ACM/1134a

Advisory Committee on the Microbiological Safety of Food

Ad hoc Group on Foodborne Viral Infections

An update on viruses in the food chain

Terms of reference

The *Ad Hoc* Group on Foodborne Viral Infections terms of reference are to –

- Assess the extent of viral foodborne infection in the UK – with particular reference to norovirus and hepatitis E. Including discussion on the issues surrounding emerging risks.
- Describe the epidemiology, sources and mode of transfer of foodborne viral infection.
- Agree a framework outlining the key criteria for assessing the foodborne risks posed by viruses.
- Review the recommendations from the 1998 report and the Governments' responses.
- Identify practical options that might exist, or be developed, for the prevention and control of foodborne transmission. Including communication strategies to target the industry and consumers.
- Assess the implication of new technologies for public health and control of foodborne viruses.
- Identify data gaps and research priorities where it would be valuable to have more information.
- Report on these matters by January 2013.

TABLE OF CONTENTS

Annex 3

List of Tables and Figures

Annex 4

Glossary

Annex 5

Abbreviations and acronyms

References

Ad Hoc Group on Foodborne Viral Infections

Membership

	Chairs
Professor Sarah O'Brien	(from April 2011) Professor of Infection Epidemiology and Zoonoses at the University of Liverpool.
Professor David Brown	(Until April 2011) Health Protection Agency.
	Members:
Mrs Rosie Glazebrook	Consumer representative
Prof Jim Gray	Consultant Clinical Scientist at the Specialist Virology Centre in Norfolk and Norwich University Hospitals and Honorary Chair at the University of East Anglia, as Professor of Clinical Virology.
Ms Jenny Hopwood	Technical manager, Microbiology, Marks & Spencer
Dr Sally Millership	Consultant in Communicable Disease Control at Essex Health Protection Unit and Consultant in Microbiology.
Mrs Jenny Morris	Food Safety Policy Officer at the Chartered Institute of Environmental Health.
	Co-opted Members:
Prof David Brown	(from April 2011) Health Protection Agency.
Dr Nigel Cook	Food and Environment Research Agency.
Dr David Lees	Cefas.
	Departmental Representative:
Mr Stephen Wyllie	Defra
	Secretariat:
	Scientific Secretary
Dr Darren A Cutts	Food Standards Agency (From January 2012)
Dr Sophie Rollinson	Food Standards Agency (December 2011)
Miss Louise Knowles	Food Standards Agency (Until December 2011)
	Administrative Secretariat
Mr Adekunle Adeoye	(Food Standards Agency)
Ms Sarah Butler	(Food Standards Agency)
Mrs Misty Gilbert	(Food Standards Agency)

Summary

In 1994, in response to the outcomes of a joint Advisory Committee of Microbiological Safety of Food (ACMSF) and Steering Group on the Microbiological Safety of Food (SGMSF) meeting, a Working Group was set up to investigate the science and epidemiology of Foodborne Viral Infections. The Working Group assessed the risk from viruses that were believed to be the primary cause of foodborne illness. This report provides an update to this information and provides a new focus on the viruses which are currently the major route of foodborne illness. Since the publication of the 1998 report, with the exception of two minor risk assessments on hepatitis E and avian influenza, no formal review on viruses had been performed by the ACMSF. It was decided that as significant developments had been made not only in the detection of foodborne viruses, but also in the amount of information obtained from the Infectious Intestinal Disease (IID) Study in England (published in 2000), which indicated a significant disease burden from enteric viruses in the community, it was important that an Ad-Hoc Group was convened to revisit these issues and to provide an update to the 1998 risk assessment.

The FVI Group first met to begin their consideration in November 2010. Over 32 months, the Group met thirteen times to discuss all aspects of viruses in the food chain from farm to fork. As a starting point for the report, the Group reviewed the recommendations from the 1998 report and gave consideration as to whether these has been adequately addressed or were still relevant. At the same time the recommendations from the 2008 World Health Organisation (WHO) Viruses in Food: Scientific Advice to Support Risk Management Activities Matrix and CODEX Criteria, and the European Food Safety Authority (EFSA) Scientific Opinion on an update on the present knowledge on the occurrence and control of foodborne viruses were reviewed.

Using this information along with data on disease burden in the community and outbreak data (from IID and IID2) the Group agreed the scope of the report and what viruses would be its main focus. It was decided that that due to their potential impact and the paucity of data in this area, norovirus, hepatitis E and hepatitis A would be the main focus of the report, although many of the recommendations would also be applicable to other enteric viruses.

During its consideration, the Group reviewed available data on commodities contaminated at source, i.e. bivalve shellfish and fresh produce and reviewed data on risks associated with infected food handlers. Environmental contamination was reviewed with consideration given to testing methods such as polymerase chain reaction (PCR), person-to-person transmission and food handlers. The Group also considered the engagement with industry and other Government departments (OGDs) regarding environmental conditions of shellfish waters and its impact on norovirus.

A review of data on issues regarding food contact surface contamination, including survivability and persistence was considered along with options for control at all stages of the food chain e.g. thermal processing, storage etc. The thermal stability of hepatitis E was considered with data presented on the increasing occurrence of the disease in older UK males and the recent case control study on pork products.

In order to obtain sentinel data the group investigated the important issue of knowledge gathering and surveillance data regarding foodborne viruses. The current limitations of the data were discussed along with what type of data was needed to provide more useful/accurate information on foodborne virus outbreaks. This review included looking at outbreaks from an Environmental Health Officer (EHO) perspective and how they prioritise what they investigate and the data they collect.

Finally, the group reviewed the consumer perspective on risk. This included looking at how risk is presented and information distributed, as this was likely to impact on any future risk assessment.

Within the report the Group has endeavoured to prioritise the recommendations by separating these into those that will inform risk assessments and those that will impact on risk assessments. Full details are provided in the report however, key recommendations include:

A better understanding of '*foodborne viral disease'* (Chapter 3) is required by investigating the correlation between infective dose and genome titre. Molecular diagnostics, typing and quantification should also be used to better understand the burden of virus contamination in foodstuffs. Work is also recommended to develop the methods used to assess norovirus and Hepatitis E infectivity in food samples. This would better inform surveys and could potentially be applied to routine monitoring.

Improved '*routine surveillance and investigation of foodborne viruses'* (Chapter 5) is required with Government agencies developing a single integrated outbreak reporting scheme. A joined up approach that would also involve the annual consolidation of records would reduce the chance of underreporting outbreaks. Further to this, reliable methods for norovirus whole genome sequencing should be developed to enable virus tracking and attribution.

More research on the *'contamination of food'* (Chapter 6) through sewage contamination is recommended. In particular work should investigate the effectiveness of sewage treatment processes in reducing norovirus concentrations, including the use of depuration on shellfish species and disinfection treatments. Similarly, research is needed to identify the most effective means of decontaminating *'fresh produce'* post-harvest (Chapter 7).

With the emerging risk of Hepatitis E in pigs from the UK, the Group recommends work is undertaken to investigate the heat inactivation of Hepatitis E in *'pork products'* (Chapter 8). Research on the effect of curing and fermentation on Hepatitis E in pork products is also recommended.

The full list of conclusions and recommendation are presented at the end of each subject area and are consolidated in Chapter 12 for ease of reference.

The assessments made and conclusions reached by the Group reflect evidence oral and written drawn from the scientific community, Government departments and

Agencies, EFSA and the scientific literature. The Group's full conclusions, identified data gaps and recommendations are brought together at the end of this report. The ACMSF accepts full responsibility for the final content of the report.

1. Background

1.1. Context of the report

The Advisory Committee on the Microbiological Safety of Food (ACMSF) was established in 1990 to provide the Government with independent expert advice on questions relating to microbiological issues and food safety. In 1994, in response to the outcomes of a joint ACMSF and Steering Group on the Microbiological Safety of Food (SGMSF) meeting, the ACMSF set up a Working Group on Foodborne Viral Infections (FVI), consisting of independent experts drawn from a wide range of interests. The Working Group was asked to focus on viruses that were thought to be of primary concern in respect of foodborne illness, primarily small round structured viruses and hepatitis A virus. The transmission of foodborne viruses, such as the problems associated with the consumption of raw or lightly cooked bivalve molluscan shellfish, as well as the problems associated with the contamination of food by food handlers were also considered.

The ACMSF published their report on foodborne viral infections in 1998. This report considered viral foodborne illness, sources, occurrence, detection, contamination and routes of transmission. The report also discussed the prevention and control measures for foodborne viruses which manifest in humans as gastroenteritis or viral hepatitis (ACMSF, 1998).

Since the publication of the 1998 ACMSF report on foodborne viral infections, with the exception of minor risk assessment work carried out on hepatitis E and avian influenza, no formal review has been undertaken on foodborne viruses. Therefore, at a March 2010 ACMSF meeting, members agreed that an *Ad Hoc* Group should be set up to revisit the issue of foodborne viruses in light of the significant developments in this area, so that an up-dated risk profile could be produced based on the findings.

This is of particular importance because there has been a wide range of significant new information on the viruses involved, the disease they cause and information on key issues for food safety. In particular, the Infectious Intestinal Disease (IID) Study in England indicated a significant disease burden from enteric viruses in the community, particularly from noroviruses and rotavirus infections (Food Standards Agency, 2000). The results from the Second Infectious Intestinal Disease (IID2) Study (Food Standards Agency, 2012) provided further data on the contribution of viruses to the burden of IID in the UK. Data provided from this report identified norovirus, sapovirus and rotavirus as being the most common viruses found in samples from those with intestinal disease.

The most important viruses associated with foodborne infection are norovirus, hepatitis A virus and hepatitis E virus. It is estimated that around 200,000 cases of foodborne illness are caused by norovirus in England and Wales each year. The virus is often associated with outbreaks of disease linked to shellfish consumption, such as oysters or contaminated fresh produce, such as soft fruits. The most commonly recognised outbreaks of foodborne norovirus cases are also thought to result from contamination of food by infected food handlers. In England and Wales, there are currently systematic seroprevalence studies underway to determine the true incidence and burden of hepatitis E infection. However, early studies suggest that there could be as many as 65,000 unidentified cases in the UK each year.

In light of the new information, developments and outbreaks due to foodborne viral infections, it was decided that illness caused by norovirus and hepatitis A and E should be the focus of the group's report, as well as other new and emerging foodborne viral pathogens. This would be concentrated mainly on viral foodborne infection in the UK.

Viruses belonging to several different viral families have been identified in human faecal samples. These have the potential to be transmitted through the foodborne route. The viruses concerned are shown in Table 2 and following paragraphs. We have chosen to focus this report on norovirus because of the high incidence of foodborne illness, hepatitis A and E because of their capacity to cause severe illness and emerging infections which pose a significant public health threat.

Two comprehensive reviews of viruses in food have been published recently (WHO risk assessment: viruses in food meeting report 2008 and EFSA: scientific opinion on an update on present knowledge on the occurrence and control of foodborne viruses, 2011). This report will not go over this information again, but will focus on key information informing risk assessment and risk management of foodborne viruses.

1.2. The ACMSF's approach to its work

The *Ad Hoc* Group met 13 times from November 2010 to July 2013 to assess the extent of viral foodborne infection in the UK and to consider the scope of this review. The members of the Group as well as the terms of reference are shown on pages 2 and 7.

1.3. Acknowledgements

The *Ad Hoc* Group wishes to thank all the organisations and individuals, detailed at Annex 1, who provided it with information or gave oral evidence.

2. ACMSF's previous report and the Government's response to it

The *Ad Hoc* Group began by reviewing ACMSF's previous report and the Government's responses to it. Table 1 summarises the recommendations made in 1998, the Government's responses and the *Ad Hoc* Group's reflections on whether or not the recommendations had been implemented. Where the *Ad Hoc* Group considered that a recommendation from the previous report needed to be re-iterated this is shown on the enclosed table.

Table 1: ACMSF Report on Foodborne Viral Infections 1998 Recommendations and Governments response

<table>
<tr><th colspan="3">Chapter 2: Infectious agents, clinical spectrum and pathogenesis</th></tr>
<tr><td colspan="3">Recommendation R2.1 (paragraph 2.38).
We strongly recommend that, for cases of infection fulfilling Kaplan criteria, control measures are instituted immediately without waiting for laboratory confirmation – although confirmation of diagnosis in due course is desirable (e.g. for epidemiological and research purposes).</td></tr>
<tr><td>1998 Government Response</td><td>2013 Government Update</td><td>Ad Hoc Group comments</td></tr>
<tr><td>The Government endorses this recommendation and will bring it to the attention of the relevant authorities.</td><td></td><td>The committee notes that FSA advice on outbreak management (http://www.food.gov.uk/multimedia/pdfs/outbreakmanagement.pdf) does not give specific guidance on norovirus. Hence, it is not clear how this recommendation has been addressed. For example, In practice there appears to be continuing uncertainty on the level of evidence needed to initiate control measures (such as closure of oyster production areas).</td></tr>
<tr><td colspan="3">Recommendation R2.2 (paragraph 2.39)
We recommend that the Joint Committee on Vaccination and Immunisation (JCVI) keep under review the question of the routine immunisation of food handlers against hepatitis A virus.</td></tr>
<tr><td>1998 Government Response</td><td>2013 Government Update</td><td>Ad Hoc Group comments</td></tr>
<tr><td>The Government endorses this recommendation and will bring it to the attention of the JCVI.</td><td>This recommendation was brought to the attention of the JCVI in October 2000 (minutes of meeting are available on Department of Health's (DH) website at: http://www.dh.gov.uk/ab/JCVI/DH_095050).
At the time the Advisory Group on Hepatitis (AGH) had been looking at immunisation against hepatitis A and felt</td><td>The Group notes the Update</td></tr>
</table>

	that there was insufficient evidence to recommend hepatitis A vaccine for food handlers.	

Chapter 3: Occurrence of foodborne viral infection in the UK		
Recommendation R3.1 *(paragraph 3.25)* We recommended that the Government takes steps to improve harmonisation of detection, reporting and surveillance of small round structured viruses (SRSV) infections throughout the UK.		
1998 Government Response	**2013 Government Update**	***Ad Hoc* Group comments**
The Government accepts this recommendation and has already initiated a study to develop a comprehensive standardised system for the investigation and reporting of cases of food poisoning in the UK.		The Committee notes large discrepancies in data holdings by different agencies and no apparent systematic sharing of information on outbreaks. In practice this recommendation appears not to have been addressed.
Recommendation R3.2 *(paragraph 3.26)* We recommend that the Government encourages thorough investigation of viral gastroenteritis with a view to establishing a comprehensive and timely picture.		
1998 Government Response	**2013 Government Update**	***Ad Hoc* Group comments**
The Government accepts this recommendation and has funded a major study to provide information about the incidence, sources, routes of transmission, risk factors and socio-economic cost of infectious intestinal disease, including viral gastroenteritis, results of which should provide a more comprehensive picture of illness.	The first study of infectious intestinal disease in the community (IID1 study) was carried out in 1993-1996 and published in September 2001. The final report/executive summary are available on the FSA's website at: http://www.food.gov.uk/multimedia/pdfs/intestexecsum.pdf The IID1 Study estimated that 20% of the population of England suffered infectious intestinal disease (IID) in a year, and 3% of the population presented themselves to GPs. Viruses (almost half of which are SRSV) accounted for 16% of cases of IID in the community. Viruses were also detected in over 20% of IID cases being presented to GPs, with rotavirus accounting for a third of these. The FSA has recently carried out a second study of the IID in the community (IID2 Study). The IID2 study was carried out in 2008-2009 and was published in	The Group noted the Research.

	spring 2011. This study estimated that IID in the community in the UK was substantial with 25% of the population suffering an episode of IID in a year (i.e. around 16 million cases annually). Around 2% of the UK population visit their GPs with symptoms of IID each year (1 million consultations annually). The most commonly identified pathogens were norovirus (16% of samples tested), sapovirus (9.2%), Campylobacter (4.6%) and rotavirus (4.1%). Further information on IID2 is available at: http://www.food.gov.uk/science/research/foodborneillness/foodbornediseaseresearch/b14programme/b14projlist/b18021/	
Recommendation R3.3 *(paragraph 3.27)* We recommend that Government maintains, develops and enhances surveillance systems throughout the UK, including the Electron Microscopy Network, in order to better define the problem.		
1998 Government Response	**2013 Government Update**	***Ad Hoc* Group comments**
The Government will review surveillance systems throughout the UK following the results of the study to develop a comprehensive standardised system for the investigation and reporting of cases of food poisoning.	The IID2 Study has defined better the burden of norovirus in the community, using more sensitive techniques than electron microscopy. Surveillance is carried out by health protection organisations across the UK, which have attempted to harmonise systems where possible.	Despite the progress that has been made with understanding disease burden there remains a need to join up and share surveillance intelligence between health protection organisations, Cefas and the FSA Incidents Branch.

