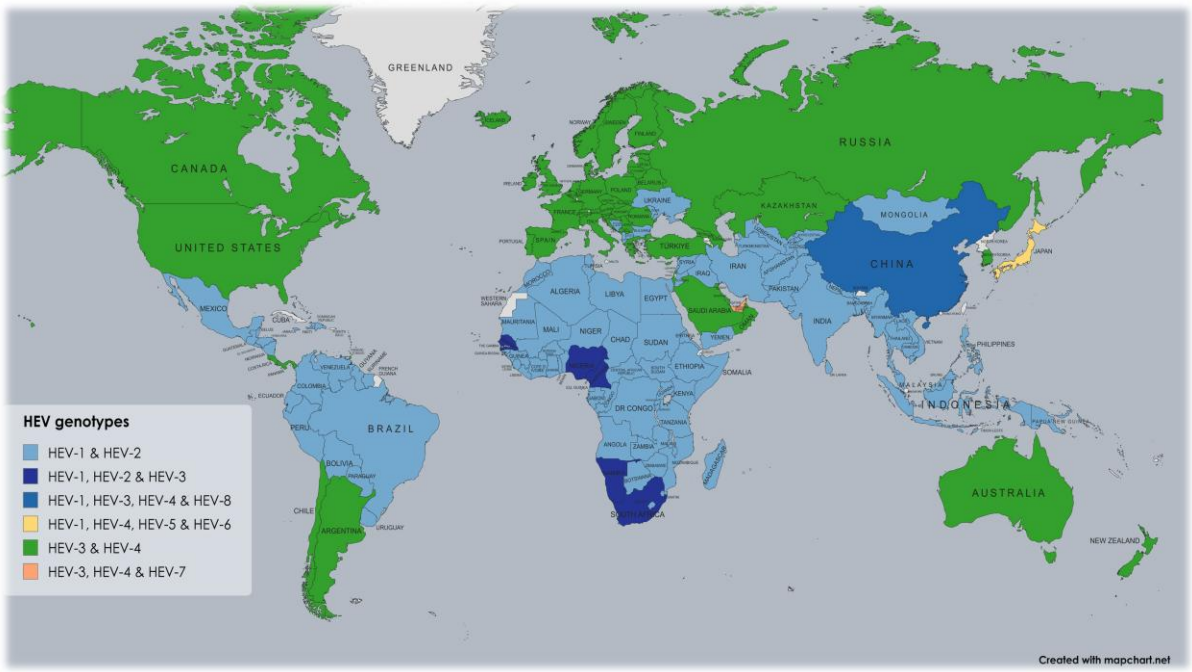


Figure 1 Distribution of HEV genotypes (HEV-1 through HEV-8) worldwide

Map created by Rose M Fitzgerald from Tene *et al.*, 2025. Map created in MapChart using the World Map: Simple (Voorrips, 2002).

Symptomatic HEV infection is primarily associated with acute viral hepatitis in humans, with a wide spectrum of clinical presentations, from mild to severe fulminant disease. Symptoms of hepatitis (jaundice, fever and abdominal pain) typically occur following an incubation period of between 2 and 6 weeks (Guerra *et al.*, 2017). For the majority of individuals, HEV infection is self-limiting and lasts from a few days up to 6 weeks (Guerra *et al.*, 2017). In most cases, clinical management is provided with supportive care. A notable exception to the self-limiting course is the observation that, in developing countries, HEV-1 infection during pregnancy is associated with a high mortality rate of up to 25% among affected expectant mothers (Webb and Dalton, 2019). The role of antiviral treatment is uncertain. Liver transplant may be required in cases associated with fulminant hepatic failure.

Extrahepatic complications of infection have also been described, including neurological issues, such as neuralgic amyotrophy, transverse myelitis, cranial nerve palsies and Guillain-Barré syndrome (Dalton *et al.*, 2016).

Human vaccines against HEV are an area of ongoing research, but no human HEV vaccine is currently licensed for use by the European Medicines Agency.

Chronic HEV infection, defined as persistent viraemia for more than 3 months, has been reported in immunocompromised individuals, such as those with uncontrolled human immunodeficiency virus (HIV) infection, or organ transplant recipients. Chronic infection has almost exclusively been associated with HEV-3 (Geng *et al.*, 2014; Murali *et al.*, 2015). Those with chronic infection show persistent elevated levels of liver enzymes, and infection can lead to progressive liver injury and cirrhosis (Sayed *et al.*, 2022).

Subclinical or asymptomatic infection is characteristically associated with HEV-3 infection, the dominant autochthonous strain in Europe. It is thought that the vast majority of HEV-3 infection is unrecognised. Infection in males is reported to be more common (Hoofnagle *et al.*, 2012).

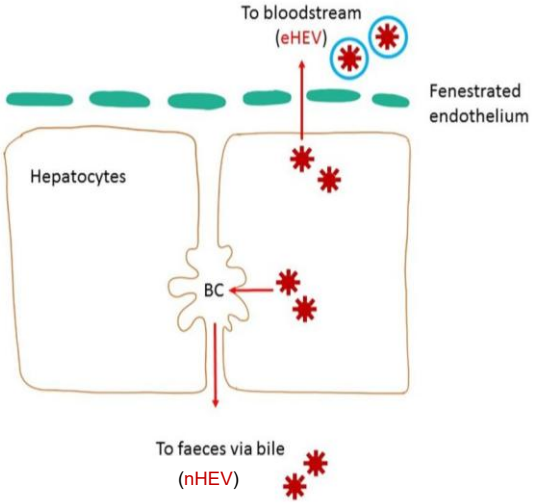
Detection of HEV is reliant on laboratory diagnosis. Commercial enzyme-linked immunosorbent assay (ELISA) kits are the preferred method for detecting HEV antibodies. The detection of anti-HEV immunoglobulin M (IgM)/immunoglobulin G (IgG) antibodies in blood samples has proven useful, with rapid IgM antibody immunoassays commonly used in the diagnosis of acute hepatitis E infection in humans (Chionne *et al.*, 2016). The detection of HEV RNA is achieved using reverse transcription-polymerase chain reaction (RT-PCR). This is important for identifying acute and chronic infections (Van der Poel *et al.*, 2018). RT-PCR is also used to detect HEV in food. Effective sample preparation is essential to release viral nucleic acid from the host cell. A number of extraction methods have been described for meat and meat products (Colson *et al.*, 2010; Szabo *et al.*, 2015).

1.2 Different forms of HEV

HEV is unusual in that both quasi-enveloped and non-enveloped forms of the virus exist within infected hosts. *In vivo*, the virus exists within the liver, where infected hepatocytes release it into the bile, where the envelope is thought to be degraded from the virions by bile salts *en route* to the small intestine. It is then primarily shed in faeces as a non-enveloped virus. In contrast, virions released from hepatocytes into the bloodstream are not exposed to bile and remain quasi-enveloped. Although both forms of the virus are infectious, the non-enveloped virus, found in faeces, is 10 times more infectious than the quasi-enveloped form, found in blood, with the latter

displaying slower entry kinetics and lower binding efficiency, resulting in lower infectivity (Yin *et al.*, 2016). However, quasi-enveloped virus is resistant to host-neutralising antibodies (Yin *et al.*, 2016).

This has potential implications when considering the relative risk of HEV infection following the consumption of meat products from infected animals, or following contact with faeces and blood products, which may contain different proportions of non-enveloped HEV (nHEV) and quasi-enveloped HEV (eHEV), as well as different viral loads. The relative risk of zoonotic transmission of HEV from infected food products, blood products and faeces is currently unknown. Figure 2 show how HEV produced from cultured cells *in vitro* is quasi-enveloped, similar to virus in the bloodstream of patients (Yin *et al.*, 2016). This further reduces the applicability of *in vitro* systems to study HEV infection in a physiologically relevant way, since quasi-enveloped virus is less infectious, and many *in vitro* models therefore do not allow for the investigation of non-enveloped HEV (Yin *et al.*, 2016).



"In vivo, HEV exists as a quasi-enveloped form in the bloodstream and a non-enveloped form in faeces, due to the removal of the viral envelope during passage of the virus through the biliary system. Hepatocytes are the main target cell for HEV infection in the liver. Upon release from the host cell, virus may bud from the apical side of the cells into the bile canaliculi (BC) where it travels to the small intestine and is excreted in faeces as nHEV or may bud from the basolateral side of hepatocytes and enter the bloodstream as eHEV via the fenestrated endothelium of liver sinusoids" (Yin *et al.*, 2016).

Figure 2 Mechanism by which nHEV and eHEV are generated in the liver

Diagram modified from Dr Nicola Fletcher, with permission.

1.3 Animal hosts of HEV

HEV may spread from human to human via the faecal-oral route, including scenarios where food or water are contaminated with human faeces. Zoonotic transmission of HEV may occur through occupational exposure, such as direct contact with infected animals (i.e. among veterinarians, farmers, slaughterhouse workers and hunters), or through ingestion of raw or undercooked meat products. Additionally, environmental contamination of water sources with infected animal faeces poses a risk to the food chain, with the potential for HEV bioaccumulation in food such as bivalve molluscs and its presence in other agricultural products (e.g. berries and leafy vegetables) (Bennett *et al.*, 2024; Crossan *et al.*, 2012; Pavio *et al.*, 2017; Said *et al.*, 2009).

HEV-1 and HEV-2 infect humans and primates, primarily in Asia and Africa, where poor sanitation and contaminated water facilitate transmission (Doceul *et al.*, 2016; Lozano *et al.*, 2012; Nidaira *et al.*, 2012; Sato *et al.*, 2011).

HEV-3 and HEV-4 have been detected in humans, pigs, deer, rabbit, hare, wild boar, mongoose and monkeys (L'homme *et al.* 2013; Nidaira *et al.*, 2012; Sato *et al.*, 2011; Tei *et al.*, 2003; Yamamoto *et al.*, 2003), and a marine mammal (bottlenose dolphin) (Villalba *et al.*, 2017).

Although pigs are likely the main reservoir of HEV-3 and HEV-4, there is evidence that wild game, such as deer and wild boars, also contribute to the zoonotic transmission spectrum in Europe (Montone *et al.*, 2019; Takahashi *et al.*, 2004). In addition, it is thought that rabbits may be potential transmission vectors, as evidence of anti-HEV antibodies has been identified in these animals (Cossaboom *et al.*, 2011). A recent study used whole virus genome sequencing (WvGS) to characterise a rabbit HEV strain (HEV-3 subtype 3ra), which was isolated from a chronically infected human patient. A temporal relationship between infection with HEV-3 subtype 3ra and direct contact with rabbits has also been observed (Klink *et al.*, 2023). These findings underline the role of rabbits as putative sources of HEV infection.