Chapter 4: : Detection methods for viruses in clinical samples and foods		
Recommendation R4.1 *(paragraph 4.36).* We recommend that all laboratories using electron microscopy (EM) and/or molecular techniques for the investigation of viral diarrhoea should be accredited and should participate in internal and external quality control arrangements.		
1998 Government Response	**2013 Government Update**	***Ad Hoc* Group comments**
The Government endorse this recommendation and will bring it to the attention of the Clinical Pathology Accreditation scheme.		The technology has now changed. QC issues remain. All clinical labs have to be accredited.

Recommendation R4.2 *(paragraph 4.37)* We recommend that schemes for quality assurance must be developed for molecular diagnostics and must be reintroduced for EM.		
1998 Government Response	**2013 Government Update**	***Ad Hoc* Group comments**
The Government endorses this recommendation and will bring it to the attention of the Clinical Pathology Accreditation scheme.		There is now a standard method available for detection of norovirus and hepatitis A virus in food – ISO TS 15216. In addition, certificated reference materials are now available commercially from Public Health England (PHE). These advances should be utilised by food testing laboratories to ensure robust analysis.

Chapter 5: Viral contamination of food, routes of spread and vehicles, prevention and control measures		
Recommendation R5.1 *(paragraph 5.29)* We recommend that the sewage sludge treatment and the Code of Practice for the agricultural use of sewage sludge be reviewed to ensure the scientific basis of the controls and the effective enforcement of the provisions of the Code. If necessary, there should be more research into the effectiveness of viral inactivation.		
1998 Government Response	**2013 Government Update**	***Ad Hoc* Group comments**
A report was commissioned by MAFF, Department of Environment, Transport and Regions (DETR), DH and UK Water Industry Research (UKWIR) in March 1997 with two main aims: to review the scientific evidence relevant to the agricultural use of sewage sludge underpinning the 1989 Code of Practice for Agricultural Use of Sewage Sludge; secondly, to consider the adequacy of the current controls in the light of more recent evidence. The work was undertaken by the WRc plc and report has now been published.	The report on Pathogens in Biosolids – Microbiological Risk Assessment was published in 2003. The risk assessments described in this report were funded by the UK Water Industry (under the management of UKWIR), Department of Environment, Food and Rural Affairs (Defra) and the Environment Agency to address the risks associated with the application of treated sewage sludges to agricultural land. A link to this report can be found below http://archive.defra.gov.uk/environment/quality/water/waterquality/sewage/documents/sludge-biosolids-report.pdf The FSA has also produced guidance on 'Managing Farm Manures for Food Safety - Guidelines for growers to reduce the risks of microbiological contamination of ready-to-eat crops'. This can be found on the FSA website, food.gov.uk, by clicking on the following link: http://www.food.gov.uk/news/newsarchive/2009/jun/manures	It is not clear from the Government response whether 'effective enforcement of the provisions of the code' is taking place and whether the Government judges the measures to be adequate for virus inactivation or not. Information on agricultural sites used for disposal of sewage sludge is not published, therefore, it is not possible to judge possible impact on vulnerable areas (e.g. shellfish harvest areas impacted by run-off).

Recommendation R5.2 *(paragraph 5.30)* We recommend that the importers of fresh fruit and salad crops take account of the hazards from contamination of growing crops by human waste material and ensure suitable precautions for food safety		
1998 Government Response	**2013 Government Update**	***Ad Hoc* Group comments**
The Government will draw this to the attention of industry and seek a report by Spring 1999 on current procedures used, with specific recommendations for improvements.		The government should provide evidence that this recommendation has been achieved.
Recommendation R5.3 *(paragraph 5.31)* We recommend that Government funds research into effective measures of food sanitisation (especially for fruit and vegetables) to remove or inactivate viruses.		
1998 Government Response	**2013 Government Update**	***Ad Hoc* Group comments**
The Government recognises the need for research in this area and accepts this recommendation. It is already funding work on viruses and on methods for cleaning fruit and vegetables.	The Agency has funded a short study (Project B02014) to determine how viruses survive on fresh produce and to investigate the effect of washing on virus removal from a range of fruit and vegetables. This project was published on the FSA website in April 2004 and is available at: http://www.food.gov.uk/science/research/foodborneillness/microriskresearch/b13programme/b13list/b02014 The FSA is currently funding a systematic review on the survival of norovirus in foods and on food contact surfaces. There is a need to review the available literature in this area to assess the likely effectiveness of measures such as physical and chemical treatment for controlling norovirus in the food chain: http://www.food.gov.uk/news-updates/news/2012/apr/novovirus A panel of international experts met to discuss foodborne viruses at an FSA research conference in London on 15-16 January 2013. The conference focused mainly on norovirus. The aims of the conference were to: • consider existing scientific knowledge on foodborne norovirus • identify areas for further research • discuss measures that can help reduce the number of cases of foodborne viruses caused by contaminated food The FSA will produce a report outlining the findings of the conference. We will	Research noted.

<table>
<tr><td></td><td>also consider objectives within the foodborne virus research programme and future Agency work in this area.</td><td></td></tr>
<tr><td colspan="3">Recommendation R5.4 (paragraph 5.32)

We recommend that there should be effective enforcement of Food Hygiene Regulations. This may be facilitated by Guides to Good Hygiene Practice, developed in accordance with Articles 5-7 of Council Directive 93/43/EEC.</td></tr>
<tr><td>1998 Government Response</td><td>2013 Government Update</td><td>Ad Hoc Group comments</td></tr>
<tr><td>The Government endorses this recommendation and recognises the important role effective enforcement and Industry Guides to Good Hygiene Practice have to play in public health protection.</td><td>The Government continues to support the development and use of the Article 7 guides.

The use of such guides supports the proportionate, consistent and effective application of food hygiene legislation and in doing so contributes positively to the protection of public health</td><td>A number of current Guides exist but do not cover all relevant sectors and sub sectors. They generally have limited information on measures relevant to food virus contamination. The main specific mention of viruses is in relation to exclusion of infected food handlers. The key reference document for exclusion is the FSA Guidance – Food Handlers: Fitness to work. N.B. Vending Guide reference is to PHE Guidance not FSA.

The Mail Order Guide talks about removing infected food handlers from handling food but does not include information on exclusion times or reference further details e.g. Food Handlers Fitness to work.

Consistency in detail and in reference documents is required.</td></tr>
<tr><td colspan="3">Recommendation R5.5 (paragraph 5.33)

We recommend that Guides to Good Hygiene Practice should be developed for more sectors of the industry. They should provide clear interpretation of exactly what is needed by way of training, personal hygiene standards and effective exclusion of symptomatic and post-symptomatic food handlers. Guides which do not provide clear guidance in these areas should not be recognised.</td></tr>
<tr><td>1998 Government Response</td><td>2013 Government Update</td><td>Ad Hoc Group comments</td></tr>
<tr><td>The Government accepts this recommendation and will continue to encourage and facilitate the production of Guides. A Government Template provides guidance on the development of Guides to Good Hygiene Practice and criteria for recognition. Guides failing to provide adequate guidance in the areas mentioned would not be recognised.</td><td>The Article 7 guides are developed by individual food sectors, in consultation with interested parties. The Agency has published guidelines for the food industry setting out the process and criteria for the development and recognition of these guides which are available via the link below:

http://www.food.gov.uk/foodindustry/regulation/hygleg/hyglegresources/goodpractice#h_5</td><td>A number of key Guides have not been updated since regulatory changes beginning in 2002. Amongst these are the Catering Guide and the Catering Guide – Ships.

The old Catering Guide – Ships had a detailed section on preventing and managing gastrointestinal illness on board ships and viral infections are considered. The Ships guide recommends 72 hours exclusion after cessation of symptoms for infected food handlers when a viral outbreak is</td></tr>
</table>

		suspected. Information on personal hygiene tends to be basic and often does not consider what is needed in terms of good hand washing. As this is a key infection control measure this should be addressed in new guides and addressed separately where there are existing guides. Generally, the key sectors of the food industry need to be covered. The major omission is the Catering Guide and given the risk of viral infection on ships, the Ships Guide. There also appears to be no current version of the Fresh Produce Guide. Updating of these should be encouraged.
Recommendation R5.6 *(paragraph 5.34)* We recommend that guides have been recognised, steps are taken to bring them, or at least the key points from them, to the attention of food business. The status, enforceability and effectiveness of guides should be kept under review.		
1998 Government Response	**2013 Government Update**	***Ad Hoc* Group comments**
The Government notes this recommendation. Pricing and publication arrangements are intended to encourage wide distribution of Guides and key related information. Free copies of Guides are also provided to all local authority environmental health departments with a request to bring them to the attention of relevant businesses.	Article 7 guides have a special status in law and act as a voluntary aid to regulatory compliance with EU food hygiene regulations and related national measures. Where a food business operator is following a recognised industry guide, the enforcement authority must take this into account when assessing compliance with the legislation.	A guide specifically for controlling norovirus on board ships has been produced by the HPA, Maritime and Coastguard Agency and the Association of Port Health Authorities. Its main focus is on outbreak management. It notes "Occasionally food may be implicated in viral trans-mission". It identifies the need to exclude infected food handlers for 48 hours after cessation of symptoms. "Guidance for management of Norovirus Infection in cruise ships" 2007

Chapter 6: Viral contamination of shellfish, prevention and control measures		
Recommendation R6.1 *(paragraph 6.30)* We recommend that the Government should remind the public of the risks from eating raw oysters, of the potential dangers from collecting molluscan shellfish from beaches, and of the need to cook molluscan shellfish thoroughly.		
1998 Government Response	**2013 Government Update**	***Ad Hoc* Group comments**
The Government accepts this recommendation and is considering the most appropriate method of reminding the public of the potential risks from eating raw oysters and of the need to cook all other molluscan shellfish thoroughly. Appropriate advice for casual gatherers of shellfish is also being considered.	Information is available on the NHS choices: http://www.food.gov.uk/news-updates/news/2011/jan/oysters http://www.nhs.uk/Conditions/Norovirus/Pages/Prevention.aspx	The advice does not unambiguously address the recommendations concerning advising the public of the danger of collecting from beaches or that molluscan shellfish should be cooked thoroughly.
Recommendation R6.2 *(paragraph 6.31)* We recommend that investment plans for improving the quality of bathing waters and urban waste waters should be required to take account of the impact on commercially important shellfisheries.		
1998 Government Response	**2013 Government Update**	***Ad Hoc* Group comments**
The Government recognises the importance of improving water quality in shellfish harvesting areas. For any new or amended discharge consent, such as those associated with improving bathing waters or implementation of the Urban Waste Water Treatment (UWWT) schemes, specific protection for commercial shellfisheries is included in the present AMP2 guidance. The Environment Agency is required, for discharges affecting commercial harvesting areas, to demonstrate that no deterioration in water quality should normally be allowed which would be expected to cause deterioration in classification. Improvements in the quality of bathing waters and implementation of the Urban Waste Water Treatment Directive (UWWTD) are bringing about significant reductions in sewage	(Defra response Feb 2013.) Shellfish waters have been included in the National Environment Plans for investment to water company infrastructure and in the AMP5 period (2010 – 15) £86m will be invested in a programme of improvements and investigations. While investments to meet the UWWTD and the Shellfish waters directive have reduced the overall levels of raw sewage discharged to shellfish waters which has improved water quality. There has been a reduction in the percentage of prohibited and class C harvesting areas from 34% in 1998 to 10% Class C beds in 2012. Compliance with the guideline microbial standard has also increased from around 11% in 2000 to 29% in 2011. We recognise that this could go further and Defra has commissioned a research contract to clarify the relationships between microbial levels in the water column and shellfish flesh to Cefas. This reported in Spring 2013 and showed that shellfish biomagnify microbial pollution significantly more than expected. Reports relating to the study can be found at:	The Committee notes the large capital expenditure committed and the improvements seen for the most polluted (class C) areas. However, attainment of good quality (e.g. compliance with guideline) still seems a remote prospect for the majority of areas.

<table>
<tr><td>contamination of coastal waters and this is likely to benefit shellfish harvesting areas.</td><td>http://cefas.defra.gov.uk/media/564615/20110401%20c3608%20wt1001%20fio%20water%20flesh%20relationships%20final%20report.pdf. http://www.cefas.defra.gov.uk/media/608187/wt0923%20impact%20of%20chronic%20microbial%20pollution%20on%20shellfish%202013%20final.pdf</td><td></td></tr>
<tr><td colspan="3">Recommendation R6.3 (paragraph 6.32)

We recommend that the Government develops a national policy for the reduction of pollution-related illness associated with shellfish consumption, containing the following elements:

• Procedures for the epidemiological surveillance of shellfish-associated incidents should be reviewed to ensure they are effective and comprehensive;</td></tr>
<tr><td>1998 Government Response</td><td>2013 Government Update</td><td>Ad Hoc Group comments</td></tr>
<tr><td>The Government will consider establishing a formal Working Group to review current procedures. Previously, meetings have been held on an ad hoc basis to discuss shellfish-associated food poisoning.</td><td>Information is being actively exchanged between FSA/CEFAS and PHE on norovirus incidents.</td><td>As far as the committee is aware written procedures addressing this recommendation are not in place and a formal Working Group has not been established.</td></tr>
<tr><td colspan="3">• All classified shellfisheries should be designated as sensitive areas under the Urban Waste Water Treatment Directive (UWWTD) and we recommend the designation without further delay of all commercial shellfish harvesting areas throughout the United Kingdom under Council Directive 79/923/EEC;</td></tr>
<tr><td>The Government recognises the need to protect shellfisheries and recently announced further designation of shellfish waters in Scotland under the Shellfish Waters Directive (79/923/EEC). Ministers will shortly be considering further designations in England and Wales of shellfish waters under the Shellfish Waters Directive (79/923/EEC). The Government considers that the protection of shellfish populations can be most effectively provided under the provisions of directive 79/923/EEC whose requirements and parameters specifically concern the quality of shellfish waters needing protection or improvement and which contributes to the high quality of shellfish products.</td><td>(Defra response Feb 2013)

In England a further 76 shellfish waters were designated in 1999 in addition to the 17 existing waters. Since then Defra has kept a broad match between harvesting areas and shellfish waters in terms of areas covered. There have been further shellfish water designation exercises in 2004 and 2010 to ensure this.

The Shellfish Waters Directive 79/923/EEC (as amended) has been revoked by the Water Framework Directive in Dec 2013. Defra has made a commitment in the Water for life white paper to maintain a similar level of protection under the Water Framework Directive. From 2014 onward there will be no EU wide framework for what protects shellfish waters should be offered and the Commission, in the "Blueprint for Water" has indicated that it will produce some guidance, but no new legislation.</td><td>The Committee notes that the Government has designated all significant shellfisheries. However, it remains unclear what protection and improvement will result from such designation.</td></tr>
</table>

• The Department for Environment, Transport and the Regions (DETR) and the Environment Agency, in consultation with MAFF and DH, should formulate a policy to reduce to a minimum the discharges from Combined Sewage Outflows (CSOs) into shellfish areas. Frequency of discharges should be monitored and summary results should be published annually to enable a view to be taken of the trend in discharges into classified shellfish harvesting areas;		
As part of the UWWTD, implementation of a programme of prioritising improvements to unsatisfactory CSOs in England and Wales was drawn up and the first stage covered the period 1995-2000. Although not primarily addressed at shellfish harvesting areas, it should ensure no deterioration in harvesting area quality. As stated, the Government recognises the need to protect shellfish and will offer guidance to the Director General of Office of Water Services (OFWAT) in July 1998 on the scope and priority for environmental improvements to be funded in 2000-2005. This will include those associated with possible further designations under the Shellfish Waters Directive in which improvements of unsatisfactory CSO discharges is a priority category. Consideration is being given by Government and regulators to the issue of CSO spill frequency and duration and their likely impact on the microbiological quality of shellfisheries.	(Defra response Feb 2013) A CSO policy for shellfish waters has been set. It is set as 10 spills per annum, annualised over a 10 year period to allow for variance in weather conditions. The majority of CSOs are not monitored nor are spills reported. However in AMP5 and for AMP6 more CSO event duration monitors are being put in place with priority given to those impacting on bathing and shellfish waters.	The Committee notes the formulation of a Government policy in line with the recommendation. However, since most CSOs are not monitored or reported compliance with the policy cannot be judged. It remains an imperative to monitor and report CSO discharges as a first step in improving controls.
• CSOs should not be directed into Class A or B shellfish harvesting areas;		
The Government recognises the importance of improving water quality in shellfish harvesting areas. Existing guidelines state that the discharge from any new CSO into designated shellfish waters should be avoided and existing unsatisfactory discharges improved. The Government will shortly review the designation of shellfish waters.	(Defra response Feb 2013) Guidance remains is in place so that new CSO's do not spill into shellfish waters. Existing CSOs have been improved where they are identified as contributing to the failure of a shellfish water.	It is difficult to see how CSOs can be identified as contributing to the failure of a shellfish water if they are not monitored. Research evidence suggests CSOs remain a potentially significant source of contamination in many shellfish harvesting areas. This is of particular concern considering rainfall patterns seen in recent years.

<table>
<tr><td colspan="3">Water companies should provide the local Food Authorities with summaries of the operation of storm discharges in the vicinity of shellfish beds and of all emergency discharges immediately they occur. Following a discharge, Food Authorities should take sufficient samples to determine the extent of contamination so that, if necessary, they can prevent harvesting for a period, either by voluntary agreement from harvesters or by using statutory powers.</td></tr>
<tr><td>The Government will bring this recommendation to the attention of the water industry. The Government will also bring this recommendation to the attention of local authorities. The Government will seek from both the water companies and local authorities a considered response to the recommendation by the end of 1998.</td><td>(Defra response Feb 2013)

We are not aware of any outcome to the work committed to in the original response. The majority of CSOs and emergency discharges do not have monitors so it would not be possible for the Water Company to know if they were spilling. This situation is being improved now with event duration monitoring being put on many CSOs at or near shellfish waters during AMP 5 and planned for in AMP6. Defra is also supporting a Seafish and Water Company trial of “real time” warnings of CSO spills.</td><td>The absence of monitoring on the majority of CSOs remains a significant concern preventing implementation of appropriate control measures. The Committee notes and strongly supports plans to resolve this over the next investment cycle. Following this it should be possible to address the original recommendations made in 1998 which remain relevant.</td></tr>
<tr><td colspan="3">Recommendation R6.4 (paragraph 6.33)

We recognise the importance of maintaining appropriate research in order to enhance current knowledge of foodborne viruses and call upon the Government and industry to continue to fund research in this area. This, in particular, should be aimed at:
Developing methods for the isolation and detection of viruses in shellfish, particularly SRSVs;
Continuing to fund the development of alternative viral indicators of shellfish pollution, in particular their practical application in the classification of harvesting areas, depuration and end product assessment, with a view to incorporating these as standards in EC hygiene control measures as soon as possible;
Investigating the behaviour of viruses during sewage treatment processes with a view to maximising virus removal; and
Investigating the behaviour of viruses during the depuration process in order to maximise virus removal and with a view to issuing guidance to operators on depuration requirements.</td></tr>
<tr><td>1998 Government Response</td><td>2013 Government Update</td><td>Ad Hoc Group comments</td></tr>
<tr><td>The Government recognises the need for research on viruses in shellfish and is continuing to fund work in this area. The aquaculture LINK programme provides opportunity for collaborative research between Government and industry. The Government would welcome relevant proposals in this area.</td><td>The FSA has a B16 Shellfish Hygiene Research Programme which focuses on 2 distinct of research, the first dealing with viruses and the second with biotoxins. Further information on this research programme is available at:

http://www.food.gov.uk/science/research/foodborneillness/shellfishresearch/b16programme/

The virus part of the B16 Shellfish Hygiene Research Programme includes the following projects:

B04001: The development of improved simplified and standardised PCR based</td><td>The Committee notes the significant research funding committed in this area and the consequential advances made in the areas highlighted. Some aspects, for example the behaviour of viruses during depuration, could usefully be revisited now that standardised quantitative methods for norovirus are available.</td></tr>
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	techniques for the detection of norovirus and hepatitis A virus in molluscan shellfish (published April 2004). **B04002:** Development of procedures for improved viral reduction in oysters during commercial depuration (published April 2004). **B04003:** Developing methods for the isolation and detection of viruses in shellfish, particularly noroviruses (published April 2004) **B04009:** Evaluation and validation of alternative indicators of viral contamination in bivalve molluscan shellfish (published April 2004) **B05001:** The survival of norovirus and potential viral indicators in sewage treatment processes and in the marine environment (published April 2004) Summarises of these projects are available on the Agency's website at: http://www.food.gov.uk/science/research/foodborneillness/shellfishresearch/b16programme/B16projlist/ A review of the Agency's B16 Shellfish Hygiene Research Programme was held in January 2004 where the B16 projects, including those listed above, were evaluated by a panel of independent experts for scientific quality and policy relevance. Delegates attending this event were also given the opportunity to comment on the research presented but also on future concerns and areas for investigation. A summary note of the B16 Programme Review including the key outputs is available at: http://www.food.gov.uk/multimedia/pdfs/b16programmereview The Agency has funded a small collaborative project (VITAL) through the EU Framework Programme 7. This project addressed a major issue regarding foodborne viruses and the lack of effective risk management strategies and prevention measures against food and environment contamination. The current epidemiological surveillance systems can only react to and provide information on disease outbreaks that occur through contamination of food. VITAL devised and recommended a framework for monitoring, risk modelling, and procedures for control of foodborne virus contamination, which will be applicable to	

	any virus that poses the danger of being transmitted by food. VITAL ran between Spring 2008 and Summer 2011 . Further information is available at: www.eurovital.org Please see attached link to a letter which was issued to a range of stakeholders in Feb 2010. http://www.food.gov.uk/multimedia/pdfs/enforcement/enfe10009.pdf The letter includes advice to Local Authorities that they may wish to advise operators to consider taking some or all of the following additional actions which, though not legally required, might be appropriate on a precautionary basis given the recent cases of illness. It is important to note these actions will still not guarantee freedom from noroviruses, but should help minimise risks:-	

3. Foodborne viral disease

3.1. Characteristics of viruses

Viruses are very small micro-organisms ranging in size from 20nm to 400nm in diameter. They are made up of the viral genome, which can be RNA or DNA enclosed within a protein coat. Unlike bacteria they are not free-living and only replicate within the living cells of humans, animals, plants or bacteria. They do not replicate in food.

3.2. Foodborne viruses of concern

The important viruses linked to foodborne transmission are shown in Table 2. These include viruses which cause a wide range of clinical illnesses.

The burden of foodborne viral infections is poorly defined. Norovirus is the most commonly recognised foodborne viral infection through consumption of shellfish and fresh produce and following contamination by infected food handlers, hepatitis A has also been linked to these routes of transmission but has been infrequently recognised in recent times. Hepatitis E is an increasingly recognised foodborne illness associated with the consumption of processed pork. The report focuses on these virus/food combinations.

Foodborne virus infections are predominantly associated with enteric viruses**.** These viruses are shed in high concentrations in faeces and vomit and remain viable in the environment for several days or months (Koo, Ajami *et al*, 2010), (Meng, 2011; Berto, Martelli *et al,* 2012b) although other enteric viruses such as rotaviruses and sapoviruses have been associated with outbreaks of foodborne gastroenteritis and over recent years a number of zoonotic viruses such as SARS and avian influenza have been recognised. These have the potential to be found in the food chain.

Animal viruses often replicate poorly in the human host but the incidental co-infection of a host with animal and human viruses may result in the mixing of virus genes, through recombination or reassortment (Iturriza-Gomara, Isherwood *et al*, 2001; Banerjee, Iturriza-Gomara *et al,* 2007). This may allow the emergence of progeny viruses with the replicative advantage of the human virus but novel antigens conferred by the animal virus. The lack of herd immunity to these novel proteins will allow the virus to spread in the human population.

A wide range of other viruses are shed in faecal specimens and therefore may have the potential to cause foodborne illness. These will not be considered further because their role in human infection and disease is not established. Viruses falling into this category include: aichi virus, bocavirus, cardiovirus, cosavirus, klassevirus, picobirnavirus and torovirus (Van Leeuwen, 2010; Neilson, 2013; Kapusinszky, 2012).

Table 2: Key criteria describing the foodborne risks posed by viruses in the food chain in the UK

1. Gastroenteritis viruses				
Virus	**Clinical Presentation**	**Epidemiology routes of transmission**	**Burden of foodborne illness**	**Considered or not considered in report**
Norovirus	Gastroenteritis	Faecal oral transmission mostly person to person. Foodborne transmission through consumption of contaminated food. Shellfish, fresh produce and food handler-related outbreaks are commonly reported.	Estimate 200,000 cases per year	Considered because high burden of disease
Rotavirus Astrovirus Sapovirus Adenovirus	Gastroenteritis Gastroenteritis Gastroenteritis Gastroenteritis	Routes of transmission as norovirus, but most infection is found in infants. Outbreaks are rarely recognised because of acquired immunity in childhood.	Few case reports	Not considered

2. Hepatitis viruses				
Virus	**Clinical Presentation**	**Epidemiology routes of transmission**	**Burden of foodborne illness**	**Considered or not considered in report**
Hepatitis A	Acute Hepatitis	Faecal oral transmission, now low incidence in west Europe, but high population susceptibility, commonly travel and foodborne infection recognised. Clinical attack rate varies with age. Causes severe hepatitis in minority of cases.	Well documented outbreaks. Sporadic cases linked to fresh produce increasingly recognised.	Considered because high burden of disease
Hepatitis E	Acute Hepatitis	Recently recognised zoonoses in UK. Genotype 1, 4 are travel associated. Genotype 3 primary contamination of pork products, little evidence of human-human spread, low clinical attack rate, rare cases of severe hepatitis.	Detected in pork products, outbreaks linked to shellfish reported (Said *et al*, 2013).	Considered because potential to cause severe diseases and presence in pork food chain.

3. Picornaviruses				
Virus	**Clinical Presentation**	**Epidemiology routes of transmission**	**Burden of foodborne illness**	**Considered or not considered in report**
Coxsackie A, B Enteroviruses Paraechovirus	Meningitis, Upper Respiratory Tract Infection, Hand foot and mouth disease.	Faecal-oral transmission but outbreaks not recognised because of low clinical attack rate.		Not considered

4. New and Emerging viruses				
Virus	**Clinical Presentation**	**Epidemiology routes of transmission**	**Burden of foodborne illness**	**Considered or not considered in report**
Nipah virus SARS Avian Influenza	Encephalitis Severe lower Respiratory Tract Infection	All can be found in animal tissues; main risk is direct contact with infected animals. All 3 viruses cause severe illness high mortality but limited human to human transmission reported.		Considered because of potential risks.

3.2.1. Noroviruses

Noroviruses are a genus of the Caliciviridae. They have a genome of single stranded (ss) RNA of approximately 7.5kb. The virus is non-enveloped, 30-35nm in diameter and has an icosahedral structure (Gray and Desselberger, 2009). The viruses are very diverse and characterised into 5 genogroups of which 3 infect humans. Within these genogroups more than 20 Genotypes have been described. The nomenclature used reflects this, for example: Genogroup 2 genotype 4 is known as GII-4. One Genotype (GII-4) has predominated in outbreaks within semi-closed communities over the last 20 years. Over this period GII-4 strains have continued to evolve and variation in the burden of infection is linked to the emergence of novel strains in a manner similar to influenza A (Lopman, 2004).

The virus is stable in the environment and resistant to inactivation by solvents and many disinfectants (Duizer, Bijkerk *et al*, 2004). Norovirus is highly infectious with a low infectious dose of approximately 10 virus particles. During the acute phase of the illness virus is excreted in faeces at concentrations of ~10^7 particles per gram or ml.

Noroviruses cause an acute self-limiting gastroenteritis. It can be transmitted by person-to-person spread, waterborne infection following exposure to contaminated drinking or recreational waters, the ingestion of contaminated foods such as uncooked shellfish, berries and salads or contact with contaminated surfaces.

The incubation period for norovirus infection is 10-50 hours and symptoms include the rapid onset of nausea, headache and abdominal cramps followed by diarrhoea and vomiting, often projectile, and lasts for only 12 to 48 hours. Immunity, even with homologous viral challenge, is short lasting with infected individuals becoming susceptible to subsequent norovirus infections after ~6-12 months. Immunity is poorly understood. There is no cross immunity between genogroups.

3.2.2. Hepatitis A virus

Hepatitis A virus (HAV) is a Hepatovirus. It has a genome of ssRNA of 7.5kb. Hepatitis A virus is found in a range of primate species. It is serologically monotypic but classified by sequence variation into genotypes, at least 5 of which are seen in human infections (1A, 1B, 3A, 3B, 7) Virions are non-enveloped, 27nm in diameter and have an icosahedral structure (Harrison *et al*, 2009).   HAV is extremely stable and can persist for more than 3 months in soil, is resistant to inactivation when dried on environmental fomites and survives for >5 days on foods stored at 4^{o}C or room temperature. It is resistant to acid and elevated temperature (60ºC for 10 minutes).

The incubation period of HAV is between three to five weeks with a mean of 28 days. Anicteric or asymptomatic infections are common in children, whereas, infection in adults results in acute icteric hepatitis in >70% of those infected with a case fatality rate of 0.3 to 1.8%. Prodromal symptoms include fever and headache followed by fatigue, anorexia and myalgia with the development of jaundice of the sclera and skin. The development of jaundice usually heralds a rapid subjective improvement in symptoms.

HAV is spread by the faecal oral route, most commonly by person to person or waterborne transmission where conditions of poor sanitation and overcrowding exist. In industrialised countries person to person transmission is rare and outbreaks of hepatitis A infection are associated with spread via contaminated food. The large number of virus particles shed in faeces and the long incubation period in which shedding occurs contributes significantly to outbreaks, particularly those associated with food handlers. Outbreaks are often associated with the consumption of raw or inadequately cooked shellfish cultivated in contaminated waters.

3.2.3. Hepatitis E virus

Hepatitis E virus (HEV) is a Hepevirus and has a genome of ssRNA of 7.5kb. Virions are non-enveloped 32-34nm in diameter, calicivirus-like in morphology. HEV is classified into four distinct genotypes (Meng, 2010). Genotype 1 has been isolated from humans in Asia, genotype 2 from humans in Mexico, genotype 3 from humans, swine and other animal species such as wild boar, deer and rodents in Europe and North America, and genotype 4 from humans and swine in East Asia (Teo, 2006).

HEV is environmentally stable in contaminated pigs' livers. Virus infectivity was completely inactivated after boiling or stir frying for 5 minutes. However, incubation of contaminated livers at 56^{o}C for 1 hour, equivalent to medium to rare cooking conditions in a restaurant, did not inactivate the virus (Feagins *et al*, 2008). Heating to an internal temperature of 71^{o}C for 20 minutes was necessary to completely inactivate HEV in experimentally contaminated foods (Barnaud *et al*, 2012).