Studies have demonstrated the detection of identical HEV strains in patients and animal products in Japan following the consumption of uncooked deer meat (Tei *et al.*, 2003) and grilled wild boar (Li *et al.*, 2022), pigmeat in Spain (Riveiro-Varciela *et al.*, 2014, as cited in Renou *et al.*, 2010) and figatellu sausage produced in France (Colson *et al.*, 2010; Renou *et al.*, 2010). A Swiss study detected a rabbit HEV-3 strain in three patients, with none of the patients having consumed rabbit meat or been in direct contact with rabbits, suggesting an alternative infection route, either by contaminated vegetables or another animal or animal product (Sahli *et al.*, 2019).

HEV-5 and HEV-6 have been detected in wild boars in Japan (Smith *et al.*, 2016). HEV-7 and HEV-8 have been detected in camels from the Middle East region and China (Lee *et al.*, 2016;

Wang *et al.*, 2019). Detection of HEV-7 in a human has been attributed to close contact with camels and the consumption of camel meat and milk (Lee *et al.*, 2016). Wang *et al*. (2019) have experimentally inoculated filtered HEV-8-infected faeces from Bactrian camels to cynomolgus macaques. The macaques developed chronic hepatitis, systemic HEV-8 infection and renal lesions.

1.4 Statistical overview of pigmeat production in Ireland

According to the National Pig Census, in 2024, there were 1,251 active pig herds in Ireland keeping 1,474,540 pigs, which comprised 133,062 breeding pigs, 1,340,670 fattening pigs and 808 non-production pigs.

Most of the pigs (1,422,080, or 96.5% of all pigs) reared in Ireland were recorded in 246 herds, each keeping more than 1,000 pigs, with 38 herds (3.04%) keeping in excess of 10,000 pigs each. These 38 herds account for 40.5% (597,480 pigs) of the total pig population in Ireland. A total of 885 active herds (70.74% of all herds) recorded keeping 20 or fewer pigs, while the 49 herds keeping between 501 and 1,000 pigs accounted for only 2.59% of the overall pig population (38,141 pigs).

Cavan recorded the largest pig population, with 270,997 pigs, representing 18.38% of the total pig population in Ireland. Cork recorded the second-highest population, with 253,032 pigs (17.16%), and Tipperary recorded the third-highest number, with 112,824 pigs (7.65%).

The Central Statistics Office reported that 5,215 live pigs were imported into Ireland in 2024, of which 4,561 (87%) originated in Northern Ireland (United Kingdom (UK)), with the rest being imported from the Netherlands (338), the USA (187), Great Britain (UK) (70), Poland (20), Sweden (18) and other European Union (EU) countries (21). The majority (5,125) were pure-bred breeding swine.

These figures show that imported live pigs constituted only about 0.35% of the total live pig population in Ireland in 2024.

Pigmeat is one of the most consumed meats in Ireland, reportedly comprising 32.5% of total meat consumed (Central Statistics Office, 2023). According to Central Statistics Office data for 2023, approximately 300,000 tonnes of pigmeat were produced through domestic slaughtering, while 83,000 tonnes were imported. Total domestic consumption of pigmeat reached 169,000 tonnes (combining both local production and imports), marking an increase from 155,000 tonnes in 2022.

These figures show that imported pigmeat constituted about 22% of the total pigmeat produced through slaughter in Ireland and imported into the country (83,000 tonnes out of 383,000 tonnes) in 2023.

In 2023, the average annual per capita meat consumption in Ireland increased by 5 kg (a 6% increase) when compared with 2022, reaching 99 kg. This increase was primarily driven by higher poultry consumption. Poultry accounted for nearly one-half (47%) of all meat consumed, followed by pork, at 32%, and beef and veal, at 18% (Central Statistics Office, 2023).

1.5 Request for advice

In order to address the concern regarding the risk of zoonotic transmission of HEV from pigs to humans in Ireland, including consumer risk from the consumption of pigmeat, the FSAI issued a request for advice (Appendix 1) to the Scientific Committee posing four questions:

1. What is the contribution of the pigmeat food chain to the risk of HEV in Ireland?
2. How do different approaches to pigmeat production influence the risk of HEV infection for people in Ireland?
3. What are the potential risk management strategies to address any identified food chain risk?
4. Given any risks identified, would active surveillance programmes on pigs and pigmeat production be beneficial?

This report presents the opinion and recommendations of the Scientific Committee on these questions.

2. Question 1: What is the contribution of the pigmeat food chain to the risk of HEV in Ireland?

2.1 Transmission pathways of HEV and the role of pigs and pig production

There are multiple postulated transmission pathways to humans for HEV (Figure 3).

Person-to-person transmission can occur through tissue exchange, such as blood transfusions or liver transplants from infected individuals. However, the dominant route is faecal-oral, typically via ingestion of water contaminated with human faeces. Food contaminated by human faeces also represents a potential transmission pathway.

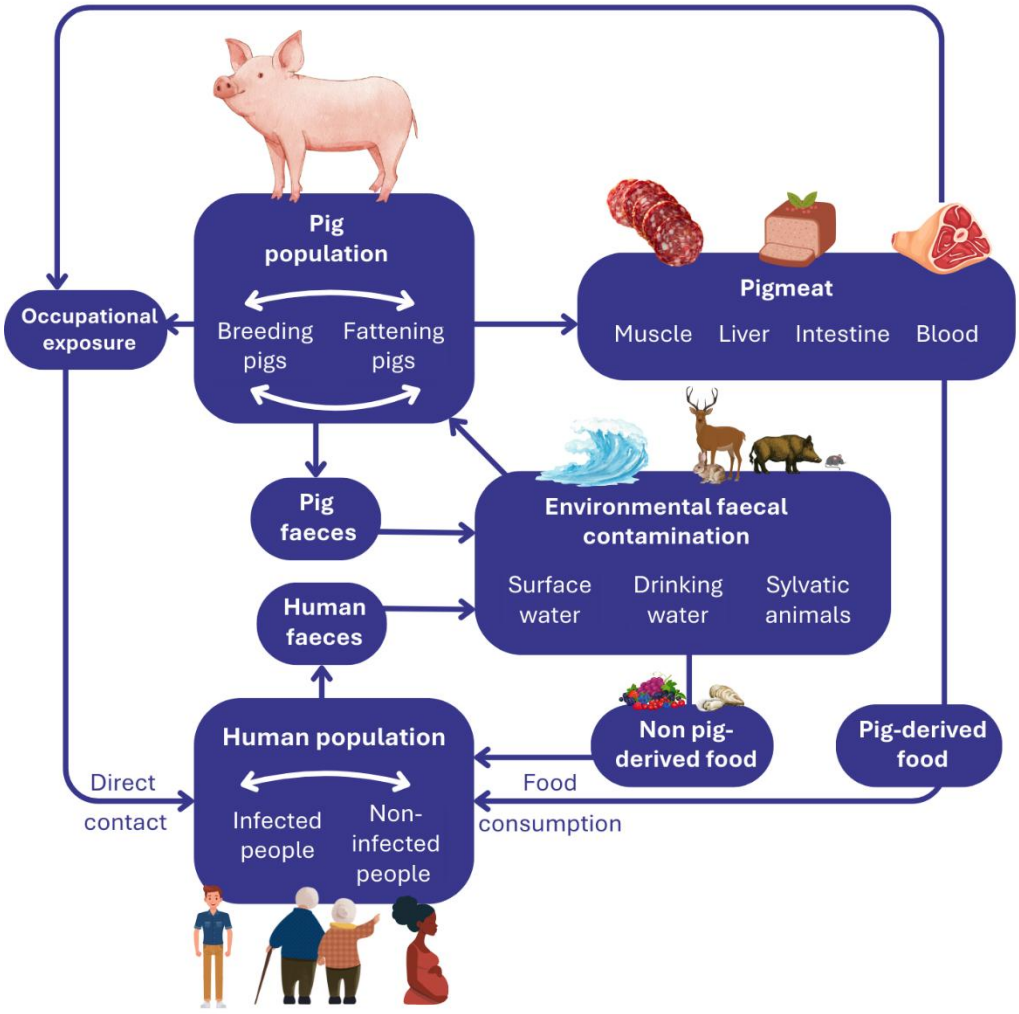


Figure 3 Source and transmission routes of HEV infection, showing the role of pigs and pigmeat

The primary consideration of the present opinion is transmission of infection through the consumption of food derived from pig tissues, or food contaminated with pig excretions/secretions. Viraemia caused by HEV infection in pigs can lead to the presence of the virus in edible tissues, such as liver, muscle or blood. Consumption of these products, especially when undercooked, poses a potential risk of infection to consumers. Multiple studies across Europe demonstrate the seroconversion of pigs, viraemia, faecal shedding and the presence of HEV RNA in pig tissues commonly consumed as food (European Food Safety Authority, 2017).

In densely populated areas with poor sewage treatment and poor water sanitation, non-foodborne hepatitis E transmission risks exist. For example, rodents may become infected through contact with human sewage and contaminate human drinking water via their faeces. Waterborne transmission is a relevant consideration in assessing overall HEV risk. Contamination may arise from both human and animal faeces. Contaminated water can subsequently contaminate other sources; for example, through irrigation of fresh produce or bioaccumulation in live bivalve molluscs. In the Netherlands, HEV-contaminated river water was found to mirror genotypes present in nearby pig farms, suggesting agricultural run-off as a contributing factor (Rutjes *et al.*, 2014). Reassuringly, chlorination of drinking water has been demonstrated to inactivate the virus (Girones *et al*., 2014).

Fresh produce – notably strawberries and raspberries – irrigated with contaminated water may serve as secondary transmission vehicles. In certain cases, HEV strains isolated from produce were genetically similar to those in local pig populations (Maunula *et al.*, 2013).

An investigation of acute hepatitis E cases in Cornwall, UK indicated that infected people were more likely to live close to the coast than close to a pig farm, which is potentially consistent with a hypothesis that agricultural and/or sewage run-off contaminating coastal areas may pose a risk for hepatitis E infection (Hunter *et al.*, 2016). Faber *et al.* (2018) identified the consumption of raw vegetables and occupational exposure to wastewater as risk factors for HEV infection, while a recent case-control study by Janssens *et al.* (2025) demonstrates that workers in the pig sector have a higher risk for HEV infection than a population that is not occupationally exposed to pigs and pork. Similar findings exist in other occupational exposure studies that demonstrated significantly higher seroprevalence among those in regular contact with pigs, such as veterinarians and slaughterhouse workers (Chaussade *et al.*, 2013; Meng *et al.*, 2010).

2.2 Considering pigmeat consumption as a source of human infection

Available epidemiological data in cases of human illness provide information about exposure to different potential sources of infection but can rarely facilitate direct attribution of human infection to particular pathways. Molecular epidemiology of viruses can elucidate relatedness between viruses causing infection in humans and those detected from different sources of human infection.