The average incubation period of hepatitis E is six weeks. HEV genotypes 1 and 2 occur frequently in tropical and sub-tropical regions where the disease is endemic. Waterborne outbreaks tend to affect young adults aged between 15 and 40 years. They cause an acute self-limiting hepatitis, overall mortality ranges from 0.5%-4% with fulminant hepatitis occurring most frequently in women during pregnancy. Babies born to women with acute disease are at risk of vertical transmission and associated morbidity and mortality. HEV infection in pregnancy increases the risk of abortions, stillbirths, deaths in new-born babies and neonatal hypoglycaemia and liver injury.

Recently, sporadic cases of hepatitis E have been reported in individuals living in non-endemic areas, in the absence of a history of travel to endemic areas (Ijaz, 2005). These cases are caused by HEV genotype 3 strains closely related to the virus found in the European pig population. Human infections tend to be milder than infection with Genotype 1 HEV. These cases are typically observed in older men and have been related to various animal reservoirs including swine, wild boar, deer and rodents. HEV RNA has been found in ~2% of pig livers sold in grocery stores in Japan and 11% in the USA (Yazaki *et al*, 2003; Feagins *et al*, 2007). In the UK, HEV RNA was detected at each of three sites in the pork food supply chain, at the slaughterhouse, the processing plant and at points of retail sale (Berto *et al*, 2012).

Precautions for prevention of spread of HEV include improvements in sanitation, education about personal hygiene including hand washing, and storage, handling and preparation of uncooked meats, particularly pork products. The role of pork consumption in transmission is not fully defined.

3.2.4. Emerging viruses

In recent years there have been several newly recognised viruses which have raised concern about the risk of transmission through the food chain. There is no direct evidence of foodborne transmissions for SARS coronavirus or influenza H5N1 (ACM/663 and ACM/850). Although both pose a theoretical risk it is likely that direct contact with infected animals is the main risk. SARS coronavirus may have been transmitted following contact with environmental surfaces contaminated with respiratory secretions.

Similarly, zoonotic viruses such as herpes viruses, simian immunodeficiency virus and simian foamy viruses may enter the food chain through the butchering of wildlife to provide bush meat (Cutler *et al*, 2010; Smith *et al*, 2012). It is probable that butchering the animal is the high risk activity, as viruses are likely to be inactivated following cooking.

3.3. Clinical diagnostics

3.3.1. Norovirus

Noroviruses (or Norwalk-like viruses as they were first known) were first recognised by Electron microscopy (EM) and Immune Electron Microscopy in faecal samples (Kapikian, 1972). For many years EM was the main diagnostic tool. EM requires a minimum of 10^6 virus particle/ml or g of sample to be present before virus can be visualised. This results in a sensitivity of detection for norovirus of ~35% to 50%. EM has now been replaced by reverse transcription polymerase chain reaction (RT-PCR) for the diagnosis of norovirus infection and outbreaks because of the reduced cost, improved sensitivity and widespread availability.

There are a range of immunologically based assays for norovirus detection available including enzyme immunoassays (EIA) and point-of-care tests. The sensitivity of these assays is better than EM with a sensitivity of detection to 50% to 75% but they rely on the presence of capture antibodies to a population of antigenically diverse viruses (Richards, Lopman et al, 2003).

The use of RT-PCR, in particular real-time RT-PCR with sequence specific oligonucleotide probes, further increases the sensitivity of detection to more than 90% and this is now the gold standard test (Kageyama *et al*, 2003). The accumulation of point mutations during replication of norovirus RNA may result in a failure to detect by RT-PCR, when these mutations occur in the primer or probe binding sites, but in over 10 years of use this assay has performed accurately.

Asymptomatic norovirus infection is common with approximately 16% of the population shedding the virus in the absence of symptoms (Amar *et al*, 2007). Asymptomatic shedding is associated with a lower viral load (Phillips *et al*, 2009). In the past it was recommended that samples should be collected from up to 6 symptomatic individuals in an outbreak before excluding norovirus to allow for differences in the sensitivity of detection. With the added sensitivity of RT-PCR an outbreak can be classified on the basis of 2-3 samples. The finding of norovirus in a sporadic case of gastroenteritis may only be diagnostic if all other causes of acute gastroenteritis have been excluded.

Noroviruses are very diverse viruses. Serological assays have been described but are not used for diagnosis because of this diversity.

3.3.2. Hepatitis A

Hepatitis A is normally diagnosed through the detection of HAV-specific antibodies in serum. Antibodies are present during the early stages of infection and HAV-specific immunoglobulin M (IgM) is detectable for 45-60 days after the onset of symptoms. HAV-specific immunoglobulin G (IgG) is detectable for many years and recovery from infection is associated with lifelong immunity. Hepatitis A virus infection can be diagnosed by genome detection using RT-PCR (Qiu, 2013). Viruses can be detected in blood and faeces for a similar period after acute illness.

3.3.3. Hepatitis E

A diagnosis of a HEV infection is generally made by detecting HEV-specific antibodies in serum. HEV-specific IgM is transient, lasting up to 3 months but is often not detected (Aggarwal, 2013). A diagnosis of HEV infection by RT-PCR on faecal, plasma or serum samples is used increasingly to diagnose infection (Baylis, 2011). HEV virus is characterised using a 170 bp amplicon of the highly conserved ORF3 region of the HEV genome (Garson *et al*, 2012).

3.4 Viral infectivity in the food chain

A key consideration for risk assessment and risk management is a quantitative understanding of the infectivity of viruses in the food chain. Our current understanding of this issue varies significantly for the viruses and foodstuffs that are the focus of this report.

Noroviruses cannot be cultured in cell lines within the laboratory despite many years of study (Duizer, Schwab *et al*, 2004). There are limited data on infectivity and on methods for inactivation derived from human volunteer studies. The only animal model is chimpanzees which are rarely used.

A range of alternative approaches to modelling norovirus infectivity have been evaluated, such as the use of surrogate viruses such as feline calicivirus (FCV) and murine noroviruses. These viruses are related to human noroviruses, but have a different pathogenesis in their hosts and, certainly in the case of FCV, follow a different route of transmission. It is not clear that they provide a more useful model for guiding inactivation protocols for norovirus than polio virus or hepatitis A.

Phages have also been used widely as a surrogate in experimental and environmental settings. FRNA bacteriophages, in particular, are small positive strand RNA viruses, ubiquitous in sewage and other faecal contamination, which were selected as potential surrogates because of their similar physical characteristics to human enteric viruses such as norovirus (Havelaar *et al*, 1993). The results produced have not been adopted, despite their having useful features (Doré *et al*, 2000). It may be useful to re-examine the findings from FRNA bacteriophage studies in the light of new data on norovirus which has the potential to verify their conclusions. The attraction of the phage approach remains the quick, easy and cheap nature of the assay and that it determines viability. A promising model for assessing norovirus capsid stability (Nowak *et al*, 2011) has recently been developed, but again concerns about the applicability to norovirus inactivation remain.

Consequently, most information about the risks of norovirus in the food chain are derived from detecting the virus genome directly by RT-PCR. Detection of virus by PCR does not directly correlate with infectivity and this complicates interpretation of the data particularly where an inactivation step, such as cooking, is integral to food processing. The current state of knowledge is that for bivalve molluscs a standard method is available, and systematic quantitative data using these tests has been acquired, with one published study suggesting a dose-response in consumers eating norovirus-contaminated oysters (Lowther et al., 2010). Quantitative RT-PCR testing of foodstuffs has the potential to inform risk management. EFSA is currently consulting about the use of RT-PCR levels to control risk in bivalves.

The picture with fresh produce is less well developed. There are now established methods to detect norovirus by RT-PCR in fresh produce, with several published studies showing a low rate of detection. It is difficult to demonstrate that the detected virus represents an infectious risk. However the presence of the norovirus genome is certainly an indication of contamination of the foodstuff by norovirus even if it has subsequently been inactivated, or has become non-infectious. Thus, for the risk manager it is prudent to treat positive RT-PCR signals from fresh produce as potentially infectious.

The picture for HAV and HEV is different. Although RT-PCR is the standard method used to detect these viruses in the food chain, effective culture methods are available for HAV (Millard *et al*, 1987) and promising culture systems for HEV have recently been described (Okamoto, 2013). These should be used to examine the relationship between infectivity and virus detection by RT-PCR in different food matrices. Indeed early work on the heat inactivation of HAV was used to inform the standard heat treatment protocol for cockles of 90 seconds at 90ºC. This has proved to be effective for both HAV and norovirus for many years (Appleton, 2000).

3.5. Detection of viruses in food products or environmental samples

Detecting enteric foodborne viruses requires a different approach to the detection of foodborne bacterial pathogens (Stals *et al*, 2012). In contrast to most foodborne bacteria, viruses cannot grow in the environment since they need specific host cells to replicate (Koopmans and Duizer, 2004). However, as most foodborne viruses lack an envelope they exhibit a high degree of resistance to environmental stressors like heat, high or low pH, drying, light and UV exposure (Baert *et al*, 2009; Vasickova *et al*, 2010). They can remain infective in foods for periods from 2 days to 4 weeks

(Bidawid *et al*, 2001; Hewitt and Greening, 2004; Butot *et al*, 2008) and sensitive methods are required when examining food products for foodborne viruses. In the absence of culture methods for most foodborne viruses, detection in foods relies upon molecular methods. Various methods exist and have recently been reviewed by Mattison and Bidawid (2009) and Bosch *et al*. (2011) whilst D'Agostino *et al*. (2011) reviewed the strategies for using and interpreting process controls correctly when detecting enteric viruses in foods.

The need for harmonised methods for molecular detection of foodborne viruses, especially for norovirus and HAV, has been emphasised repeatedly, most recently by Stals *et al.* (2013). The European Committee for Standardization/Technical Committee 275/Working Group 6/Task Group 4 on virus detection in foods (CEN/TC275/WG6/TAG4 working group) has been tasked with this and a standardised method for detection and quantification of norovirus and HAV contamination in foodstuffs has been developed (Lees, 2010). This international standard method – ISO/TS 15216 – has now been published. The ISO contains both quantitative (ISO/TS 15216-1:2013) and qualitative (ISO/TS 15216-2:2013) parts for analysis of norovirus and HAV in bivalve molluscs, soft fruit, fresh produce, bottled water and on food surfaces. The method is standardised and, hence, suitable for use within a legislative context. Formal international validation studies of this method have been funded by the EU Commission and are currently on going. Formal validation will advance the current technical specification to a full standard.

Standardised protocols (based on this standard) for detecting foodborne viruses have been developed for soft fruit[1] and bivalve shellfish.[1] In addition, standardised norovirus and HAV reference materials for quality assurance purposes are now available commercially from PHE[2]. These procedures and reagents, developed to support the ISO standard method, will facilitate implementation and harmonisation of foodborne virus detection in contaminated foods (Hartnell *et al*, 2012). However, as Stals *et al.* (2013) point out there will be challenges in interpreting results in a public health context given that many foods may be found to be contaminated with viruses. These challenges include confirmation of positive PCR results, developing critical thresholds for virus genome copy levels in food products and interpreting positive PCR results alongside levels of faecal indicator organisms. Nonetheless, in foodstuffs such as leafy green vegetables and berry fruits, noroviruses should under no natural circumstances be present. Whether infectious or non-infectious, if norovirus is detected in a fresh produce item it indicates that a failure in good practice has occurred at some point in its supply chain. Therefore, in this regard, PCR-based analysis is highly useful.

[1] http://www.crlcefas.org

[2] http://www.hpa.org.uk/ProductsServices/MicrobiologyPathology/ExternalQualityAssessmentProficiencyTesting/ReferenceMaterialsForNorovirusAndHepAVirus

In a recently completed FSA-funded review, the methods currently available for norovirus detection in food products and environmental samples were described (Knight *et al*, 2012). These included RT-PCR to detect and estimate the titre of norovirus present and enzyme-linked immunosorbent assay (ELISA) methods, which are considered to be less sensitive. The major gap at present is that the methods available do not provide information on whether or not the detected virus is capable of causing human infection or the degree of any degradation/damage to the RNA or capsid. However, human volunteer studies (Teunis *et al*, 2008) have shown a correlation between the amount of norovirus genome ingested (as measured by PCR) and the likelihood of becoming ill. Teunis reports a 10% probability of becoming ill following ingestion of a dose of 1000 norovirus genome copies rising to a 70% probability of becoming ill at a dose of 10^8 genome copies. However, these estimates were very dependent on the state of aggregation of the virus inoculums used. Aggregates were calculated to contain an average of about 400 virus particles. If aggregation was allowed for dose response estimates were much lower – for completely disaggregated particles the 50% probability of infection was 18 genome copies. There was also a relationship between dose and likelihood of symptoms with lower doses more likely to lead to infection without illness symptoms (subclinical infection). The establishment of a dose response model for norovirus is important as it enables evaluation of the possible health protection afforded by different possible legislative standards for norovirus in foodstuffs (as measured by PCR). This concept of a dose response is supported by data from a restaurant study where norovirus contamination of oyster batches served, measured by quantitative PCR, was compared with self-reported illness complaints from diners (Lowther *et al*, 2010). A significant correlation was found between presence of norovirus and illness complaints. In addition, the batch with the highest level of norovirus contamination also resulted in the highest rate of reported illness suggesting a linkage between virus RNA levels and health risk. Norovirus levels recorded in outbreak-associated oyster samples in the UK are summarised in Lowther *et al*. (2011). Norovirus levels in outbreak related oyster samples were in the range 152-8215 genome copies/g (average 1,048). Other available data for outbreak related oyster samples is presented in EFSA 2012 and is consistent with the UK data. In summary, there is good evidence that absence of norovirus in oysters by the standard ISO method is protective of public health, but also that low levels of norovirus may not always present an acute illness risk. The available data suggests that higher levels present a dose dependant probability of acute illness. Missing data is the likely state of virus aggregation in foodstuffs and the ratio of infectious to non-infectious virus in such samples. A recent paper, however, concluded that there is unlikely to be a large fraction of un-infectious (defective) virus genome found in oysters (Thebault *et al*, 2013) and it is known that oysters do not bioaccumulate naked RNA (Dancer *et al,* 2010).

Finally, there is no formal international standard method to detect HEV in food products but several methods exist in the scientific literature (van der Poel and Berto, 2013). A standardised real-time PCR assay has been used successfully by researchers in several European countries to detect HEV in pork products (Berto *et al*, 2012; Di Bartolo *et al*, 2012), on leafy vegetables (Kokkinos *et al*, 2013) and in shellfish (Diez-Valcarce *et al*, 2012). Considering the successful development of standard methods for norovirus and HAV in foodstuffs it would seem feasible to also address the development of standard methods for HEV.

We conclude that:

- The public health significance of viral contamination as indicated by PCR results is an important issue for the food producing sector that requires:
- Effective, quantitative tools for detecting viruses in the foodstuffs are now available. These methods are based on the direct detection of viral nucleic acid by PCR and viral nuclei does not necessarily equate to infectious virus, for example virus may be inactivated. However preliminary evidence suggests a dose-response relationship between viral RNA and subsequent illness at least in oysters.
- Validated quantitative methods are available for Noroviruses and Hepatitis A in molluscs. Methods have been described for other viruses such as Hepatitis E and for other food matrices as part of research studies, but these are not yet suitable for control purposes.
- A major change since the last review by ACMSF is the ability to detect viruses in food matrices and the existence of standardised methods suitable for use in a risk management context.

We recommend that:

	Recommendations that Inform Risk Assessments*	**Lead Department/s**
R3.1	Wider use of food and environmental testing should be employed to support outbreak investigations this will need to include methodological refinements targeting characteristics indicative of viable virus eg. intactness of genome or protein coat.	PHE and devolved equivalents
R3.2	Molecular diagnostics, typing and quantification should all be used more systematically to understand the burden of virus contamination in foodstuffs on the UK market to help identify the potential control points this might include validation of potential virus indicator organisms.	PHE and devolved equivalents
R3.3	Further work is undertaken on the correlation between infective dose and genome titre (as measured by PCR) in order to help develop risk management criteria that will adequately protect public health without imposing	PHE lead with FSA support

	disproportionate burdens on the food industry. This might include food consumption studies focussing on infection outcomes related to virus titre.	
R3.4.	Further research is undertaken on the development of methods for assessment of norovirus and Hepatitis E infectivity in food samples to inform surveys and that could potentially be applied to routine monitoring.	FSA
R3.5	Further research is undertaken on appropriate surrogates in other food matrices to help identify suitable control treatments.	FSA
R3.6	Research is undertaken on processing methods that are effective for virus decontamination and appropriate for the food product.	FSA

* The recommendations have been separated into those that we consider will ***inform risk assessments*** and those that will ***impact on risk assessments***. For recommendations that inform risk assessments we have identified the lead Department.

4. Burden of illness

4.1 Infectious intestinal disease

The recently completed IID2 Study emphasised the importance of norovirus as the most common cause of IID in the community and presenting to general practice in the UK (Tam *et al*, 2012a; Tam *et al*, 2012b). In 2009 there were around 1 million cases of norovirus in the community and around 130,000 people presenting to primary care. As well as a high burden of overt clinical disease, norovirus is known to be excreted by a significant proportion of people who have no symptoms of infection (Phillips *et al*, 2010), although at lower levels than people with clinical disease (Phillips *et al*, 2009).

Various methods have been used to attempt to estimate the proportion of enteric pathogen burden that is transmitted through food including expert elicitation (Havelaar *et al*, 2008), use of outbreak data (Adak *et al*, 2002) and microbial subtyping and source tracking methods (Batz *et al*, 2005). Similarly outbreak data have been used to estimate the burden of foodborne enteric pathogens by food commodity (Adak *et al*, 2005; Greig and Ravel, 2009; Painter *et al*, 2013). However, various attempts to attribute norovirus by foodborne transmission and food commodity have suffered from lack of suitable, available data (Lawrence 2004). Estimates of the proportion of norovirus that is foodborne undertaken by international experts vary quite widely as shown in Table 3 below.

Table 3: Estimates of foodborne transmission of norovirus by country

Country (Lead author)	**UK** (Adak *et al*, 2002)	**US** (Scallan *et al*, 2011)	**France** (Vaillant *et al*, 2005)	**Australia** (Hall *et al*, 2005)	**The Netherlands** (Havelaar *et al*, 2008)
Estimate of proportion of norovirus that is foodborne (%)	11	25	14	25	17

In a recent systematic review of the international literature (La Rose *et al.* – in press) the estimated proportion of norovirus that was foodborne was 2.7%, which is considerably lower than any of those in Table 3. However, assigning norovirus, which is predominantly transmitted from person to person, to other transmission routes is notoriously difficult. Foodborne norovirus outbreaks are not consistently recognised, unlike outbreaks due to foodborne bacterial pathogens (Koopmans, 2008), and a seeding event that is foodborne can easily be missed as the epidemiology quickly becomes obscured by secondary transmission. This means that all current estimates of the proportion of norovirus that is foodborne are likely to be highly biased.

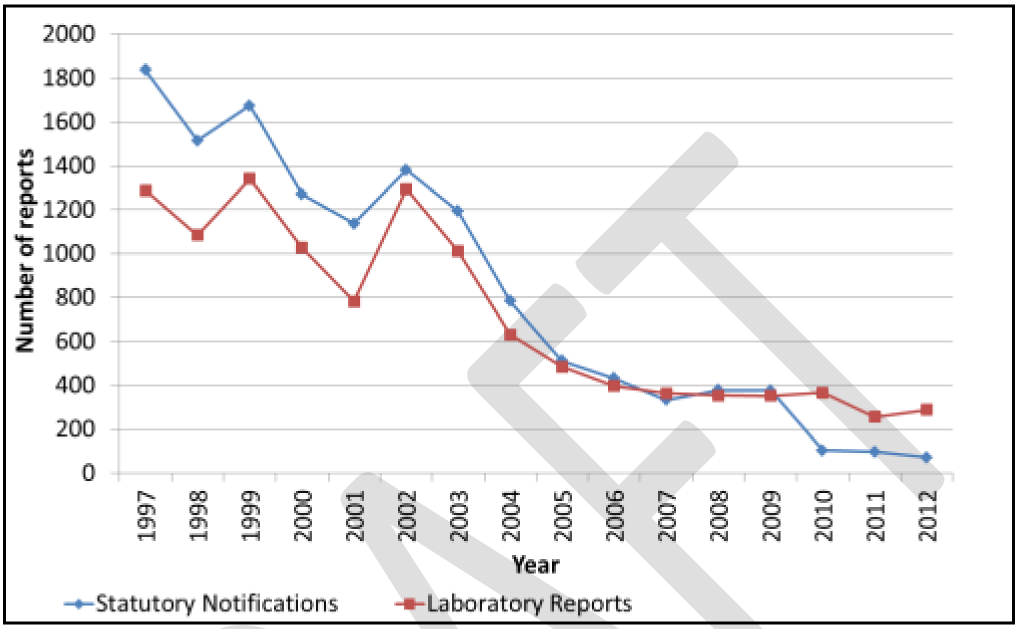
Recently it has been suggested that norovirus genetic diversity and genotype profiles can be used to differentiate foodborne from non-foodborne outbreaks (Verhoef *et al*, 2009) and to discriminate between foodborne outbreaks linked with transmission via food handlers from those associated with food contaminated at source (Verhoef *et al*, 2010). These studies suggest that (a) GII-4 strains are less likely to be associated with foodborne outbreaks and are more often associated with person-to-person transmission and (b) that strains other that GII-4 are more often found in bivalve shellfish, one of the most frequently recognised sources of foodborne outbreaks (Hughes *et al*, 2007; Gormley *et al*, 2010).

Foodborne outbreaks associated with the consumption of shellfish or other foods contaminated with sewage are often associated with multiple strains of norovirus, including genotype GII-4, among the people implicated in the outbreaks (Gallimore *et al*, 2005a; Gallimore *et al*, 2005b), whereas in outbreaks associated with transmission via a food-handler, the same strain is often found in all involved, including the food-handler (Daniels *et al*, 2000; Sala *et al*, 2005; Vivancos *et al*, 2009).

4.2 Hepatitis A

Hepatitis A virus infection is unusual in the UK (Figure 1) and reports of infection have fallen substantially over the last decade.

Figure 1: Hepatitis A laboratory reports and statutory notifications, England and Wales, 1997-2012



Source: Public Health England

However, susceptibility to Hepatitis A infection in the population is high. In a recently published survey of the seroepidemiology of hepatitis A in 10 European countries more than 80% of the population in England aged over 30 years was susceptible to hepatitis A infection (Kurkela *et al*, 2012). Analysis of HAV seroprevalence by birth cohort demonstrated that endemic circulation of HAV continued in England until the early 1960s. In other countries of low endemicity in Europe, outbreaks related to contamination from food and/or food handlers have been reported so that continued vigilance to prevent contamination of food is required (Pebody *et al*, 1998; Prato *et al*, 2006; Schenkel *et al*, 2006; Robesyn *et al,* 2009).

4.3 Hepatitis E

In the UK, between 1996 and 2003, 17 (9%) of 186 serologically confirmed cases of Hepatitis E were acquired in the UK. These non-foreign travel associated cases were older men infected with the genotype 3 (porcine) strain. Since 2010 numbers of cases have increased substantially and, in 2012 the total of laboratory confirmed cases was 579 ((http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/HepatitisE/Surveillance/). Non-travel cases accounted for the majority (64%) of cases in 2011/12 compared with an average of 43% of cases between 2004 and 2011. Over 60% of the non-travel cases were in men over 50 years of age.

In the south west of England hepatitis E infection was found to be more common than hepatitis A infection (Dalton *et al*, 2008). Of 838 people tested for HEV, 28 who were positive were found to be cases of locally acquired hepatitis E. Of 4,503 people tested for HAV, 17 were found to be cases of locally acquired hepatitis A. Hepatitis E patients were significantly older than hepatitis A patients and were less likely to present with symptoms in the winter.

In response to the changing epidemiology of hepatitis E infection, PHE (formerly the Health Protection Agency) has undertaken a case-control study of sporadic HEV infection to investigate routes of acquisition in non-travel related cases. They concluded that infection with locally-acquired hepatitis E in England and Wales was associated with the consumption of processed (raw and ready-to-eat) pork products (Said *et al*, 2013). In a systematic review and meta-analysis of hepatitis E virus occupational exposure to swine was found to be a more important route of transmission to humans than eating contaminated pork (Wilhelm *et al*, 2011). However, this finding is unlikely to explain the change in the epidemiology of acute hepatitis E infection that has been witnessed in the UK.

We conclude that:

- Although the IID2 Study provided valuable information on the overall burden of norovirus, the proportion of norovirus transmitted by food is still uncertain.
- Pork products have been implicated in foodborne hepatitis E infection in the UK and abroad. However, the burden of HEV transmitted by food, including pork and pork products, is still uncertain.

We recommend that:

	Recommendations that Inform Risk Assessments*	**Lead department/s**
R4.1.	Further research is undertaken to estimate the contribution of foodborne transmission to the burden of enteric virus disease and to identify the most important foods	FSA/PHE Joint
R4.2.	Further studies are undertaken to identify sources, and risk factors for HEV infection and the role of the food chain in transmission.	PHE

* The recommendations have been separated into those that we consider will ***inform risk assessments*** and those that will ***impact on risk assessments***. For recommendations that inform risk assessments we have identified the lead Department.

5. Routine surveillance and investigation of foodborne viruses

5.1 Statutory notifications

“Food poisoning” is a legally notifiable infection under the Health Protection Regulations 2010. Notifications are made to the local Health Protection Team (HPT) because Consultants in Communicable Disease Control working for the team are usually the nominated “Proper Officers” for the local authorities in the area for this purpose. Formal notifications are made by clinicians seeing patients with a diagnosis of food poisoning, although anyone else including members of the public, other health care professionals and environmental health officers may informally make the HPT aware of suspected case(s) of food poisoning. There has been a steep fall in the numbers of food poisoning notifications since the 2010 regulations were introduced – from 72,649 in 2002 to 24,362 in 2011. Recent changes in interpretation of the regulations, such that a formal notification on paper is not required, may overcome this.

The 2010 regulations also placed a duty upon laboratories to report specified positive results, including those relating to organisms likely to cause food poisoning. *Campylobacter* and *Salmonella* spp. are included in the list, as are HAV and HEV, but other viruses, in particular norovirus, which is one of the commonest causes of gastroenteritis outbreaks, (some of which are food related) are not.

Notification should be on clinical suspicion, but frequently awaits a positive laboratory result some days after the patient first presents to medical care. This makes follow up more difficult as patients have to remember what they ate and where they did so days or weeks in the past in order to aid investigation. Furthermore, the meaning of “food poisoning” is not clearly defined. It is a matter for the judgement of the clinician seeing the patient. Although some infecting organisms are usually foodborne, and others are usually transmitted by person-to-person spread, this is by no means an absolute distinction. So far as viral causes of gastroenteritis are concerned, apart from rotaviruses, the limited availability of resources and the expense of the necessary investigations mean they are not usually carried out on sporadic cases, i.e. those not linked to outbreaks.

The investigations carried out on receipt of a notification are a matter for individual local authorities and their advisers in health protection units. This varies throughout the country. Attempts have been made to develop a standardised questionnaire[3] but this appears not to have been widely adopted yet. An audit of 9,595 notifications showed that only 62 resulted in any public health action including visiting suspect premises or identification of an outbreak not otherwise ascertained (Personal communication). If the aim of investigating sporadic cases is to provide public health benefit by establishing the underlying cause(s) of food poisoning and identifying

[3] http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1296687054255

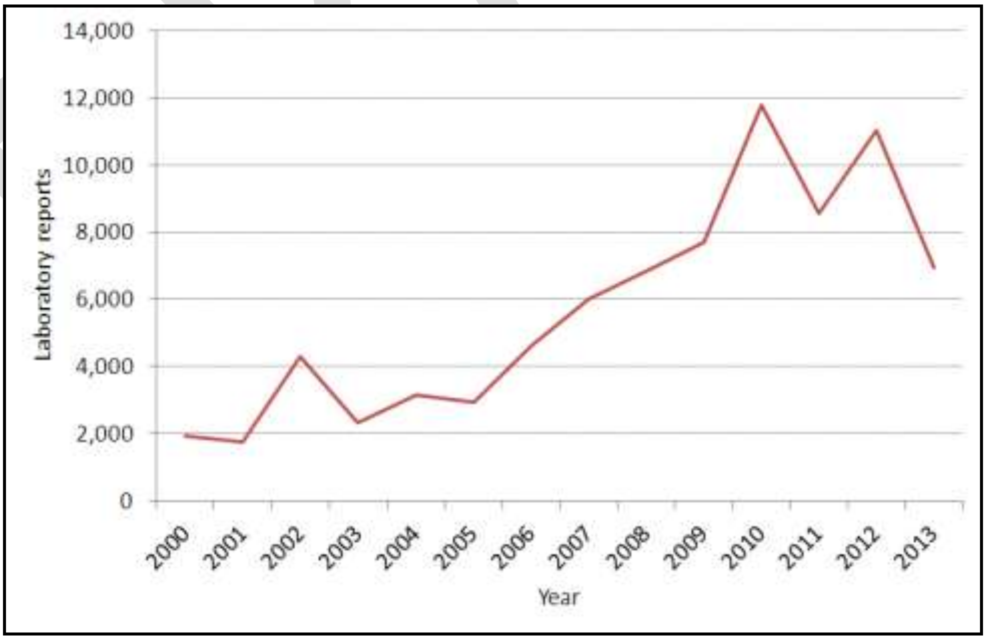
outbreaks which would not otherwise be recognised, there is little evidence that this occurs. Although individual organisations may undertake some analysis, there is no mechanism for co-ordinated analysis of returned questionnaires to detect multiple cases associated with a common food service or even identify which are most likely to be acquired through food rather than spread from person to person.

5.2 Laboratory-based surveillance

5.2.1 Norovirus

Figure 2 shows the trend in norovirus reporting in England and Wales between 2000 and 2012. However, routine, laboratory-based surveillance is considered to be of limited use for assessing disease burden for norovirus in the absence of calibration through the use of population-based studies. This is because of extensive under-ascertainment of foodborne viruses, as evidenced by the IID2 Study (Tam *et al*, 2012a). Only 4% of people infected with norovirus present to primary care because the illness is generally mild and self-limiting. Furthermore, outbreak-based diagnostic testing algorithms in many clinical laboratories severely limits laboratory-based surveillance as a useful source of information for estimating burden of illness in the absence of supplementary epidemiological investigations (O'Brien, 2008).

Figure 2: Trend in norovirus reporting in England and Wales between 2000 and 2013



Source: Public Health England

5.2.2 Hepatitis A

Figure 1 (see Section 4.2) shows the trend in laboratory-confirmed hepatitis A infections in England and Wales, which has been falling for the last decade and closely mirrors statutory notifications.

5.2.3 Hepatitis E

As noted in Section 4.3, laboratory-confirmed cases of hepatitis E infection have been increasing in England and Wales.

5.3 Surveillance of outbreaks

Many countries collect data on foodborne disease outbreaks. Since norovirus often presents as an outbreak-related disease, surveillance of outbreaks of norovirus should provide good insight into modes of transmission and the food vehicles associated with foodborne outbreaks. However, like routine, laboratory-based surveillance outbreak surveillance systems may be biased towards bacterial pathogens because bacterial pathogens are more likely to produce symptoms that cause people to present to health services.