Although the number of documented cases of HEV infection in humans with established links to meat or liver consumption remains low, the European Food Safety Authority (EFSA) in its 2017 scientific opinion on HEV-related public health risks, considers foodborne transmission to be a major route of human infection in the EU. Consumption of uncooked or undercooked pork and wild boar meat, liver and liver sausages is identified as the main source of HEV infection (EFSA Panel on Biological Hazards (BIOHAZ) *et al.*, 2017).Case-control studies in Germany, Switzerland and other European countries point to consumption of these pork products as risk factors for infection (Faber *et al.*, 2018; Müller *et al.*, 2017). Specific strong associations between outbreaks of illness in people and the consumption of pigmeat have been described in the literature (Miao *et al.*, 2024) but are not prominent in the EFSA report (EFSA Panel on Biological Hazards (BIOHAZ) *et al.*, 2017)., although there are occasional reports of association (News Desk, 2023).

In a study carried out to determine the prevalence and genetic diversity of HEV strains causing human infections in England and Wales from 2003 to 2012, phylogenetic analysis was used in order to classify the HEV strains and understand their evolutionary history. Analysis found that HEV subtype 3e was closely related to strains found in other European countries. The study also found that the HEV strains prevalent in the region showed genetic diversity and were associated with different risk factors, including travel to endemic regions and consumption of pork products (Ijaz *et al.*, 2014). Another study determining the genetic characterisation of HEV in pork products sold at retail in Canada used phylogenetic analysis in order to determine the presence of diverse HEV genotypes. Phylogenetic analysis revealed that HEV isolated from the pork products belonged to genotype 3. This genotype is known to be circulating in many countries and showed a close genetic clustering with strains found in swine (Mykytczuk *et al.*, 2017). Phylogenetic analysis is a powerful molecular tool for providing insight into the sources of contamination and potential transmission routes.

In one outbreak, evidence based on the genetic comparison of HEV sequences from clinical cases and food products strongly supported the hypothesis that the transmission of HEV to humans was linked to the consumption of a specific product, figatellu pork sausage (Colson *et al.*, 2010). An association between the consumption of ready-to-eat (RTE) spreadable liver products (e.g. pâté)

and acute HEV cases has been determined in Germany (Faber *et al.*, 2018), the Netherlands (Tulen *et al.*, 2019), and the UK (Said *et al.*, 2014). Said *et al.* (2014) conducted a case-control study in England and Wales that found that the consumption of sausages, ham and pork pies correlated with HEV infection.

As an RNA virus, detection of HEV by RT-PCR is likely to correlate reasonably well with infectivity for non-thermally treated fresh products. The infectivity of food products containing HEV RNA is rarely examined. However, a paper by Feagins *et al.* (2007) investigated polymerase chain reaction (PCR)-positive homogenates obtained from retail packages of commercial pig liver, inoculating them in pigs in order to determine whether the PCR-positive pig livers still contained infectious virus. The results showed that pigs inoculated with two of the three PCR-positive pig-liver homogenates became infected, as evidenced by the detection of faecal virus shedding, viraemia and seroconversion. In a different study, Van der Poel *et al.* (2014) used a three-dimensional cell culture system in order to demonstrate viable HEV in a figatellu sausage. The findings indicate that the HEV in non-heat-treated products containing pig liver has infection potential.

2.3 Overall appraisal of pigmeat consumption as a pathway of infection

There is evidence that:

- The genetic type of viruses causing human HEV infections in Europe matches those frequently present in farmed pigs and present in pigmeat products.
- The viruses present in pigmeat products have the potential to cause HEV infection.
- Pigmeat product consumption has been epidemiologically associated with human illness.

As such, and in agreement with EFSA (2017), the data qualitatively support a hypothesis that in a European context, pigs are the principal livestock species acting as hosts for HEV, supporting its replication as an ongoing source of infection for humans, with pigmeat products facilitating transmission to humans. Although data from Ireland are limited, available studies suggest similar HEV prevalence on pig farms and transmission risk from the consumption of high-risk pigmeat products, such as liver and liver-based sausages (Bennett *et al.*, 2024; 2023).

The scientific literature also supports a hypothesis of an ongoing role for animal and human faecal run-off as a potential human infection pathway. Available data are not sufficient to support an adequate quantitative assessment of the extent to which human HEV infections might be attributable to pigmeat consumption, or pigs' faecal contamination of water or other foods.

3. Question 2: How do different approaches to pigmeat production influence the risk of HEV infection for people in Ireland?

3.1 Pre-harvest pig production and HEV risk to humans

Pigmeat production can be regarded as relatively homogenous in Ireland, with a similar intensive housed model across the bulk of the approximately 300 farms in the country. Breeding sows produce an estimated 8 million pigs per year. The vast majority of pig units consist of integrated piggeries where farrow-to-finish takes place. Piglets are suckled for the first month of life and slaughtered at between approximately 5 and 6 months of age. These farms account for almost all pigmeat produced in Ireland (see Section 1.4 for more details on pig production figures in Ireland). Older sows are also slaughtered for human consumption following several years as breeding animals. Smaller quantities of pigs (and pigmeat) are produced in more extensive systems, which tend towards outdoor rearing and slower growth, and therefore later slaughter.

3.1.1 Age of pigs

Young piglets become susceptible to HEV infections after the level of maternal antibodies drops at around 8 weeks of age (Feng *et al.*, 2011; Kanai *et al.*, 2010). Infected pigs start to shed the virus in faeces between 1 and 2 weeks after the infection, and the shedding lasts for up to 7 weeks (Meng, 2011; Widen, 2016; Yugo and Meng, 2013). Infection results in seroconversion and abatement of detectable shedding of virus at about 6 months of age, when commercial pigs are usually sent to slaughter (Davin, 2019; Jiménez De Oya *et al.*, 2011; Li *et al.*, 2022).

This seroconversion and apparent clearance of infection could explain the difference at slaughter between the seroprevalence rate and the HEV detection rate in faeces, liver and blood, with the seroprevalence rate always higher than HEV detection rate.

Many studies have shown that viraemia and live virus shedding is reduced as the pigs get older and develop immunity (Raspor Lainšček *et al.*, 2017). However, a Dutch study has shown that a prolonged interval until slaughter correlates with increased risk of pig infection (Meester *et al.,* 2023). An Irish on-farm survey reported that 27% of pigs tested were seropositive for HEV, and the seropositive pigs were from 81% of the farms surveyed (O'Connor *et al.,* 2015). A longitudinal Irish study (Davin, 2019) showed peak viraemia and faecal shedding at 12 weeks, and substantial seroprevalence at weeks 12–20. A large study in the UK determined that 93% of pigs tested at slaughter were seropositive, with a current infection prevalence of 21% of the pigs based on HEV

RNA in plasma or faecal samples (Grierson *et al.,* 2015). A study in Serbia reports a cultural practice of slaughtering young pigs and showed a higher prevalence of infection in pigs younger than 3 months (44%) than in pigs older than 3 months (34%) (Milojević *et al.*, 2024).

Although the infectiousness of pigs on the farm is important for people who have direct contact with the animals, from a food safety point of view, foodborne HEV transmission is the main focus of this document.

In Appendix 2, Table 1 demonstrates different seroprevalence and HEV RNA detection rates in different countries at farms and slaughterhouses. Viraemia in slaughter-age pigs shows considerable variability in the literature studied, ranging from 0.0% to 44.4%. The lowest values were reported in the Irish study (Davin, 2019), where no viraemic animals were detected at 20 weeks, while modest levels were observed in Spain (6.7%), Canada (2.3%) and the USA (6.3%) (García *et al.,* 2020; Le Blanc *et al*., 2020; Sooryanarain *et al*., 2020). A higher prevalence was recorded in the Netherlands (16.1%) and the UK, where studies reported 20.5% and, in one cohort of slaughter-age pigs, 44.4% (Boxman *et al.,* 2022; Grierson *et al.,* 2015). These findings indicate that although viraemia is generally less common than seropositivity, actively infected animals can still be present at slaughter, with prevalence varying widely across regions and studies.

These figures from other countries are relevant to Ireland, as intensive pig farming tends to be similar, particularly with regard to slaughter age, irrespective of country. Table 1 cannot be regarded as exhaustive and other data exist in the literature (for example, Boxman *et al.*, 2022; Li *et al.*, 2022), although the data in these publications are older than the data in the current review.

3.1.2 Biosecurity measures and infection control

Intensive pigmeat production brings a risk of many infections, including, but not limited to, hepatitis E. The range of measures to prevent the introduction of infectious diseases to the farm, and their spread on the farm, is referred to as biosecurity. It is unlikely that any of the on-farm biosecurity measures have been designed specifically to manage the risk of introduction or spread of HEV; however, it is likely that many of those measures will help to manage such risks. Intensive production with high animal density, and overlapping cycles of pig production, are among the factors that seem to have allowed HEV to become established and achieve a high prevalence.

In a Dutch study conducted in 2019 on pig farms where HEV was present, Meester *et al.* (2023) identified biosecurity practices with a positive or negative correlation to the delivery of HEV-negative batches of pigs to slaughter. Cleaning and the cleanability of floors and other surfaces, as well as adequate fly control, were among the measures correlating with low HEV infection.

In a study of farms in nine European countries (Dubbert *et al.*, 2024), factors correlating with lower HEV risk included the use of a graphical tool to summarise and analyse hygiene findings (hygiene-ogram) in breeding or fattening units, the presence of quarantine areas, heat treatment of feed, and lower numbers of people involved in husbandry.

Evidence indicates that HEV-3 can persist in farms operating closed herd systems with frequent between-pen mixing and poor biosecurity. Withenshaw *et al.* found high HEV prevalence in faeces and the farm environment, and higher prevalence in growers (85.8% overall) compared with older fattener pigs (26.0%), while active infection was absent in farrowing sows and young piglets (Withenshaw *et al.*, 2022).

Suboptimal biosecurity measures – such as mixing of different age groups, a lack of building-specific clothing, the absence of disinfectant boot dips, a lack of quarantine of newly purchased pigs, uncleanable floors, and pooling of water in the farmyard – have been positively correlated with high HEV transmission rates and persistent infection in farms (Andraud *et al.*, 2013; Lopez-Lopez *et al.*, 2018; Withenshaw *et al.*, 2022). Production methods that involve potential exposure to human sewage (e.g. extraction of untreated surface water for washing pig housing) may empirically be regarded as risk factors.

3.1.3 Extensive husbandry and outdoor access

Biosecurity can be more challenging in outdoor circumstances, but there is no clear evidence of whether extensive and outdoor farming constitute a higher risk of HEV introduction to the herd in Ireland. In this regard, some studies in France and Spain suggest that outdoor pig herds are more likely to get infected than indoor herds (Jori *et al.*, 2016; Lopez-Lopez *et al.*, 2018) through their greater likelihood of exposure to the faeces of other pigs, wild animals, or humans infected with HEV. While one Dutch study did not observe a significant difference between organic, free-range and conventional farming systems (Rutjes *et al.*, 2014), a later Dutch study found evidence of higher seroconversion and lower at-slaughter viraemia in organic outdoor pigs when compared with conventional pigs (Meester *et al.*, 2022). A higher within-herd seroprevalence of pigs farmed extensively outdoors is consistent with either higher infection with HEV from outside the herd and/or a higher transmission rate within the herd for pigs farmed extensively or organically (Jori *et al.*, 2016; Lopez-Lopez *et al.*, 2018; Rutjes *et al.*, 2014). A higher within-herd transmission rate may be due to more exposure to other pigs' manure, or greater contact frequency among pigs (Rutjes *et al.*, 2014) or with other animals and/or humans carrying or shedding HEV (Lopez-Lopez *et al.*, 2018). Later slaughter age may be a contributing factor to lower viraemia at time of slaughter.