Foodborne transmission of norovirus can result from foods becoming contaminated in kitchens and processing plants via direct or indirect contamination from food handlers working while they are excreting the virus or from foods such as oysters and produce becoming contaminated with human faeces prior to harvesting. Control of foodborne norovirus infection therefore requires different intervention strategies. Outbreak surveillance provides some useful information on the relative importance of foodborne transmission due to these separate mechanisms.

National surveillance data from England and Wales show that 16% (47/295) of foodborne outbreaks of norovirus reported between 1992 and 2012 were attributable to pre-harvest contamination of foods (all oysters).

Where data on norovirus are collected the predominant mode of transmission tends to be identified as person-to-person and healthcare settings stand out as those most affected in outbreaks (Blanton *et al*, 2006). In a European survey of countries that conduct broad-based outbreak surveillance, the proportions of viral gastroenteritis outbreaks that were associated with food- or waterborne transmission were: - Finland (24%), the Netherlands (17%), Slovenia (14%), Spain (7%) and England and Wales (7%) (Lopman *et al*, 2003). In the survey, laboratory evidence (detection of the same organism in the vehicle and stool specimens) or analytic epidemiological evidence (from case-control or cohort studies) that demonstrated the association between the suspected food vehicle and illness was rare. The survey illustrates the degree of uncertainty that surrounds foodborne attribution with respect to norovirus.

More recently, of 2.7% (N=61) of 2,228 outbreaks of norovirus reported in the UK between 1 January 2001 and 31 December 2008 were judged to be foodborne.

However, this is likely to be an underestimate because norovirus outbreaks frequently go undetected (only 4% of people affected by norovirus present to general practice (Tam *et al* 2012a)). Anecdotal evidence from recent investigations into foodborne norovirus in various parts of England suggests that people affected in outbreaks were reluctant to provide specimens and histories to investigators. It has also been suggested that the role of foodborne transmission in institutional outbreaks might be underestimated because many of those associated with nursing homes and schools are not investigated.

Between December 2012 and April 2013 the Incidents Branch at the FSA logged around 50 incidents related to oysters. It is not known is how many of the incidents logged by the FSA meet the EFSA definition of a foodborne outbreak and whether or not they had been brought to the attention of, or investigated by, health protection organisations. It is essential to join up the various data sources to be able to improve ascertainment, and timely investigation, of norovirus outbreaks acquired through the food chain or attributable to different food commodities.

Until norovirus diagnostics are widely applied, clinical and epidemiological criteria, known as Kaplan's criteria (Kaplan *et al*, 1982), can be applied to outbreaks to determine the likelihood of a viral aetiology. Turcios and colleagues (2006) reviewed 4,050 outbreaks reported to the Centers for Disease Control and Prevention in the US to examine how well clinical and epidemiological profiles discriminated between foodborne outbreaks of gastroenteritis due to norovirus and those due to bacteria. They also estimated the proportion of reported outbreaks that might be attributable to norovirus. They concluded that Kaplan's criteria were highly specific (99%) and moderately sensitive (68%) in discriminating confirmed outbreaks due to bacteria from those due to norovirus and that at a minimum, 28% of all the foodborne outbreaks reported could be attributed to norovirus on the basis of those criteria. However, not all surveillance systems capture sufficient clinical or epidemiological information to be able to apply these criteria as a matter of routine.

Extrapolating information from outbreak datasets to assess foodborne norovirus burden is very difficult. Outbreak cases might not be representative of all cases in the population either in terms of their illness (only the more severe case present to a GP) or in terms of food or other exposures. Since there have been very few population based studies of infectious intestinal disease similar to the IID studies (Wheeler *et al* 1999, Tam *et al* 2012a) and Sensor (de Wit 2003) it is difficult to put national outbreak data from most countries into a community context. However, an estimate of 11% by Adak *et al.* (2002), which used outbreak data to determine the proportion of norovirus that was foodborne was closer to that of a 12% estimate by de Wit *et al.* (2003), which employed a case-control study, than either were to two US estimates of 40% (Mead *et al*, 1999) or 25% (Scallan *et al*, 2011). Further support for estimates closer to those of Adak and de Wit came from a review of outbreaks of norovirus in Switzerland in which 13% of outbreaks were foodborne (Fretz *et al*, 2005). Yet if Widdowson *et al.* (2005) are right, the proportion of norovirus outbreaks that are foodborne might be as much as 50%. This illustrates further the degree of uncertainty that surrounds foodborne attribution with respect to norovirus, due, in part, to the fact that different administrations conduct surveillance in different ways. Clearly the proportion that is chosen is affected enormously by the surveillance system which yields the data and, in turn, affects greatly the estimate of the total burden of foodborne norovirus and, indeed, foodborne disease as a whole (O'Brien, 2008). Furthermore, since norovirus is highly infectious, secondary and tertiary cases may result from an initial foodborne insult, so that the total proportion of norovirus burden that might be reduced by eliminating foodborne transmission may be greater than the burden of primary cases alone. However, it is impossible to quantify this at present.

5.3.1 Outbreak tracking

The ability to link individuals, animals, certain food products or environmental contamination to an outbreak is becoming increasingly possible through the use of molecular techniques. Detection of viruses by PCR or RT-PCR followed by nucleic acid sequencing allows phylogenetic analysis to determine the relatedness of virus strains isolated from the patient, animal, food or the environment. Next generation sequencing may provide further insight into foodborne and environmental routes of contamination. The potential of these techniques for characterisation of multiple contaminating virus strains maybe useful for outbreak investigation and food attribution, e.g. the possibility of demonstrating a sewage contamination event through the identification of multiple strains.

Currently Noroviruses are genotyped on the basis of sequence differences within the capsid region and the RNA polymese region (green).

Greater discrimination to enable tracking within Genotypes has been described for G11-4 Noroviruses. This is based on capsid sequence on the P2 domain which contains most variation (Sukhrie F, 2010, 2013).

Methods for sequencing the whole genome are becoming available and these offer the potential for more precise linking of cases to contaminated food.

Phylogenetic analysis of the HEV genome has been used to link human and animal disease (Bouquet *et al*, 2011), individuals to a foodborne HEV outbreak (Said *et al*, 2009), to show the relatedness of HAV strains found in clinical samples and the environment (Kokkinos *et al*, 2010) and to identify individuals linked in norovirus outbreaks (Xerry *et al*, 2010), for example detecting hygiene failures in food premises where a sick food handler has been working when ill.

5.4. Outbreak investigation

Under Directive 2003/99/EC there is a responsibility for competent authorities to investigate food-borne outbreaks with designated authorities (Article 8). Public health agencies and local authorities have an obligation in law to investigate and report foodborne outbreaks. Public Health England is responsible for collating and assessing epidemiological information on foodborne outbreaks in collaboration with stakeholders in Scotland, Wales and Northern Ireland. There is an obligation to transmit these data to the European Commission each year.

Outbreaks of suspected food poisoning should be reported to the local authority environmental health department and the health protection team of PHE and equivalent bodies in the devolved administrations. This is important to initiate timely action to prevent further primary cases and secondary spread, trace potentially contaminated food items and learn the lessons from poor catering practices. In addition to the duties on local authorities to inform FSA of all serious or large outbreaks of food borne disease[4] there is also a duty on food business operators to immediately notify the competent authorities (their local authority and FSA) of a suspected outbreak or infection which has rendered food unsafe or injurious to health.[5] (See further below).

Current health legislation[6] relates to individuals, premises or things made but not to clusters of cases unless an organism has been identified or clinicians have made a diagnosis of food poisoning. This can result in substantial delays in initiating control measures[6] with the potential for continuing spread of disease.

Although FSA has produced general guidance on investigation of food poisoning outbreaks, the degree to which an outbreak is investigated at all is a matter for the local authority and Health Protection Team. In the early stages of an outbreak of gastroenteritis it may not be clear whether it is caused by contaminated food item(s) or person to person spread. This is a particular problem with norovirus, the commonest cause of infectious gastroenteritis, where explosive outbreaks caused by person to person spread have an epidemic curve similar to that of a point source. The large number of cases and outbreaks in hospitals and care homes particularly during the winter months has threatened to overwhelm investigative capacity at peak times. These outbreaks are widely assumed to be person to person spread and investigation of possible food vehicles may be minimal. Thus the role of foodborne transmission in hospitals and care homes is poorly understood.

Where a catering establishment is involved and spread is likely to be foodborne there has been confusion about when to notify the local authority before any control

[4] http://www.food.gov.uk/multimedia/pdfs/codeofpracticeeng.pdf
[5] under Article 19 of the EU General Food Law Regulation(Regulation (EC) No 178/2002)
[6] The Health Protection (Notification) Regulations 2010

actions are taken or to preserve suspect food items for examination. An outbreak of foodborne illness is evidence that the food business in question has placed unsafe food on the market and it, thus, has an obligation to report the matter under the EU General Food Law Regulation, Article 19(3) and (4) of which states: "(3) A food business operator shall immediately inform the competent authorities if it considers or has reason to believe that a food which it has placed on the market may be injurious to human health. Operators shall inform the competent authorities of the action taken to prevent risks to the final consumer and shall not prevent or discourage any person from cooperating, in accordance with national law and legal practice, with the competent authorities, where this may prevent, reduce or eliminate a risk arising from a food. (4) Food business operators shall collaborate with the competent authorities on action taken to avoid or reduce risks posed by a food which they supply or have supplied". The competent authorities in this context are the food business operator's local authority and FSA. Further guidance on notifications under Article 19 is available[7].

Catering establishments attempting to carry out their own investigations can seriously hamper public health actions. These issues have been well described[8]. This again makes determination of the cause of an outbreak more difficult to ascertain, and thus will decrease the number ascribed to food poisoning from any cause including viruses.

However, even when reporting is prompt and investigation thorough, establishing the contribution of food poisoning to the burden of illness is fraught with difficulties. Large and complex analytical studies, such as that in the outbreak cited above, where food(s) known to be contaminated with pathogenic viruses at source are involved it may not be possible to say with any certainty what proportion of cases were a result of consumption of the implicated foods. Some cases may have been caused by cross contamination to other foods, some by person to person spread and some directly from the environment.

Health Protection organisations in the UK collect datasets on all outbreaks of suspected food poisoning reported to them in accordance with specifications developed by the European Food Safety Authority. Reports are collected for those outbreaks where investigators find evidence of foodborne transmission of infection. Outbreaks reported to other agencies including local authorities, Cefas and Defra will not be included unless also reported to the Health Protection organisations. In some cases communication difficulties may delay or prevent effective public health action as the legal powers for investigation and control rest with local authorities.

[7] http://food.gov.uk/multimedia/pdfs/fsa1782002guidance.pdf, paragraphs 52-53 and online reporting form: http://www.food.gov.uk/policy-advice/incidents/report/

[8] http://www.hpa.org.uk/NewsCentre/NationalPressReleases/2009PressReleases/090910FatDuckReport/

There seems to be variation across the country about the extent to which viral outbreaks are investigated so that in many incidents where a viral aetiology is suspected full investigations are not performed. This appears to be due primarily to a general (and growing) lack of resources at the local authority level. Other contributory factors are said to be:-

- lack of access to, or lack of submission of samples for, testing for viruses (both clinical and food samples)
- in small outbreaks insufficient numbers of ill individuals to allow robust association with a food vehicle
- the unwillingness of individuals to contribute faecal samples for analysis, the time and effort required to instigate outbreak management teams and to write up and submit outbreak investigation reports

We conclude that:

- Currently the burden of foodborne illness associated with norovirus is likely to be an under-estimate. The impact of foodborne transmission in health and social care settings, in particular, may be higher than is currently recognised because the possibility of foodborne transmission in these settings is likely to be under-investigation. Variation in the extent to which potential foodborne outbreaks are investigated also militates against a good understanding of the scale of foodborne transmission.
- Next generation sequencing may provide further insight into foodborne and environmental routes of contamination.
- Multiple agencies at local, regional and national level across the UK are responsible for public health surveillance but other organisations also hold relevant data and this information needs to be coordinated.
- Current legislation appears not to be applied by all food business operators e.g. in relation to notifying suspected foodborne enteric virus outbreaks immediately to allow the relevant statutory authorities to perform a thorough public health investigation.
- Failure by any food business operator to report immediately to the competent authority "when it has reason to believe that a food it has placed on the market is injurious to human health" constitutes a criminal offence[9].
- In almost all incidents where a viral aetiology is suspected proper investigation is not performed.

[9] See http://food.gov.uk/enforcement/regulation/foodlaw/ and Regulation 4 of the General Food Regulations 2004, SI 2004 No.3279.

We recommend that

	Recommendations that Inform Risk Assessments*	Lead Department/s
R5.1	Reliable methods for Norovirus WGS should be established so its use to track transmission of norovirus and attribute potential food vehicles/sources in outbreaks should be investigated. The value of WGS to link food stuff, infected cases, food handlers for Norovirus, Hepatitis A, and Hepatitis E should be defined.	PHE with FSA support
R5.2	Public health agencies need to work together and with other relevant organisations to develop a single, integrated outbreak reporting scheme, (this was previously recommended in the 1998 FVI report) involving all aspects of enteric virus transmission through the food chain. In the meantime we reiterate recommendation R3.1 from the 1998 Report that all relevant authorities who maintain outbreak records (PHE and equivalents in devolved administrations, FSA, local authorities, other Government laboratories and agencies) should contribute to an annual reconciliation and consolidation of outbreak records. PHE, and equivalent authorities in devolved administrations, should take the lead on this activity. In the absence of a reconciled system the impact of food related viral illness and outbreaks will continue to be under-estimated.	PHE, with Defra and FSA
R5.3.	Studies are required to investigate the best way(s) of gathering and analysing information from sporadic cases of suspect food poisoning to ensure public health benefit without wasting scarce resources. For example, the FSA should consider funding a local or regional pilot study to elicit the costs and benefits of developing a sentinel surveillance system for investigating foodborne enteric viruses.	PHE with FSA
R5.4.	Viral foodborne outbreaks should be reviewed periodically (e.g. annually) to evaluate lessons learned, to identify any reoccurring problems or issues, and to review the effectiveness of control measures and potential improvements.	PHE with Defra and FSA
R5.5.	National surveillance of foodborne viruses should include	PHE

	the foodborne component of hepatitis A and hepatitis E.	

	Recommendations that Impact on Risk Assessments*
R5.6	*The FSA reviews its guidance to local authorities and all food business operators, including caterers, to clarify their legal obligations to notify immediately "when it has reason to believe that a food it has placed on the market is injurious to human health".*
R5.7	*All food business operators, including caterers, need to be reminded of their duty to inform competent authorities immediately (Local Authorities and, when appropriate, the FSA) they suspect a foodborne virus outbreak so that appropriate public health investigations are not hampered by destruction of evidence before EHOs have been alerted to a problem.*
R5.8	*The FSA's 2008 Guidance on the management of foodborne illness[10] should be updated and the latest information on norovirus incorporated. These Guidelines need to ensure that investigations of suspected foodborne outbreaks are consistent. They should incorporate advice on the use of new virological tools to detect viruses in the environment and in food matrices. The Guidelines need to define when it is appropriate to investigate a potential foodborne virus outbreak and, if investigation is performed, the minimum dataset of evidence required for recording a foodborne outbreak in national surveillance systems.*

* The recommendations have been separated into those that we consider will ***inform risk assessments*** and those that will ***impact on risk assessments***. For recommendations that inform risk assessments we have identified the lead Department.

[10] Management of outbreaks of foodborne illness in England and Wales. FSA 2008. http://www.food.gov.uk/multimedia/pdfs/outbreakmanagement.pdf

6. Contamination of food

Viruses are closely adapted to their hosts and generally only replicate in the cells of their host species. Viral contamination of food is either through primary contamination or through secondary contamination. Primary contamination is when the virus replicates within an animal, products from which are then consumed without the virus being inactivated. This type of zoonotic infection is rare. Indeed only a few documented examples are known, such as tick borne encephalitis (TBE) virus. This is excreted in the milk of infected sheep and goats and consumption of the raw milk has been linked to human infection. The most important source of foodborne viral infection is through secondary contamination of food either through sewage contamination of waters used for growing bivalve molluscs or in the production of fresh produce, or through direct contamination of food during preparation and harvesting.