Although intensive indoor pig farming is predominant in EU countries, outdoor farming systems also exist, such as backyard or organic pig farming. Backyard and organic pig farming typically involve partial outdoor rearing. However, backyard pig production accounts for only 3%, and the organic pig sector represents less than 1%, of the total EU pig population. The countries with the most backyard pig farms are Lithuania, Romania and Slovenia, while Austria, Denmark and Sweden are leading in organic pig production (Augère-Granier, 2020). There is a very small number of free-range and organic pig farms in Ireland, and their produce is commonly supplied to the local market (Ethical Farming Ireland, n.d.).

3.1.4 Temporal or geographic variation

Commercial pig production in Ireland is indoors, continuous and year-round, and therefore there are no grounds to expect temporal variation in HEV risk. While there are data to show seasonality in human HEV infection (Dalton *et al.*, 2008), it is difficult to separate zoonotic risk from non-zoonotic risk, such as heavy rainfall and flooding resulting in human sewage contamination of human drinking water, which may be relevant to public health if consumed untreated. Studies from Asia have indicated evidence of seasonality in HEV prevalence in pigs at slaughter (Lu *et al.*, 2013). However, the husbandry practices in farmed animals in Asia appear to be more extensive than those observed in Irish pig production, with ongoing potential for both sylvatic and domestic viral circulation resulting in differences in the epidemiology of HEV infection (Wang *et al.*, 2025). Seasonality in pig HEV status has also been described more recently in Serbia (Milojević *et al.*, 2024).

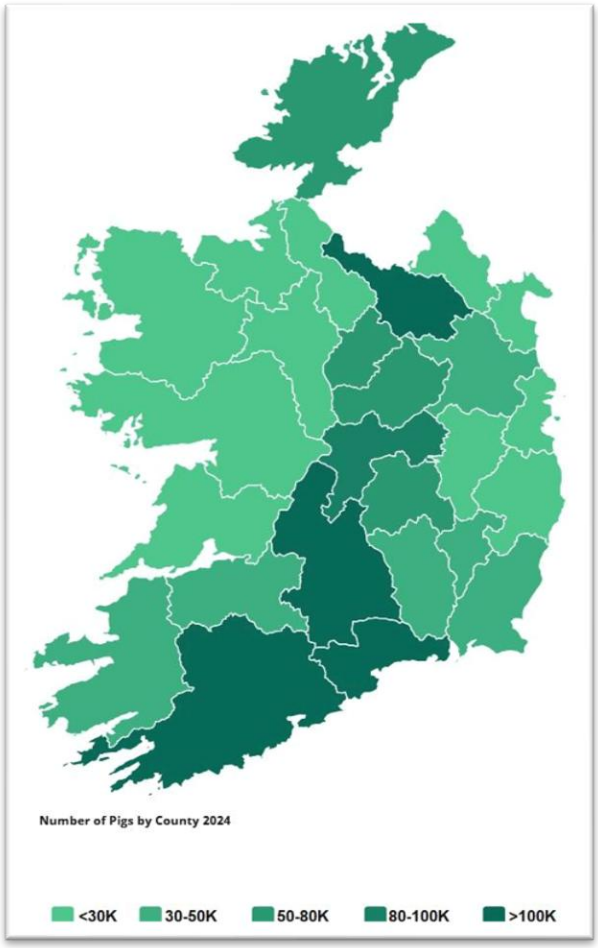


Figure 4 Number of pigs per county in Ireland, 2024 (Department of Agriculture, Food and the Marine, 2025).

Figure 4 shows a map of the number of pigs per county in Ireland as of 2024. Although this does not depict the density of pigs, it is indicative of the counties with the highest pig populations, and it illustrates the non-uniform distribution of pig farms. While pig farms are concentrated in certain parts of Ireland, the method of production and husbandry varies little, and thus there are no grounds to expect a variation in geographical risk. Studies have shown variations in different countries in the prevalence of virus detection in animals or their products at the time of slaughter (see Tables 1 and 2 in Appendix 2), but sampling strategies appear to involve convenience samples. Consequently, there is no statistical power to enable a comparison of geographic risk. Available evidence would tend towards a hypothesis of HEV being endemic in modern pig production irrespective of region.

3.2 Harvest and post-harvest risk of HEV

Food is harvested from pigs through slaughter. While the primary pig tissue consumed is muscle (meat), pig livers and pig blood are also harvested for human consumption.

Pig muscle may be marketed as fresh meat, or may be further processed (for example, cured in nitrate brine to produce different types of bacon and ham). Some pig products are sold raw, with cooking instructions. Other products that are RTE products include those that undergo a thermal treatment step at the production site (cooked deli ham, cooked gammon or honey-roasted ham) and those that do not (dry-cured York-style ham, prosciutto or jamon serrano).

In addition, pork is often consumed as pigmeat preparations consisting of comminuted pork with spices and seasonings, shaped as sausages in either synthetic or natural casings, and intended to be cooked prior to consumption.

RTE non-thermally treated pork meat products comprising comminuted meat or offal as cured, fermented or air-dried sausage – such as salami, chorizo and figatellu, and RTE thermally treated pig liver pâté and bratwurst – are not a traditional aspect of Irish pigmeat production, but they are imported and consumed in Ireland. Pig intestines are frequently used as natural casings for such sausages.

Pig's blood is used in black pudding manufacture, which includes a step of boiling or steaming at between 71 °C and 75 °C in order to set the mixture. Furthermore, black pudding is traditionally fried before consumption in Ireland.

3.2.1 Slaughter process hygiene

Pigs infected with HEV show no clinical symptoms of the disease while alive, nor gross pathology after death. Thus, currently and previously infected animals can enter a slaughterhouse without detection at ante-mortem inspection (Khuroo *et al.*, 2016) and be processed along with other pigs, with all tissues entering the food chain without abnormality detection during post-mortem meat inspection.

Slaughtered infected pigs can be a source of contaminated food because:

- HEV infection in pigs can result in virus presence in the edible tissues of pigs, such as the liver, intestines, muscle or blood. The liver may be the tissue with the most infectivity potential, given that it is an established tissue type in which HEV replicates. In addition, the liver, as harvested at slaughter, may contain non-enveloped virions due to exposure of the

virus in the biliary system to bile, and it is known that nHEV is the more infectious form of the virus.

- Infectious virus in blood (viraemia) has the potential to contaminate muscle or offal, or to be processed to produce black puddings.
- Faecal shedding by infected pigs has the potential to contaminate pigmeat and offal at slaughter, although food safety management systems should mitigate this risk.

At harvest/slaughter, pigs are eviscerated in order to separate the thoracic and abdominal organs from the carcase, which is not usually de-hided. Instead, the outside is de-bristled through singeing and scraping. Normal slaughterhouse hygiene strives to prevent the faecal contamination of products that are destined for human consumption, but a contamination risk may arise due to leakage from the oesophagus or rectum, or through persistent faecal contamination on the skin. Livers are harvested hygienically, but generally without measures to prevent the contamination of other tissues with bile.

3.2.2 HEV in pigmeat and pig products

Table 2 in Appendix 2 presents a number of surveys and studies examining RNA HEV detection from different porcine products, including meat cuts and livers, as well as processed porcine products such as meat sausages, liver sausages and pâtés, intestines used as natural casings for sausages, and blood used as an ingredient. Table 2 in Appendix 2 cannot be regarded as exhaustive, and other relevant literature reviews have been published, e.g. Kanda and Okamoto (2025).

A considerable variation in the frequency of HEV detection in different surveys is noted, but sample size and sampling strategy also vary considerably. In particular, since there is no ISO standard for HEV detection in food matrices (see Section 5.2 on methods of analysis), differences in analytical methods may contribute to the differences in the results. Surveys of particular tissues (e.g. pigs' tissues or products) at slaughterhouses may be extrapolated 'backwards' as indices of animal infection prevalence and/or extrapolated 'forwards' as prevalence in those foods.

The liver is an organ with significant potential to be infectious to consumers, since it is likely to contain a mixture of quasi-enveloped viral particles in its vascular network and non-enveloped virions exposed to its bile canalicular system. HEV RNA has been detected in pig liver samples. The prevalence of HEV RNA in pork liver collected at slaughter has been found to be 1.3% in Switzerland (Müller *et al.*, 2017), 2.8% in France (Feurer *et al.*, 2018), 2.5% in the UK (Berto *et al.*, 2012) and 12.7% at point of retail in the Netherlands (Boxman *et al.*, 2019). A 2018 study of 296 livers from an Irish abattoir yielded only 1 positive sample (Britton, 2018).

Pork muscle may contain viable viruses due to circulation in the blood during the viraemic stage; however, these viruses are quasi-enveloped. Pork meat may also be contaminated by faeces or bile at the time of slaughter, in which case the viruses are non-enveloped and more infectious. Pigmeat product surveys have been conducted around the world, often including those products where liver is the main ingredient, such as in figatellu (a Corsican sausage made of liver and pork) and pork liver pâtés. The frequency of detection of HEV in pig products other than liver and liver-containing meat products seems to be lower. This may indicate a limited risk of human infection with HEV through the consumption of intact cuts of meat, as concluded by Feurer *et al.* (2018). They found a high load of HEV RNA in pork livers, but an absence in pork muscle, at French slaughterhouses. In that study, none of the 1,134 ham muscles tested were positive for HEV, while HEV prevalence in paired liver samples was 2.8%, with a level of contamination of up to 1.46×10^{8} copies per gram. Similarly, García *et al.* (2020) found a lower frequency of detection in a Spanish abattoir in muscle samples than in livers: liver: 7/45; kidney: 5/45; heart: 4/45; serum: 3/45; and diaphragm: 1/45.

In Belgium, Locus *et al.* (2023) conducted a survey of non-thermally processed RTE raw hams and raw dried pork sausages, and thermally processed RTE pork liver pâtés, at retail. In total, 31% (n=17) of products tested positive, with HEV RNA being found in 65% of the pork liver pâtés, 15% of raw dried hams and 0% of raw dried sausages.

In Italy, Di Bartolo *et al.* (2015) found that 53% of pig livers had detectable HEV RNA at the time of slaughter. In Germany, an investigation by Szabo *et al.* (2015) detected HEV RNA in 20% of raw sausages and 22% of liver sausages.

In Ireland, HEV RNA was detected in 9 out of 188 (4.8%) pork products tested. The highest incidence of HEV RNA was found in pork liver, with 6 out of 25 (24.0%) showing detectable viral RNA, while in sausages it was between 1.5 and 2.0%. The reported concentration of HEV ranged from 0.02 to 9.24 genome copies/gram of pork (Bennett *et al.*, 2024).