The most significant infection posing a direct risk through the food chain is HEV. Genotype 3 and 4 HEV infection is widespread in European pigs. The virus has been demonstrated in pork products and linked to human infection through consumption of a range of these products. The relative importance of this route of transmission compared with human-human transmission and through direct contact with infected animals is not yet established.

The most important source of foodborne viral infection is through secondary contamination of food either through sewage contamination of waters used for growing bivalve molluscs or in the production of fresh produce, or through direct contamination of food during preparation and harvesting.

Norovirus is the virus most commonly implicated in foodborne transmission. However, data on food attribution tend to be fairly sparse. In two expert elicitation studies carried out in the Netherlands and Canada, that included foodborne norovirus, the highest proportions of illness were attributed to fish and shellfish and fresh produce (Table 4), (Havelaar *et al*, 2008; Davidson *et al*, 2011). In the Dutch study the contribution of infected food handlers (51%) was considered to be very high. Infected food handlers were not considered in the Canadian study.

6.1 Food chain management

Common risks are seen across the food supply chain with poor hygiene and illness at work or in the home occurring frequently. Cross contamination of food by other food stuffs, or from environmental surfaces, including poor decontamination following high risk food handling, are also common.

Table 4: Estimated fraction (%) of norovirus transmitted by food commodity

Food commodity	Netherlands	Canada
Beef	3	2.6
Pork	3	2.2
Poultry	3	2.1
Eggs	2	0.85
Dairy	2	2.4
Fish and shellfish	16	34
Fruit and Vegetables (Produce)	7	30
Beverages	3	1.1
Grains	5	-
Composite foods	5	7.4
Infected humans or animals	51	-

6.2 Shellfish

6.2.1 Bivalves

Bivalve molluscs are filter feeders that process large amounts of seawater to obtain their food. Bivalve molluscs commonly sold as food in the UK include oysters, mussels, clams, cockles and scallops. During filter feeding bivalves accumulate a wide variety of micro-organisms potentially including, if present, human pathogens. Since there are no known animal reservoirs for HAV or for norovirus strains that infect humans, contamination of bivalves with these pathogens is always associated with human faecal pollution in some form. Contamination of bivalves with human pathogens through faecal pollution of their growing areas has been recognised as an important public health issue in the UK for more than 100 years (Dodgson, 1928). Currently, world-wide, norovirus and HAV infections feature as an important cause of public health incidents associated with bivalve shellfish consumption. Zoonotic viruses shed via the faecal oral route, particularly from agricultural animals, also have the potential to accumulate in bivalve molluscs and indeed this has been demonstrated for hepatitis E virus in the UK (Crossan *et al*, 2012). However, an epidemiological linkage with human illness has yet to be established for this possible transmission route in the UK (Ijaz et *al*, 2005, Lewis *et al*, 2005). Since pathogens are accumulated during filter feeding they are concentrated primarily in the bivalves' digestive system. Consequently bivalve species that are eviscerated prior to sale or consumption, for example scallops, present a low risk of infection. The other major risk factor is whether bivalves are cooked (either commercially or in the home or restaurant) prior to consumption. Species that are commonly eaten whole and raw (e.g. oysters) present the highest risk whereas species that are eaten whole but commonly cooked (e.g. mussels, cockles and clams) present a lower risk. However, the protection offered by cooking also depends on the properties of the virus with HAV being more robust and requiring thorough cooking for effective inactivation (Millard *et al*, 1987). The degree and level of control of cooking is a significant risk factor with, for example, products subject to well controlled commercial cooking presenting a low risk. For all products the risks may be mitigated by harvesting from areas with good water quality and, to a lesser extent, by post-harvest processing interventions. The latter include self-purification of bivalves in tanks of clean seawater following harvest – a process termed depuration, relaying, cooking, high pressure processing (HPP) and other techniques (e.g. smoking, freeze drying) (Richards *et al*, 2010). In the UK, the shellfish industry have traditionally used depuration, relaying and approved heat treatment processes (since these are required by regulation) and therefore there is little evidence as to the extent to which other methods would enhance shellfish safety. It should be noted that only depuration, relaying and HPP can satisfy consumer demands for raw bivalves.

6.2.2 Faecal contamination of shellfish production areas

It is fundamentally important to protect and improve the water quality of coastal areas intended for the harvesting of shellfish for human consumption since most post-harvest processing methods are not effective in reducing virus contamination of shellfish (see below). Sources of faecal contamination in bivalve shellfish harvesting areas can be diverse but frequently includes: continuous pipeline discharges of municipal sewage; periodic (intermittent) untreated discharges from combined surface water/foul sewage systems (combined sewer overflows, storm tank overflows); leaks from ageing or poorly maintained sewerage infrastructure; smaller discharges from individual properties e.g. septic tanks and discharges from boats and water courses (e.g. rivers, streams etc.) entering the harvest area that have been contaminated higher in the catchments. Urban runoff often includes sewage contamination from human and animal sources. Faecal pollution from non-human sources is even more diverse and includes: agricultural run-off from livestock fields and buildings; discharges from slurry pits; manure spreading; wildlife (e.g. birds and marine mammals) and pets etc. (Garreis, 1994). Faecal pollution associated with the application of human sewage sludge to land also represents a potentially significant source, especially where this takes place in close proximity of shellfish harvesting areas.

The risks from individual sources are associated with the densities of human and animal populations, the existence of hydrological connections between these and the shellfish harvesting areas, and the microbiological content and volume of the discharges (Campos *et al*, 2013). In relation to human enteric viruses it is clear that reduction of inputs of faecal contamination from human sources of pollution should be prioritised since these often contain viral pathogens in significant numbers (Cantalupo *et al*, 2011). Assessments (termed sanitary surveys) of the sources and types of faecal pollution have now been performed for many shellfish waters (see below). It is clear from these surveys that many shellfish production areas are subject to impact from human pollution sources, including municipal discharges. Key risk factors for norovirus contamination are the level of treatment of discharges, the proximity to shellfish beds, the degree of dilution and dispersion received by the discharge, and the capacity to store storm sewage to prevent the operation of combined sewer overflows (CSOs).

Since even sewage subject to modern biological (Henshilwood, 2002; da Silva *et al*, 2007; Lowther, 2011; Palfrey *et al*, 2011) or filtration (Nenonen *et al*, 2008) treatment may contain high concentrations of norovirus, it is clear that large continuous municipal discharges in close proximity to harvested commercial beds present a very significant risk factor for norovirus contamination. For UV disinfected discharges (commonly used in the UK) this risk may not be apparent through monitoring of faecal indicator bacteria in shellfish because of the differential behaviour of these organisms and viruses (Wyn-Jones *et al*, 2011). In the majority of shellfish associated norovirus outbreaks in the UK bivalves are harvested from officially classified waters impacted by continuous and intermittent sewage discharges. It would seem a sensible control measure to prevent harvesting of bivalve shellfish in proximity to such discharges.

Since CSO overflows are essentially untreated sewage (diluted with rainwater) there is an increasing awareness of the importance of this source of contamination for norovirus. Research in this area suggests that CSOs may be the dominant source of faecal contamination during high-flow conditions (Wither *et al*, 2005; Stapleton *et al*, 2008; Crowther *et al*, 2011). This risk is further emphasised by the increase in extreme rainfall events in recent years – possibly climate change associated – which has revealed the insufficient capacity of many sewage treatment plants to treat the increased flows and the possibility of gross contamination events associated with flooding, sewer rupture and operation of emergency overflows.

Overboard discharges from boats are a well-recognised source of faecal contamination leading to norovirus outbreaks (CDC, 1997). Since moorings, anchorages and marinas are frequently found in the close proximity of shellfish production areas this is a significant risk that, in the UK at least, is mostly unregulated. Experiences in the USA have demonstrated that faeces from a single individual disposed overboard can contaminate an area 1 mile away with infectious quantities of norovirus (California Department of Health Services, 1998).

Septic tanks from individual dwellings, or small groups of dwellings, if discharging direct to the watercourse or where poorly maintained, can represent a potentially significant point source locally. Septic tanks may also contribute an important diffuse source in the wider catchment of some harvesting areas. Septic tank discharges may have a similar microbiological impact to primary-treated effluent and may contaminate surface waters with norovirus sufficiently to cause human illness (Cook *et al*, 2009). These small discharges may present a significant risk of norovirus contamination in less densely populated areas.

In summary, the highest risk of norovirus contamination is associated with continuous discharges from municipal sewage treatment works and with their associated storm overflows. In the absence of significant sewage treatment work effluents impacting the shellfishery, storm water discharges may be the largest single contributor to norovirus contamination in urban catchments with aging combined sewerage infrastructure. In rural catchments local septic tanks discharges may be a significant source of norovirus contamination. Overboard discharges from boats are a significant, largely unregulated, norovirus risk in many shellfisheries. Extreme weather events pose new risks from flooding, sewer rupture and operation of emergency overflows.

6.2.3 Protection for shellfish waters against faecal pollution

In the EU the quality of municipal sewage discharges is controlled through the Urban Wastewater Treatment Directive (UWWTD), (European Communities, 1991). This Directive requires the collection and provision of secondary treatment in urban areas (agglomerations) with more than 2,000 population equivalent (p.e.)[11] and 'more advanced treatment' (e.g. disinfection by UV or membrane filtration) for agglomerations with more than 10,000 p.e. in the hydrological catchments or for 'sensitive waters'. Sensitive waters are defined as estuaries, bays and other coastal waters where there is poor water exchange with the ocean and which are therefore susceptible to eutrophication. For this reason, a recommendation of the previous ACMSF report in this area (ACMSF, 1998) was that all shellfish production areas should be designated as 'sensitive waters' to ensure they received 'more advanced treatment'. This would potentially have reduced the risk from norovirus contamination. The UWWTD does not set any minimum treatment levels for discharges from PEs of <2,000.

In addition to the UWWTD, protection is provided by the Shellfish Waters Directive (European Communities, 2006). This Directive is intended to protect coastal and brackish waters in order to support shellfish life and growth and thus to contribute to the high quality of shellfish products edible by man. The Directive sets a guideline microbial standard which has driven significant sewage improvements both within the UK and in other EU countries. This Directive will be repealed and replaced by the

[11] Population equivalent is a term used in wastewater treatment equivalent to the organic biodegradable load which has a 5-day biochemical oxygen demand of 60g of oxygen per day.

Water Framework Directive (2000/60/EC) in December 2013. This Directive does not contain any specific microbiological standards for shellfish waters however it does require that the introduction of the legislation does not lead to any deterioration in water quality. This requirement is currently being considered and it is understood that the policy throughout the UK is to maintain a broadly comparable measure of environmental protection through the use of *E. coli* standards for designated water bodies. It is understood that in England and Wales Defra have given a commitment to maintain the guideline faecal indicator shellfish flesh standard set out in the Shellfish Waters Directive. Implementation of SWD policy, including ensuring appropriate protective measures are in place, is the responsibility of the Environment Agency in England, Natural Resources Wales in Wales, Scottish Environment Protection Agency in Scotland and Northern Ireland Environment Agency in Northern Ireland.

The Government has ensured that all significant commercial shellfish production areas are designated under the Shellfish Waters Directive. However, in 2012, only 34% and 15% of designated shellfish waters complied with the current guideline microbiological standard in England and Wales, respectively. In addition, a recent evaluation on temporal trends of *E. coli* in shellfish from England and Wales for the period 1999–2008 revealed that only 12% of the shellfisheries were showing a downward trend in average levels of the microbiological indicator (Campos *et al*, 2013). This low compliance rate reflects the faecal pollution challenges facing the majority of shellfish production areas which is confirmed by the low numbers of UK Class A production areas reported under the food hygiene legislation (see below). Since a correlation has been shown between average *E. coli* levels and norovirus risk (Lowther *et al*, 2012) clearly norovirus contamination levels seen in designated shellfish production areas (see below) would be likely to be reduced if more waters complied with the guideline microbiological values set out in the legislation.

In England and Wales Defra is responsible for determining the policy on protection of marine waters. The Environmental Agency (EA) is responsible for implementation of policy including ensuring that the necessary protective measures are in place and are appropriately monitored and enforced. Water Companies operate discharges according to an EA permitting scheme which species the level of treatment required and the volume of discharge permitted. In England and Wales, discharges of sewage effluent to shellfish waters are regulated under the Environmental Permitting Regulations 2010 (Statutory Instrument 2010, No 675). Under these, discharge operators (often water companies) must apply to the EA for a discharge permit which contains the conditions that the operator should meet in order to comply with the relevant legislative requirements. The EA has developed a policy for consenting discharges impacting shellfish waters, which recommends the use of advanced forms of sewage treatment for continuous discharges (usually UV disinfection) and reduction of the impact of storm overflows through spill volume and frequency controls (Environment Agency, 2003).

It seems clear that norovirus contamination in shellfish production areas (see below) could be reduced through the improvement of controls on human faecal pollution sources impacting such areas. A critical consideration is the discharge point for sewage discharges with protection best afforded by ensuring that discharge points and commercial shellfish areas are sufficiently well separated such that the discharge receives sufficient dilution and dispersion to minimise impact. This can be achieved by relocating the discharge or by preventing harvest of molluscs in the proximity of the pipe. Providing advanced forms of treatment (e.g. disinfection) to municipal impacting shellfish beds discharges may also assist (note: many discharges, but not all, do currently have UV disinfection). However, it is very important to ensure that such treatment is effective against norovirus as well as against bacterial faecal indictors to avoid aggravating the public health risks. Further research is necessary in this regard.

Government policy is that a designated shellfish water should not be impacted by more than 10 significant CSOs spills per year (agglomerated for all potentially impacting CSOs). Applications to the EA for new infrastructure developments need to demonstrate that the planned system can achieve this criterion. However, in practice many shellfish waters are impacted by many more than 10 CSO spills per year. Whilst Government policy is considered appropriate, the consequence of the focus of regulation on the design of the system, rather than on the actual spills occurring, means that systems can exceed their designed spill performance without any regulatory penalty. Furthermore, the absence of spill monitoring or reporting on most CSOs means that the risks cannot be accurately estimated or the risks controlled by measures such as short term closure of beds to harvest. A requirement for all CSOs impacting shellfish beds to be compliant in practice with Government policy on the number of spills permitted (<10 per year in agglomeration), to be monitored for operation and flow, and for spills to be reported such that food control risk management measures can be taken (e.g. temporary closure of areas), would potentially significantly enhance public health.

Regarding overboard disposal of faeces from boats, there is no national legislation in place in the UK. This risk could be substantially reduced by requiring provision of the use of holding tanks and shore based or floating pump out stations for moorings, anchorages and marinas in the proximity of shellfish beds – and then prohibiting overboard discharges in such locations. This is common practice in some European countries (e.g. France and the Netherlands) and in other countries such as the USA and New Zealand.

Regarding septic tanks it is noted that in England there is no requirement to register septic tanks at present unlike in Scotland, Wales and Northern Ireland. In case of non-compliance with consent conditions, such discharges should be subject to investigation and programmes of remediation work similar to those applied to regulated discharges.

6.2.4 Food legislation

Worldwide, the management of the sanitary risk from bivalves is based on a combination of interventions, including harvesting area management, post-harvesting management practices and education and public awareness. In the EU there are specific provisions within food hygiene legislation as described below. However, worldwide, these controls rely on traditional bacterial indicators of faecal pollution (*E. coli* in the EU).