Although most papers show a higher frequency of HEV RNA detection for liver than meat, Li *et al.* (2022) carried out an estimation of the detection in different porcine products based on published papers and showed HEV RNA detection in pork meat, liver and sausage in retailers of 9.50% (95% confidence interval (CI): 5.14–14.90; I^2 = 94%) overall, with 13.27% (95% CI: 0.99–35.12; I^2 = 98%) in meat, 6.59% (95% CI: 1.83–13.49; I^2 = 92%) in liver and 11.70% (95% CI: 7.62–16.47; I^2 = 71%) in sausage. They further compared the HEV positivity between liver sausage and pork sausage, finding a nearly threefold higher HEV positivity of 15.23% (95% CI: 11.62–19.21; I^2 = 0%) in liver sausage compared with 5.54% (95% CI: 0.19–15.20; I^2 = 82%) in pork sausage.

In addition to the risk of HEV being present in the primary tissue of pigmeat products, some pork meat products are formed in natural casings that are produced from the intestines of animals, including pigs. In normal production, processes include tissue scraping, de-fatting, washing, and either wet or dry salting, leaving what is primarily the submucosal layer. HEV is shed from the liver into the intestine as the non-enveloped virus, which is more infectious to hosts (including humans) than the quasi- enveloped virus found in blood. The potential for HEV presence in fresh intestines is clear. However, the potential to survive casing manufacture is less well understood (Jelsma *et al.*, 2021).

4. Question 3: What are the potential risk management strategies to address any identified food chain risk?

4.1 Pre-harvest risk management strategies

4.1.1 Minimise infection of pig herds, and pigs within infected herds

Effective biosecurity can contribute to management of the introduction of infection and control of the spread of HEV in pig farms. Together with its stakeholders, Animal Health Ireland has produced an extensive code of practice for indoor pig production (Animal Health Ireland, 2023). Considering ingress potential at a herd level, intensive fully housed pig production is more amenable to effective risk management of the main ingress sources; namely, contact with tissues or faeces of infected animals, particularly pigs or humans. Contact of pigs with human or extraneous animal faeces needs to be considered in inputs such as animal feed, drinking water and water used to clean pig housing. Quarantine of incoming breeding animals is always wise and would be adequate provided that the quarantine period is long enough to allow seroconversion. Nevertheless, in the absence of clinical symptoms, this is not a practical solution against HEV without testing. Controlling rodents and birds can help minimise contact with their droppings or tissues.

Once the infection is introduced, the main biosecurity challenge in fully housed pig production arises from the continuous introduction of new batches of pigs and overlapping production cycles, which increase the risk of current or future groups being exposed to infectious material shed by previous ones. Focusing on managing this inter-compartment movement of infection can be beneficial for HEV infection control (Meester *et al.*, 2021). Reducing the direct or indirect contact between pig groups and production cycles at farm level and increasing the biosecurity between groups of pigs are husbandry practices that could control the spread of the infection within a farm. Controlling infection spread may require keeping pig groups well separated and implementing secure measures in order to avoid the infection moving between groups. Rigorous inter-batch hygiene in order to manage the risk of contact with the faeces of previous batches, manure management in order to ensure time for anaerobic digestion, and adherence to good agricultural practices when spreading slurry can assist with reducing the spread of HEV infection. Managing spread among groups of pigs by farm personnel requires, for example, having staff dedicated to one area and/or significant hygienic measures when moving between different on-farm environments.

Animal hygiene maintenance, particularly in later fattening stages (e.g. through appropriate stocking density, dietary management and enteric infection control) should help manage the faecal

contamination of hides, facilitating hygienic butchering and minimising the quantity of faecal-origin HEV on skin-on meat products following normal singeing/scraping.

Responsible welfare practices, such as the assessment and prevention of tail-biting, are potentially important in reducing the within-herd spread of HEV by minimising contact with the blood and tissues of viraemic pigs.

Vaccination of pigs could have the potential to control infection or reduce the spread of the virus (Dähnert *et al.*, 2024). However, there are currently no commercially licensed vaccines against HEV that are approved by the European Medicines Agency for use in pigs in the EU. Research projects in Europe are exploring possible vaccine strategies (European Food Safety Authority, 2017). In 2025, the UK Government commissioned a 3-year project to comprehensively test different vaccine approaches against HEV in pigs (Service.gov.uk, 2025). Further research is needed in order to understand the efficacy of vaccination in commercial pig production models in Ireland.

In order to prevent the transmission of HEV from infected human faeces to pigs and subsequently into the pigmeat supply chain, sludge and biosolids must be treated in strict accordance with the relevant legislation and the guidelines issued by the Environmental Protection Agency (Sludges, Biosolids and other Organic Fertilisers Working Group, 2025). This is especially critical for pigs with outdoor access, as well as for the safety of water used in pig watering systems (e.g. nipple drinkers, drinking troughs) and for cleaning pig housing, both of which may serve as indirect routes of exposure. Farm workers may also become infected with and shed viruses; therefore, post-toilet hand hygiene and return-to-work protocols, including sick pay, should contribute to risk management.

Management of pig faecal waste may also be associated with wider environmental food chain contamination risks, such as the contamination of food of plant origin or bivalve molluscs, although this is outside of the scope of the current scientific opinion.

4.1.2 Minimise active infection of pigmeat/pig products at the time of slaughter

Pigs with HEV viraemia and the presence of HEV in their tissues and faeces at the time of harvest represent the highest risk of HEV contamination in food derived from those animals. Pigs that have been infected in early life and are slaughtered after they have seroconverted and the active infection has passed represent a much lower risk of producing contaminated food. Thus, there exists a paradox in managing HEV risk to consumers, whereby notwithstanding the validity of

adapting biosecurity actions in order to minimise pig infection overall, pigs remaining sero-naïve in later life are at more risk of active infection with a virus that appears endemic in pig production at the time of slaughter.

HEV seems endemic in Irish pig production, and it is quite well documented that viraemia and viral shedding abate on seroconversion. Although seroconversion before slaughter would be expected to reduce risk, it is not practical to verify the immunoglobulin G (IgG) titre of slaughter-age pigs with on-farm surveillance for every batch. From a virological perspective, older pigs present a lower risk. Therefore, HEV risk management could potentially benefit from imposing a minimum slaughter age (e.g. 20 weeks), or from delaying pig slaughter by several weeks (e.g. from 24 to 28 weeks), as this would allow more time for any infected pigs to clear the virus before slaughter.

From a practical perspective, this would be difficult to implement. Pig farms have a fixed capacity, and any extension to the slaughter age would create an increase in the number of pigs being kept on a farm at any given time; this is not feasible without a huge capital investment to construct new buildings and an increase in the ongoing current costs of feeding and ventilating animals as a result of moving to slower growth and feed conversion efficiency. This would also result in larger pig carcases with a higher fat-to-muscle ratio, which would then not match market specifications.

Possible alternatives might involve logistical practices at the abattoir, with younger pigs being slaughtered separately or last, and more slowly. This would achieve some reduction in the risk of cross-contamination of carcases with infected blood and tissues.

Achieving effective HEV risk management requires regular and practical communication with farmers on biosecurity, with an emphasis on the importance of blocking entry routes and breaking transmission pathways. These messages may be delivered by veterinarians and herd health advisors, who can give farm-level practical advice and incorporate good hygiene practices into the overall herd health plan.

4.2 Peri- and post-harvest risk management

4.2.1 Slaughterhouse hygiene

Good hygienic slaughter processes can contribute to managing the risk of contamination of pork meat through faeces or bile. Furthermore, certain slaughterhouse procedures for decontaminating pigs' skin, such as scraping or singeing, can help manage pre-slaughter faecal contamination.

In order to reduce the risk of cross-contamination of tissues harvested for human consumption (such as meat or blood) with infected faecal material, food business operators (FBOs) should apply an effective hazard analysis and critical control point (HACCP) system and observe strict slaughter

hygiene during evisceration, oesophageal and rectal bunging, effective singeing, and, where relevant, hygienic closed-loop harvesting of blood. EU food law obliges FBOs involved in pig slaughter to have slaughter hygiene controls in place in order to manage the risk of faecal contamination of tissues harvested for food, and to apply specific process hygiene criteria for *Salmonella*, Enterobacteriaceae, and aerobic colony counts on pig carcases in order to validate the effectiveness of such systems to prevent faecal contamination. Indications of unacceptable faecal contamination should trigger corrective actions aimed at implementing improvements to the overall system, including biosecurity measures at farm level.

Special attention is necessary at liver removal and bile duct severing, as these organs show the highest titres of infectious virus. When harvesting the diaphragm muscle, thorough examination is necessary in order to ensure that pieces of liver are not attached to it and that they are not mixed with it.

For meat inspection, palpation and incision of the liver or intestines is kept to a minimum in accordance with EU legislation (Commission Implementing Regulation (EU) 2019/627).

4.2.2 Tissue-specific management considerations

When harvesting liver or intestines for human consumption, if HEV is identified by FBOs as a hazard in their HACCP system, then specific controls to manage any risks could be considered.

When manufacturing pork meat products using liver or intestines, FBOs should consider the HEV risk and incorporate appropriate controls into their food safety management systems, including, for example, raw material microbiological prerequisites, hazard identification, risk assessment, and verification procedures in order to ensure end-product safety. In some cases, such as casing manufacture, the production process may be capable of reducing contamination; but in other instances, such as curing, there may need to be a specification for incoming raw materials in order to manage the risk. These specifications may involve excluding liver, or the diaphragm (which is often contaminated with liver), or sourcing raw materials from HEV-negative herds or HEV-negative pigs (Crotta *et al.*, 2021).

4.2.3 Food processes as hurdles to limit HEV transmission and risk of infection

Viruses such as HEV are obligate pathogens, requiring live host cells in which to replicate. Thus, the maximal contamination for a food product is that arising from the live animal, and food safety connotations of preventing ‘growth’ in food are not applicable to HEV. Viruses, by their nature, do

not multiply in foods. Refrigeration or modified atmosphere packaging, for example, does not assist in managing HEV risk. However, various food production techniques have the potential to reduce the quantity of infectious virus on or in food.

High-pressure processing is the uniform application of pressure on food for a certain duration in ambient or controlled temperatures. Nasheri *et al.* (2020) treated HEV-3 in media with different conditions of high-pressure processing at between 400 and 600 megapascals (MPa) and treatment duration of between 1 and 5 minutes at ambient temperature, and consistently observed a 2-log reduction in viral load. However, application of the same treatments to artificially contaminated pork pâté resulted in a 0.5-log reduction in viral load. Pellerin *et al.* (2025) used high-pressure processing at different pressure/time combinations on raw pork livers that were artificially contaminated with HEV-3. After a treatment of 600 MPa for 1 minute in a refrigerated room, they did not detect any residual infectious HEV particles. In contrast, when Johne *et al.* (2021) tested the efficacy of high-pressure processing on phosphate-buffered saline that was artificially inoculated with HEV-3, they still detected low amounts of infectious virus after treatment at 600 MPa for 2 minutes, both at 4 °C and 20 °C. These results indicate that the efficacy of high-pressure processing treatment is matrix-, pressure-, and treatment-duration-dependent, and although it reduces the HEV-3 load in pork liver and pâté, it might not be sufficient to completely eliminate the risk.

Some ‘cold’ technologies, such as ultraviolet treatment, would have limited efficacy beyond surface contamination, and therefore are not relevant to HEV other than for surface contamination. While ionising radiation might have penetrative ability, such treatments would require specific approval for use in pigmeat following evaluation of their efficacy and safety (European Food Safety Authority, 2017).

Hepatitis E is susceptible to thermal inactivation; therefore, heating food can reduce the risk, while foods consumed without thermal treatment may pose a higher risk. Higher temperatures and times of exposure result in greater inactivation of the virus (Stunnenberg *et al.*, 2023). Most available evidence suggests that normal commercial or domestic cooking results in substantial inactivation of typical contamination loads of HEV on food (Imagawa *et al.*, 2018).

4.2.4 Thermal processing during manufacture

In Ireland, most pigmeat products are placed on the market without thermal treatment and are intended for cooking prior to consumption. Some pigmeat products are cooked during processing and sold RTE, and some products that are not RTE have also been thermally treated and sold ready-to-heat.

The destruction of viruses by heat follows a thermal inactivation curve, where both temperature and time contribute to effectiveness. Additional factors include the initial viral load, the protective properties of the specific food matrix, differences among virus types, the virus envelope status, and whether contamination is internal or limited to the food surface. Current findings suggest that the heat resistance of HEV (i.e. the kinetics of infectivity reduction) varies depending on the strain or genotype and the matrix studied (e.g. meat, sausages, by-products, mussels) (European Food Safety Authority, 2017). Barnaud *et al.* (2012) suggest that heating the food to an internal temperature of 71 °C for 20 minutes completely inactivates HEV, as demonstrated in experimentally contaminated food. Kanda and Okamoto (2025) showed that heating food to an internal temperature of 95 °C for 10 minutes is also a safe option.

Pâté preparation processes, which include a heat step of heating food to an internal temperature of 71 °C for 20 minutes in a water bath, have been reported to inactivate HEV (Barnaud *et al.*, 2012). Both boiling and stir-frying pig liver to an internal temperature greater than 71 °C for 5 minutes resulted in inactivation of HEV (Feagins *et al.*, 2008).

For those pigmeat products that undergo thermal processing during manufacture prior to being placed on the market, all non-retail establishments carrying out such processing should be approved for meat product production and have a food safety management system in place in order to identify and manage relevant risks. Heat treatments should be designed with consideration of HEV, particularly if tissues posing a high risk of HEV contamination are incorporated (e.g. liver).

Effective communication with food processors and producers about the risks associated with certain products is essential in order to ensure that the HEV risk is properly managed. Such communication may include messages to educate FBOs about the risks posed by viraemic pigs, specifically their blood, faeces, and tissues such as the liver and intestines; advice on mitigation strategies and processes that inactivate the virus versus the ones that do not; and advice on labelling in order to ensure the protection of consumers and maintain confidence in pigmeat products.

4.2.5 Cooking

Normal cooking protocols appear to have the ability to inactivate HEV (Imagawa *et al.*, 2018). However, cross-contamination during food preparation, tasting during cooking, and eating raw or undercooked meat may reasonably be considered as higher-risk behaviours.

Blood may carry quasi-enveloped viruses if the animal is viraemic, or it may become contaminated with faecal matter during collection. Traditional Irish black pudding undergoes thermal treatment

during production; however, typical time/temperature protocols may not be sufficient to eliminate HEV. This product is not placed on the market as an RTE food, but rather as one that requires further cooking before consumption.

In Ireland, pigmeat, including pig liver, is generally well cooked prior to consumption. The Food Safety Authority of Ireland (FSAI) has pre-existing advice for consumers that meat such as pork and products containing pork should be cooked to a minimum temperature of 75 °C at the centre of the thickest part of the meat product (Food Safety Authority of Ireland, 2006). This is framed as a peak-temperature recommendation as opposed to a time/temperature combination, based on understanding of typical 'come-up' and 'cool-down' times in domestic settings. The FSAI has also published various advice materials on hygiene during food preparation.

4.2.6 Non-thermally treated RTE products

Some pigmeat products are produced without thermal steps and placed on the market as RTE products for consumption without cooking. Non-thermally treated RTE pork sausages or whole-cut pork products are generally prepared using processes such as cold-smoking, fermentation and drying,[2] sometimes referred to under the umbrella term of 'curing'. Some RTE sausages may contain tissues other than muscle, such as offal, blood and natural casing. *In vitro* studies indicate that typical commercial 'curing' production practices have little to no effect on HEV inactivation (Loikekanen *et al.*, 2025; Schilling-Loeffler *et al.*, 2025; Stunnenberg *et al.*, 2023). These findings explain data showing a higher detectable presence of HEV in such products when surveyed (Boxman *et al.*, 2020; Giannini *et al.*, 2018), and more frequent implication of such products in human illness (Muji *et al.*, 2018; Tulen *et al.*, 2019).

In the specific group of sausage containing liver, Di Bartolo *et al.* (2015) found that curing seems to have an effect on the levels of HEV. They compared the detection rate in raw and dry liver sausages and found a decrease in the detection rate, with 10 of 45 raw slices (22.2%) and 1 of 23 dry slices (4.3%) of liver sausages testing positive for HEV RNA. It must be noted that the infectivity of the virus was not investigated in this study. However, recent reviews suggest that standard commercial production practices, such as those used for RTE sausages, often involve little risk management for hazards like HEV (Loikekanen *et al.*, 2025; Schilling-Loeffler *et al.*, 2025; Stunnenberg *et al.*, 2023).

[2] This involves non-thermal drying of pork sausages at cool temperatures with humidity control that aims to remove the moisture and allow the fermentation and maturation of the meat without cooking it (e.g. salami, chorizo, pepperoni).

Boxman *et al.* (2017) demonstrated the presence of HEV RNA in porcine blood ingredients (liquid whole blood, plasma and fibrinogen) that are not heat treated prior to their processing into food. They pointed to these as potential vehicles for HEV transmission. Thirty-three out of 36 batches of (non-heated) liquid products and 7 out of 24 spray-dried powder products were examined, and contamination levels varied among the products, but were highest in liquid whole blood, plasma and fibrinogen, reaching levels of 2.2×10^2 to 2.8×10^2 HEV genome copies per 0.2 grams of sample.

If tissues posing a high risk of HEV contamination (e.g. liver) are incorporated without specific steps to manage HEV risk, then HACCP systems should identify appropriate control points, including the use of labelling to recommend thorough cooking before consumption.

In addition to good hygiene practices and all the mitigation measures mentioned above, consumers may benefit from information on risks and how to prevent illness from consuming high-risk products. Risk communication messages for consumers could include advice on thorough cooking of pigmeat and on domestic hygiene during storage and preparation to avoid cross-contamination and avoid tasting during cooking. Risk messages directed to people at high risk of disease (for example, people with a compromised immune system, organ transplant recipients, older people with comorbidities, and pregnant women) are of paramount importance on non-thermally treated RTE products, especially ones containing pig liver and blood.

The FSAI publishes advice on food choices and cooking practices for people at increased risk of serious infection. The current advice is primarily focused on the prevention of pathogenic bacteria. Reviewing the relevance of that advice to the prevention of viruses such as HEV could make it more beneficial.

5. Question 4: Given any risks identified, would active surveillance programmes on pigs and pigmeat production be beneficial?

5.1 Potential benefits of implementing a surveillance programme on pigs and pigmeat

In this context, a 'surveillance programme' implies a structured, ongoing plan in which samples are tested and data are collected regularly and the resulting information is analysed in order to measure the virus prevalence in people, pigs and pigmeat. A surveillance programme would drive actions in response to the findings. It is important to differentiate surveillance (information for action) from monitoring and research. Monitoring in this context is understood to mean an ongoing information-gathering programme that is not linked to specific actions. Research projects are typically time bound and designed to answer specific questions or test a hypothesis.

In general, surveillance of infection works to protect public health by enabling early detection, fast response and better targeted control measures against disease. Evidence linking the active surveillance of HEV in pigs to reduced incidence of human HEV infection and disease is limited or lacking. Surveillance of HEV in pigs and pigmeat could use serology as well as the monitoring of HEV RNA in pig herds, aiding in the identification of potential risks in pork products and potentially improving food safety protocols. This has the potential to reduce zoonotic transmission to, and disease in, humans. Notably, systematic sequencing of HEV strains isolated from pigs, pigmeat products and humans, when combined with good epidemiological information, may elucidate sources of infection and transmission pathways and help to track the emergence of new HEV genotypes.

Moreover, surveillance could facilitate zoonotic risk management by identifying farms with active HEV circulation. This approach links to the development of One Health strategies that integrate human, animal and environmental surveillance, ultimately strengthening both disease prevention and consumer confidence in pork safety.

Targeted monitoring of HEV in environmental samples (particularly run-off water from pig farms) could present a valuable epidemiological tool for identifying endemic HEV circulation, localised hotspots and seasonal transmission dynamics. This is an area that would benefit from further research. As HEV is shed in pig faeces and can persist in wastewater, its detection in farm run-off offers a non-invasive method to survey viral activity beyond direct herd testing (Meester *et al.*, 2021). HEV-infected pigs are always asymptomatic; thus, environmental sampling can capture

viral signals from asymptomatic carriers and pooled populations, enabling early-warning systems and geographic risk mapping. Furthermore, temporal analysis of sample data can reveal seasonal patterns in HEV shedding that are potentially linked to pig production cycles or climatic factors influencing virus survival and dissemination. Incorporating this approach into One Health research not only enhances our understanding of environmental HEV persistence but could also strengthen zoonotic risk mitigation strategies across agricultural and public health sectors.

5.2 Barriers to HEV surveillance in pigs and pigmeat

Surveillance of HEV in pigs and pigmeat presents substantial challenges, stemming primarily from technological, logistical and economic barriers.

HEV is not specifically listed in the EU's Directive 2003/99/EC on the monitoring of zoonoses and zoonotic agents. The Directive obliges EU Member States to collect data on the occurrence of certain zoonoses and zoonotic agents in the food chain, including in primary production. It specifies an 'A' list of eight zoonoses and zoonotic agents to be included in such monitoring, and a 'B' list to be monitored if justified by the epidemiological situation. While the 'B' list includes various viruses (e.g. hepatitis A virus and a generic category of 'other zoonoses'), there is not an explicit mention of hepatitis E. The absence of HEV from these lists does not strengthen the case for HEV surveillance and the allocation of resources for this purpose. Furthermore, HEV is not included in implementing regulations derived from that Directive, such as those mandating coordinated monitoring programmes across EU Member States (such as baseline surveys), or those mandating control programmes for specific hazards in certain species, such as *Salmonella* control programmes in specific animal populations (Regulation (EC) No 2160/2003).

The complexity of farm-level HEV surveillance is evident from the wide variability in methodological approaches across regions. Within Europe, HEV prevalence studies have typically been embedded within time-limited research initiatives or surveillance efforts linked to broader pathogen monitoring programmes, most notably those targeting *Salmonella* (Dubbert *et al.*, 2024; Iarino *et al.*, 2023; Meester *et al.*, 2021; Salines *et al.*, 2017). Studies are hindered by the limited availability of affordable, high-sensitivity diagnostic assays and the lack of reliable differentiation between infectious and non-infectious viral particles (Carella *et al.*, 2023; Di Cola *et al.*, 2021; Dzierzon *et al.*, 2022; Grierson *et al.*, 2015; Monini *et al.*, 2023). The majority of studies rely on convenience sampling strategies, typically focusing on faecal samples that are collected either directly on farms or during ante-mortem inspection, with additional tissues (such as liver, blood and muscle) examined post-mortem at slaughterhouses. This approach offers pragmatic access to biological material but limits the representativeness and continuity of data. A smaller number of

investigations have assessed serum samples at selected production stages or at slaughter, providing insights into seroprevalence and historical exposure (Krog *et al.*, 2019; O'Connor *et al.*, 2015; Rutjes *et al.*, 2014). Some of these efforts have been carried out independently, while others have leveraged statutory surveillance infrastructure for notifiable diseases such as swine vesicular disease and Aujeszky's disease (Pavia *et al.*, 2021). The reliance on time-bound research projects and opportunistic sampling, as demonstrated across numerous European studies, suggests that there are logistical and institutional hurdles to establishing continuous surveillance.

While active surveillance using molecular testing and genotyping at production and processing points has theoretical merit, and although informative, its implementation remains resource intensive and difficult to scale. Additionally, mandatory surveillance could cause delays in product release and slaughter timelines, with uncertain benefits, given that infectivity is dose dependent and current assays do not reliably differentiate between infectious and non-infectious viral particles (EFSA Panel on Biological Hazards (BIOHAZ) *et al.*, 2017). While reverse transcription-polymerase chain reaction (RT-PCR) detection methods remain reliable when conducted with appropriate laboratory techniques, the interpretation of positive results in food samples is a subject that is continually discussed. This is primarily due to the challenge of differentiating between the presence of amplifiable viral fragments and actual infectious viral particles, a distinction for which limited information is available (Di Cola *et al.*, 2021).

The detection of HEV in food matrices (particularly pork products) is further complicated by low viral loads and the presence of polymerase chain reaction (PCR) inhibitors (Martin-Latil *et al.*, 2014). While real-time reverse transcription-quantitative PCR (RT-qPCR) is widely used and effective (Jothikumar *et al.*, 2006), its quantitative accuracy can be compromised. Digital PCR has emerged as a promising alternative for low-concentration quantification, offering improved reproducibility along with a reduced susceptibility to inhibition (La Bella *et al.*, 2024; Wang *et al.*, 2023). However, the lack of standardised RNA template extraction protocols and robust integrity assays limits consistency across laboratories and challenges study comparisons (Boxman *et al.*, 2019; Di Bartolo *et al.*, 2012; Szabo *et al.*, 2015; Wilhelm *et al.*, 2014). The extraction process itself is critically important, particularly in tissues such as liver where HEV replicates, necessitating thorough cell disruption in order to ensure reliable detection (Hennechart-Collette *et al.*, 2019).

The presence of viral RNA alone does not equate to infectivity, and widely accessible methods to distinguish between genome fragments and intact, infectious virions are not yet available (Di Cola *et al.*, 2021). Based on a review by Cook *et al.* (2017), no cell culture models have been proven to be suitable for all strains of HEV, nor have any been standardised. Additionally, few studies have illustrated their effectiveness in measuring HEV infectivity in food samples (Cook *et al.*, 2017). Alternative approaches exist that allow for the differentiation between infectious and non-infectious

viral particles, based on the use of viability markers that represent viral capsid integrity (Di Cola *et al.*, 2021). These methods are experimental, are not suitable for routine surveillance, and are not currently available in Ireland in a streamlined or cost-effective manner. They remain confined to specialised research settings, and their adoption for national food safety monitoring would require significant investment, validation and standardisation.

Genotyping typically requires RT-qPCR amplification followed by sequencing, and Sanger-based methods continue to have limitations in epidemiological resolution and detecting mixed or minor variants (Baylis *et al.*, 2021; Smith *et al.*, 2016). Whole virus genome sequencing (WvGS), even when supported by target enrichment strategies, can address some of these constraints but remains challenging and is not yet practical for routine HEV surveillance in food; this is due to low viral loads, technical complexity and the lack of standardised workflows (Davis *et al.*, 2021; Hakze-van der Honing *et al.*, 2024). The National Institute for Public Health and the Environment in the Netherlands now provides an online tool (Hepatitis E Virus Genotyping Tool, available at https://www.rivm.nl/mpf/typingtool/hev) for the genotyping of HEV by submission of FASTA and FASTQ files[3] (Boxman *et al.*, 2019).

These cumulative gaps highlight the need for international standardisation efforts (such as those being pursued by ISO/TC 34/SC 9/WG 31) and point to the critical role of harmonising methodologies before HEV surveillance in pigs and pigmeat can become viable at scale.

5.3 Targeting research efforts

A recent FSAI report on risk ranking of microbiological hazards places HEV seventh in the national risk ranking, with 1.25 foodborne DALYs annually, highlighting that data on HEV epidemiology are incomplete in Ireland and that this ranking may reflect data limitations. The report highlights that Ireland lacks the data needed in order to quantify HEV in pork and to map foodborne transmission pathways. However, while HEV data gaps warrant attention, its relative priority must be balanced against pathogens that have a greater established public health impact.

Focused research projects are essential in order to advance our understanding of HEV in pigs and the food chain. Such projects could continue to develop analytical techniques for RNA in food matrices – including emerging technologies such as digital PCR – towards the reliable assessment of HEV presence, quantity and infectivity.

[3] FASTA and FASTQ are foundational, text-based file formats in bioinformatics for storing biological sequences

Targeted research is also required in order to establish the true endemicity of HEV in pigs in Ireland and to determine how infection varies across production systems, regions and particularly pigs of different ages.

Targeted monitoring would enhance our understanding of HEV infection dynamics in pig farms in Ireland. This could take the form of longitudinal studies or projects, with samples at slaughterhouses and farms using both serological and molecular diagnostics in order to monitor infection seroconversion and viraemia resolution within farms.

Environmental sampling from farm run-off and wastewater could identify infection hotspots and provide insight into seasonal dynamics.

Risk-based monitoring focused on samples from high-risk tissues such as pig liver, intestines and non-thermally treated pigmeat foods could explore and establish attribution of human infections to these foods.

WvGS of HEV-positive samples from people and animals could be embedded within disease investigations and shared in One Health databases in order to aid in identifying circulating strains and understanding epidemiological links between farms, food products and human cases.

Given the risks, evidence base and uncertainty outlined in this report, it is difficult to determine with confidence the potential benefits for public health of implementing a programme of HEV surveillance in pigs.

6 Overall conclusion

Current food safety knowledge about HEV in pigs and pigmeat in Ireland is limited, creating uncertainty in assessing the risk of HEV to human health arising from the consumption of pigmeat products. Available data in Ireland do not support the quantitative attribution of risk of human infection to pigmeat consumption, or to pig production. Key data gaps include measurement of the true prevalence of HEV in pig herds, understanding the extent and persistence of infectious virus in pigs at slaughter age, and clarifying the infectivity of specific tissues and the strength of the epidemiological link(s) between HEV in pigs, pigmeat product and human infection. However, available qualitative data support the hypothesis that pigmeat and pig production in Ireland are potential contributors to the risk of HEV infection in the Irish population.

The most prevalent pig production system in Ireland – namely, intensive production – does not prevent the persistence of HEV due to the overlap in time and space of different ages and cohorts of pigs.

The likelihood that pigs are infectious with HEV at slaughter reduces with increasing age of the pigs. Most pigs have cleared the virus by the age of slaughter (5–6 months), but some may be viraemic, posing a risk to food safety.

HEV risk from pig tissues is not uniform. Bile-extruded virus poses a higher risk than blood-borne virus. Higher-risk tissues (those most likely to have higher titres of infective virus) include those from recently infected, typically younger animals, especially the liver and the intestine.

Higher-risk food products include higher-risk tissues that are not thermally treated before consumption.

HEV is effectively inactivated by heating to an internal temperature above 71 °C for 5 minutes. Commercial processing of natural casings also contributes to reducing HEV risk. Drying, salting/curing and fermentation do not reliably eliminate HEV. High-pressure processing can reduce HEV viral load, but its effectiveness is limited and is matrix- and treatment-level dependent.

Normal slaughter hygiene, including efforts to manage faecal contamination risk and offal harvest hygiene, contributes to managing HEV risk.

Despite growing recognition of the zoonotic potential of HEV and its relevance to food safety, active surveillance for HEV on pig farms remains rare globally.

HEV is not identified as a public health priority in EU legislation as certain other zoonotic biological hazards are (Directive 2003/99/EC). There is no clear international consensus regarding the value of HEV surveillance and how a surveillance programme would be structured.

7 Future considerations

Targeted research is needed in order to generate data that build an evidence base around the attribution of human HEV to different sources in the Irish context. Addressing current knowledge gaps would likely reduce the uncertainty pertaining to the risk to human health and transmission pathways, thereby enabling the development of focused risk management strategies.

Producers of pigmeat products may benefit from a clearer understanding of the risk of cross-contamination from pig liver and bile duct to other edible tissues during carcase dressing, as these organs contain the highest titres of infectious virus.

Incorporating HEV as a hazard to be addressed by prerequisite and HACCP programmes of food safety management systems during the harvesting of higher-risk tissues, especially livers, at abattoirs and during the production of non-thermally treated RTE foods from higher-risk tissues at processing plants would be likely to systematically reduce the risk of infectious food entering the market.

General food safety and hygiene messages apply to HEV, as they do to other biological hazards. However, HEV-specific risk factors, such as the risks associated with pig livers and the influence of slaughter age, may warrant specific consideration. These HEV-specific risks, along with protective measures such as thorough cooking of high-risk foods, could form the basis of consumer-facing messages developed and delivered by communication specialists and tailored to different audiences, especially consumers who are at increased risk of disease.

When considering future research, efforts focused on higher-risk pigmeat scenarios incorporating detection, quantitative assessment and genetic characterisation would help improve our understanding of the extent of their contribution to overall human infection dynamics.

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Appendix 1 Request for advice

Topic title: Foodborne risk to human health of hepatitis E virus in pigs and pigmeat in Ireland

Date requested: 22 May 2023

Date accepted: 18 July 2023

Target deadline for advice: 18 months after the work is initiated

Form of advice required: Report with recommendations to the Food Safety Authority of Ireland

Subcommittee: Biological Safety Subcommittee

Background/context

Hepatitis E is an inflammatory condition of the liver (hepatitis) caused by infection with hepatitis E virus (HEV). This is the most common type of acute viral hepatitis occurring in people worldwide. The illness is generally self-limiting, although greater severity of acute illness is reported with immunosuppression, pre-existing liver disease, or pregnancy. Infection that persists for a long time (chronic infection) is increasingly recognised in immunosuppressed people.

HEV is shed in the faeces of infected persons. Infection can arise following the ingestion of substances contaminated with faeces containing the virus. Transmission through human faecal contamination of water or food is a significant component of the virus's epidemiology in regions where sanitation is poor and human infection is endemic.

In Ireland, hepatitis E became a notifiable disease in 2015. This means that all human cases must be reported to the Department of Public Health. The reported incidence since then has been in the order of 50–80 cases per year. This includes both symptomatic clinical cases and cases that do not present with any illness, but that are identified by detection of the virus in blood samples as a result of routine testing of blood donors (Health Service Executive Health Protection Surveillance Centre, 2023). Active surveillance in Irish blood donors indicates that approximately 5% of people have antibodies to HEV, indicating that they have been infected at some time (seroprevalence). Approximately 0.02% of donors have detectable virus nucleic acid in their blood at the time of donation, indicating that they are infected at the time of donation (O'Riordan *et al.,* 2016).

HEV nucleic acid detection, consistent with infection, has been reported in the organs, tissues and faeces of animals. Molecular analysis shows that this includes animal species-specific strains, and strains implicated in human infection. Animals may acquire the virus through contact with the faeces

or tissues of infected hosts. This includes animals of their own species, animals of other species, or humans.

Human infection may arise from human-to-human transmission, both direct and indirect. Human infection may also be zoonotic, arising from direct animal contact or consumption of food products derived from infected animals or contaminated with the faeces of infected animals. In low- and middle-income countries, rats may play a role in the epidemiology of human illness. Within the European Union (EU), concern centres around the role of pigs and, consequently, pigmeat as a source of human infection (EFSA Panel on Biological Hazards (BIOHAZ) *et al.*, 2017).

HEV is a single-stranded positive-sense non-enveloped ribonucleic acid (RNA) virus with a genome of approximately 7.2 kb encoding three open reading frames. HEV is taxonomically regarded as the family *Hepeviridae* with two genera, including the *Orthohepevirinae* genus, comprising isolates from mammals and birds and composed of four species and (currently) eight genotypes. Four of those genotypes are of known human health importance. Genotypes 1 and 2 are associated only with human infection, while genotypes 3 and 4 are associated with both animal and human infection.

Clinical hepatitis due to HEV is poorly described in animals. A syndrome with significant liver pathology is attributed to host-specific HEV in commercial poultry (Su *et al.*, 2018). HEV RNA has been detected in the faeces or enteric tracts of various animals, including domestic pigs, wild boar, deer, rabbits, rats, oysters and poultry, while HEV has also been detected in the liver and blood of several animal species, including food animals (Si *et al.*, 2023). Seropositivity (the presence of antibodies) and transient viraemia are repeatedly reported in pigs and wild boar, consistent with HEV replication in those animal species (Li *et al.*, 2022), and molecular analysis of HEV strains demonstrates similarity between some of the strains detected in people and some of the strains detected in pigs, notably genotypes 3 and 4.

In Ireland, a limited survey of the sera of 330 breeding pigs reported 27% animal seropositivity and 81% herd seropositivity (O'Connor *et al.*, 2015). This reflects relatively high pig seropositivity, as has also been observed throughout the world. The results of a more recent longitudinal study of Irish pig production await publication, but are understood to be consistent with a hypothesis of high incidence of early-life pig infection (viral RNA in blood) resulting in immune response with seroconversion and low prevalence of infection at the time of slaughter (Davin, 2019). An assessment of the genetic relatedness of animal, food and human isolates of HEV is also anticipated in that work (Bennett *et al.*, 2019).

Concern therefore exists regarding the risk of zoonotic transmission of HEV from pigs to humans, including consumer risk from the consumption of pigmeat (Yodjan, 2023). HEV in humans has been associated with occupational exposure to pigs (Meng, 2010) and with the consumption of

undercooked pigmeat products. It has also been associated with the consumption of raw vegetables and with occupational exposure to wastewater (Faber *et al.*, 2018). Viral RNA is detectable in uncooked pigmeat products (Locus *et al.*, 2023). There has also been speculation that the emergence of a subtype that is more transmissible between humans and pigs may have contributed to the increased human risk from pigs (Ijaz *et al.*, 2013). The European Food Safety Authority (EFSA) regards foodborne transmission to be a major route of human infection in the EU, with pigs and wild boar as the main source of HEV (EFSA Panel on Biological Hazards (BIOHAZ) *et al.*, 2017).

The literature provides substantial evidence of a high prevalence of seropositivity in farmed pigs. This is indicative of a high incidence of infection in pigs at some stage in their life. However, understanding the risk from pigmeat requires further consideration of the pathogenesis of HEV in pigs. This includes the chronology of viraemia, its presence in tissues other than blood, enteric shedding, a quantitative understanding of the extent of food contamination, and the public health significance of strains causing infection in pigs and the impact of food processing on the risk of infection (Müller *et al.*, 2017).

There is an empiric basis to consider that generic food safety precautions, such as reducing faecal contamination of pigmeat and applying heat treatment, significantly contribute to the risk management of foodborne HEV (Barnaud *et al.*, 2012). A greater risk of foodborne infection might reasonably be associated with the consumption of pigmeat products that are subject to only moderate heat treatment, and/or that contain offal. This includes fermented pigmeat products. Management of pig faecal waste may also be associated with wider environmental food chain contamination risks, such as the contamination of foods of plant origin.

Interventions to manage the circulation of HEV within animals might reduce the risk of transmission from pigmeat. It is also possible that endemicity in pigs resulting in infection with seroconversion early in life may reduce the risk of foodborne HEV if pigs are infected early in life and have recovered from the infection before slaughter. This may reduce the risk of viraemia, the presence of the virus in tissues, and faecal shedding at slaughter age. Similarly, while extensive pig production might be expected to be associated with a greater risk of HEV infection in pigs from external sources, intensive pig production may provide greater potential for rapid spread within the herd if the virus is introduced.

Questions to be addressed by the Scientific Committee

The Food Safety Authority of Ireland posed the following four questions to the Scientific Committee

- What is the contribution of the pigmeat food chain to the risk of HEV infection among people in Ireland? This should take account of the risk of human HEV infection through the consumption

of pigmeat and the potential for pigs to act as reservoirs of HEV strains with public health significance.

- How do different approaches to pigmeat production influence the risk of HEV infection for people in Ireland? This should include an assessment of relevant pre-harvest (animal husbandry) and post-harvest (food processing and preparation) approaches to pigmeat production, and temporal or geographic variation in pigmeat risk.
- What are the options for risk management strategies to address any risks of human HEV infection from pigmeat? This should include an appraisal of steps to reduce entry to, and circulation of, HEV among pig populations in Ireland, and steps to reduce transmission to humans through pigmeat consumption.
- Given any risks identified, is it likely that active surveillance programmes for HEV in pigs and pigmeat production would reduce the risk of human infection? If so, how should those programmes be designed? This should include consideration of the molecular epidemiology of the virus present in animals, food and people.

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Appendix 2 Tables

Table 1 Detection of serum antibodies against hepatitis E virus, and hepatitis E virus ribonucleic acid in pigs in different countries at farms and slaughterhouses: A non-exhaustive list of surveys and studies

Country	Seroprevalence	Viraemia (PCR)	Faecal (PCR)	Liver (PCR)	Pig stage/age	Reference
Ireland	27%	N/R	N/R	N/R	Breeding animals, so likely >6 months	O'Connor *et al.*, 2015
Ireland	19.2% 1.3% 55.7% 90.8% 85.3%	0.0% 1.3% 11.4% 0.0% 0.0%	1.4% 8.1% 43.6% 2.6% N/R	 0.34%	4 weeks 8 weeks 12 weeks 16 weeks 20 weeks (slaughter)	Davin, 2019
Netherlands	68%	16.1%	26% caeca	11%	Slaughter	Boxman *et al.*, 2022
Netherlands	67.8%	-	14.0%	-	Slaughter	Rutjes, 2014; 2009
France	31%	-	-	3.4%	Slaughter	Rose *et al.,* 2011
United Kingdom	-	-	13%	3%	Slaughter	Berto *et al.,* 2012
United Kingdom	93%	21%	-	-	Slaughter	Grierson *et al.,* 2015
United Kingdom	61.4%	44.4%	3.5%	-	Slaughter-ready	Crossan *et al.,* 2014
Spain	73%	6.7%	13.3%	15.5%	Slaughter	García *et al.*, 2020
Italy	76.8%	4.4%	1.9%	2.1%	Slaughter (10 months)	Chelli, 2021
Italy	- 24.4% 44.9% 64.5%	-	10.6%	-	On farm (age not reported) <2.5 months 2.5–4.5 months >4.5 months	Pavia *et al.*, 2021
Denmark	-	-	2.5%	-	Slaughter	Machnowska, 2014
Slovenia	0%	-	-	0.25%	Slaughter	Raspor Lainšček *et al.*, 2017

Serbia	-	-	-	44% 0%	<3 months >6 months	Milojević *et al.*, 2024
United States of America	40%	6.3%	-	-	Slaughter	Sooryanarain *et al.*, 2020
Canada	N/R	2.3%	14%	21%	Slaughter	Le Blanc, 2020

Note: PCR = polymerase chain reaction; N/R = Not reported

Table 2 Hepatitis E viral ribonucleic acid detection in different pig tissues and pigmeat products: A non-exhaustive list of surveys and studies

Country	Likely to be cooked pigmeat products						Unlikely to be cooked by consumer		References
	Intact tissues/organs			Comminuted/sausage					
	Muscle	Liver	Other	Liver-based	Blood-based	Muscle-based	Liver-based	Other	
Ireland	-	24%	-	-	-	2%	-	-	Bennett *et al.*, 2024
Switzerland	-	-	-	58%	-	-	-	-	Colson *et al.*, 2010
Switzerland	-	1.3%	-	-	-	-	-	-	Müller *et al.*, 2017
France	0%	2.8%	-	-	-	-	-	-	Feurer *et al.*, 2018
United Kingdom	-	2.5%	-	-	-	10%	-	-	Berto *et al.*, 2012
Spain	8.8% 2.2%	16%	12%	-	-	-	-	-	García *et al.*, 2020
Netherlands	-	-	13%	-	-	-	71% 69%	-	Boxman *et al.*, 2019
Belgium	-	-	-	-	-	-	61%	15% 0% dried	Locus *et al.*, 2023
Italy	2%	2%	-	-	-	-	-	-	Di Bartolo *et al.*, 2012
Germany	-	-	-	22%		20%	-	-	Szabo *et al.*, 2015

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