6.2.5 Controls at primary production

Risk management legislation for sanitary production of bivalve shellfish worldwide depends on assessment of the impact of such faecal pollution and then the prescription of food processing measures, if necessary, prior to placing the bivalves on the market. Legislative standards controlling permitted levels of faecal pollution worldwide utilise faecal indicator bacteria, for bivalve shellfish most countries employ either faecal coliforms or *E. coli*. These may be measured in the water column (USA system) or directly in the flesh of the bivalves (EU system). It is also possible to stipulate, on a precautionary principle, sea areas that should not be permitted for production based on the presence of known polluting sources such as sewage pipe discharges. However, this is not an explicit requirement of EU food legislation and is not currently the policy in the UK. The faecal indicator legislative standards governing commercial production of bivalve molluscs in the EU (and thus the UK), and in third countries importing into the EU, are summarised in Table 5. Competent Authorities in EU Member States are required to define the location and boundaries of production (and relaying) areas and to classify the areas according to one of the three categories set out in Table 5. They are further required to establish a sampling (monitoring) programme, which should be representative, to ensure that bivalve molluscs harvested from the area comply with the established classification. If bivalves do not comply with the criteria, the Competent Authority must close or reclassify the area. An essential first step prior to setting up a sampling programme is to survey the faecal pollution inputs, and their potential circulation within the production area, so that sampling points can be determined as representative according to scientific principles. This 'sanitary survey' has been a requirement of EU regulations since 2006. A comprehensive programme is underway in the UK to ensure that a sanitary survey has been performed for all commercial bivalve mollusc production areas by 2015. A sanitary survey provides an objective comprehensive assessment of the impact of pollution sources on the sanitary quality of bivalve shellfish production areas and also, thus, an ideal platform for any pollution remediation initiatives. Sanitary surveys for bivalve mollusc areas in England, Wales and Scotland are available in the public domain[12]. EU legislation does not contain

[12] http://www.cefas.defra.gov.uk/our-science/animal-health-and-food-safety/food-safety/sanitary-surveys.aspx

detailed rules for implementation of monitoring programmes – for example, key aspects, such as the required monitoring frequency, is not specified. However, the EU has recently established officially endorsed guidance[13] to assist Competent Authorities to achieve compliance with the legal requirements. In general the UK monitoring programmes are conducted in accordance with this guidance. The *E. coli* methods that may be used for monitoring are stipulated by EU legislation. The *E. coli* data generated from the monitoring programmes is available in the public domain for all commercial harvest areas in England, Wales and Scotland[14]. The classification status of each commercial production area is published by the FSA[15].

Table 5: Summary of EU sanitation requirements for live bivalve mollusc production areas[1]

EU Classification	Microbiological standard per 100g shellfish flesh and intravalvular liquid	Risk management measure required
Class A	all samples < 230 *E. coli*[2]	Non required
Class B	90%[4] of samples < 4600 *E. coli*	Depuration or relaying[1] or heat treatment by an approved method[3]
Class C	all samples < 46,000 *E. coli*	Relaying over a long period[1] or heat treatment by an approved method[3]

[1] Regulation 854/2004.
[2] Regulation 2073/2005.
[3] Regulation 853/2004.
[4] EC 1021/2008.

For the highest quality (class A) areas EU legislation does not require any further food processing to reduce the risk from faecal contamination. However, even such high quality areas are still occasionally associated with virus outbreaks (Maalouf *et al*, 2010a). For other more contaminated areas, the food processing measures required by legislation are either depuration (self-purification) in tanks of clean seawater, relaying (self-purification in the natural environment) or commercial heat treatment (cooking) by an approved method. Bivalve molluscs that do not conform to any of the classification categories (i.e. that exceed class C levels) cannot be classified and hence cannot be placed on the market for human consumption. In the

[13] http://ec.europa.eu/food/food/biosafety/hygienelegislation/good_practice_en.htm
[14] http://www.cefas.defra.gov.uk/our-science/animal-health-and-food-safety/food-safety/classification-and-microbiological-monitoring.aspx
[15] http://food.gov.uk/enforcement/monitoring/shellfish

UK such sites are designated as ‘prohibited’. The operation of depuration, relaying and approved heat treatment processes by food business operators is subject to further detailed legislative rules under EU Regulation 853/2004; this is further discussed below. In all cases following such treatments the end-product prior to marketing must comply with a standard of <230 *E. coli* per 100g of shellfish flesh and intravalvular liquid (EU Regulation 2073/2005).

A recent study by the EU Reference Laboratory[16] showed that 40% of EU production areas fall into the class A category and thus do not require post-harvest treatment. The figures for the UK as a whole were 27% class A, 64% class B, 7% class C and 1% prohibited. Thus, there is clearly potential to further improve the quality of UK shellfish production areas, in comparison to the wider EU, which would contribute towards reduction of risk for enteric viruses.

6.2.6 Virus contamination in primary production

Unfortunately, it is well documented that outbreaks associated with enteric viruses may occur despite the conformity of commercial production with the requirements of the above legislation. Thus, there is recognition by most regulatory authorities that viral contamination of bivalves is not currently sufficiently controlled. Importantly, this should not be misconstrued as suggesting that the current controls do not have any public health benefits. Currently in the UK (and in the EU) faecal bacterial causes of infection associated with bivalve consumption, such as salmonellosis, are at a very low level. There is good evidence that this is due to the effectiveness of *E. coli* as a bacterial sanitary indicator in predicting the general risk from bacterial faecal pathogens. A number of approaches to refinement of legislation to better address viral contamination issues are possible, including: further reduction of pollution of production areas through environmental measures; preventing bivalve production in the most high risk areas - such as in the immediate proximity of sewer outfalls; tightening of faecal indicator standards for harvest areas; improvement of depuration practices and direct standards for enteric viruses. EFSA have recently published two opinions concerning risk management approaches for viruses in bivalves and other food commodities which cover these options (EFSA, 2011; EFSA, 2012). A key recommendation was that that risk managers should consider the adoption of direct virus controls into EU food legislation through the setting of virus criteria.

A number of studies have examined enteric virus contamination of bivalve molluscs in near shore waters using PCR. Typically such studies have reported rather high prevalence and longer persistence of norovirus contamination in comparison with that of *E. coli*. Recently, more systematic surveillance studies have been undertaken for norovirus using the standardised ISO method. A comprehensive study in the UK (Lowther et al, 2012) reported that 76% of samples from classified commercial oyster

[16] Comparison of bivalve mollusc harvesting area classifications under EC Regulation 854/2004 across EU Member States (2009). Dated 11/4/2011. www.crlcefas.org.

areas were positive for norovirus with marked winter seasonality. In samples testing positive in the majority of cases (52%) levels were below the limit of quantitation of the assay. However, levels exceeded 10,000 virus genome copies per gram for a small number of samples. It was noted that sites varied markedly in the degree of norovirus contamination with some clearly presenting a consistently elevated risk – over the study period site specific geometric mean norovirus levels ranged from 50-2243 copies per gram. Enhanced risk management controls instigated at high risk sites clearly has the potential to benefit public health. The norovirus data from this UK surveillance study is consistent with the findings from *E. coli* monitoring data which shows a low percentage (27%) of the highest quality (class A) production areas under the EU food hygiene legislation and also a fairly low percentage (34% and 15% in England and Wales respectively) compliant with the guideline value of the Shellfish Waters Directive.

EFSA 2012 reported norovirus surveillance data for the UK, France and the Republic of Ireland. Compared with the UK France had, in general, lower levels of norovirus contamination and Ireland had higher levels. However, in respect of data from Ireland the report noted that data were not collected systemically and were biased towards problematical sites. The report evaluated the impact, in each of the three countries, of potential levels for norovirus controls. During winter months a low norovirus standard (e.g. 100 copies per gram) would fail between 34-83% of samples whereas a high standard (e.g. 10,000 copies per gram) would fail a relatively small number of samples (0-11%). The report recommended that risk managers should consider adopting a norovirus standard into legislative controls but did not suggest a particular limit.

6.2.7 Post-harvest controls

The risk management measures prescribed by EU legislation vary in their effectiveness for reducing virus risk. Commercial heat processing can be very effective if performed correctly and in the UK following the introduction of revised criteria (raising core mollusc temperatures to 90ºC for 90 seconds) hepatitis outbreaks from cockles harvested in the Thames estuary were bought under control (Lees, 2000). These cooking parameters (or their equivalent) are now an EU legal requirement for bivalve shellfish from class B or C areas placed on the market following heat processing under EU Regulation 853/2004. These controls, for this product, are considered to be effective and do not require any modification to improve health protection against enteric viruses.

The only alternative treatments permitted under EU legislation for class B or C bivalves molluscs placed live on the market are depuration and relaying. Both essentially rely on continuation of the normal mollusc filter-feeding processes using clean seawater to flush or purge out faecal contaminants. In EU regulations the distinction between treatments allowed for class B and class C products (class C products may not be depurated directly), reflects a long standing concern over the adequacy of depuration for successful treatment of more highly contaminated products – in particular those potentially contaminated with enteric viruses. Relaying is conducted in the natural environment for a comparatively long period; depuration (also termed purification) is performed in shore based tanks generally for a much shorter period. These processes, whilst effective at controlling bacterial infections (such as salmonellosis and typhoid), have been less effective for viruses. Depuration, in particular, is a widely used commercial process both in the EU and in the UK. Relaying is much less widely used both in the UK and elsewhere in the EU.

Molluscs need to be in good physiological condition to purify successfully. Hence, it is important to ensure that critical parameters such as temperature, salinity, oxygen levels etc. are well controlled. This creates a significant problem for regulation since there is insufficient knowledge of critical physiological parameters for the range of commercial species and habitats. Although, in line with general food law, depuration is required to be operated according to Hazard Analysis and Critical Control Point (HACCP) principles, the historic inability to measure virus contamination has left operators and authorities with little information on which to base virus removal criteria. In practice compliance with the *E. coli* end–product standard (<230 *E. coli* per 100g) has been, and continues to be, the main determining factor and this is reinforced by the legislative text (Regulation 853/2004). The key problem here is that viruses are removed much more slowly than bacteria during depuration and relaying and hence molluscs compliant with the *E. coli* standard may still contain enteric viruses and cause outbreaks. Both epidemiological and laboratory studies show that depuration times and conditions currently used are inadequate to remove viruses (Lees, 2000; Richards *et al*, 2010). Unfortunately it is well documented that, even if bacterial end product standards are reached, depuration may be ineffective for safeguarding against viral contamination (Doré *et al*, 1995; Schwab *et al*, 1998; Lees, 2000; Richards *et al*, 2010; EFSA, 2012). Alternate indicators such as coliphages, or adenovirus have been suggested (Dore *et al*, 2000; Formiga-Cruz *et al*, 2003), but none have yet been accepted. A consequence of the reliance on *E. coli* monitoring is that in most EU Member States previous statutory minimum purification time standards have now been replaced by reliance on operator compliance with *E. coli* criteria – with the result that depuration times are commonly much shorter. Short depuration times (e.g. <24 hours) are even more unlikely to be effective for removal of norovirus. The dangers of reliance on *E. coli* criteria for regulation of key depuration parameters have been recently highlighted by EFSA.

Now that robust and quantitative virus methods are available a much more effective strategy would be to require food business operators to validate their treatment processes (including depuration) against a norovirus criterion. This would also be in conformity with the standard HACCP approach for operation of food processes. Removal of norovirus to non-detectable using the standardised CEN methods would be likely to ensure a high level of consumer protection but may be difficult to achieve in practise. Alternative approaches would be to require removal to below a target level (Dore *et al*, 2010) suggested 200 genome copies per gram) throughout the depuration process. Reduction of viral load during the depuration process, even if complete elimination cannot be achieved, can be considered to have a beneficial public health effect since recent data suggests that risk of infection is related to viral dose consumed. However, it should be noted that there is evidence for specific binding of norovirus to bivalve tissues which would influence the potential effectiveness of depuration depending on the norovirus strains and the shellfish species (Maalouf *et al*, 2010b; Zakhour *et al*, 2010). Several studies have examined norovirus during depuration using PCR methods and have shown persistence of contamination at 23 hours (McLeod et al, 2009), 10 days (Nappier et al, 2008) and 29 days (Ueki et al, 2007). A recent study by Cefas using the quantitative ISO methodology found no significant reduction of norovirus in tank based depuration experiments over a 14 day period at 8ºC and only a marginal reduction at 16ºC under conditions similar to those used during commercial depuration (Neish, 2013). However, a recent field study following an outbreak (Westrell *et al*, 2010) used quantitative PCR to monitor norovirus levels in oysters and suggested that virus contamination can be reduced to safe levels through a combination of extended relaying (at least 17 days) and depuration for an extended period (4 to 8 days) at elevated temperatures (15-17ºC) (Dore *et al*, 2010). In this case norovirus monitoring by quantitative PCR provided an effective assessment of virus risk and permitted effective risk management controls to be implemented. Further research in this area is necessary to improve understanding of the possible options to enhance virus removal during commercial depuration.

The limitations of depuration for norovirus removal are recognised by producers and by their representational bodies. The Shellfish Association of Great Britain has previously alerted its members during periods of high risk (e.g. cold weather and elevated levels of norovirus in the community) to take additional precautions through, for example, extending depuration times and/or increasing depuration temperatures. More recently norovirus testing has become available commercially which presents additional risk management tools to producers. A number of producers have now adopted norovirus testing into their quality assurance regimes. The Committee took evidence from one large oyster producer and processor who test all oyster batches prior to depuration and only accept into the processing chain those returning a result below an acceptance level determined by the company. This strategy ensures that oysters moderately or highly contaminated with norovirus do not enter the depuration processing chain. The company reports that, in their view, this strategy has been successful in preventing any norovirus illness associated with their product for several years. Clearly norovirus testing of products, particularly oysters, has the potential to add value to quality assurance within a commercial setting.

In summary, it is clear that commercial depuration as currently practiced cannot be relied upon as a control measure to effectively remove norovirus from bivalves. The limited quantitative data available suggests that depuration at elevated temperatures for extended periods may enhance norovirus removal at least to some extent. Relaying combined with depuration at elevated temperatures has been demonstrated to achieve a reduction of >1 log in one field study (Dore *et al*, 2010). However, genotype specific binding patterns may mean that meaningful reductions of norovirus during relaying and/or depuration may not be feasible for all genotypes. There remains a clear need for further investigations to establish elimination patterns of norovirus from oysters during depuration and relaying regimes.

We conclude that:

- Many bivalve mollusc production areas in the UK are subject to significant human faecal contamination as evidenced by the low percentage of the highest quality (class A) areas and the high percentage of samples found to be contaminated with norovirus during surveillance studies.
- Consuming raw bivalves (e.g. oysters) is generally accepted as an important foodborne risk for enteric virus infection. The direct impact at population level is likely to be small, given that the people who eat raw bivalves are probably relatively limited in number. Assessing exposure is hampered by lack of consumption data. However, the contribution of raw bivalves to the overall burden of norovirus through seeding of the community, introduction of new strains through trade, opportunities for recombination events within multiply infected cases, secondary and tertiary cases, might be important.
- Whilst cooking provides effective health protection the available post-harvest treatment processes for bivalves sold live (particularly depuration) have limited effectiveness for control of norovirus.
- Norovirus testing of bivalves is now available, which can contribute significantly to risk assessment and risk management for producers and for Government.

We recommend that

	Recommendations that Inform Risk Assessments*	**Lead Department/s**
R6.1	The potential value of routine norovirus monitoring for better risk management during primary production should be evaluated by the FSA.	FSA
R6.2	There is a need for further research into the effectiveness of depuration and relaying in reducing the viral content of shellfish species commercially harvested in the UK to try and establish ways of improving the performance of this commercial process for removal of norovirus.	Defra
R6.3	There is a need for further research into the effectiveness of sewage treatment processes in reducing the norovirus	Defra

	concentrations in sewage and the effectiveness against norovirus of disinfection treatments.	

	Recommendations that Impact on Risk Assessments*
R6.4	*The FSA should reinforce its advice on the risk of consuming raw oysters and that cooking of shellfish reduces the risk of exposure to human enteric viruses as stated in the 1998 Report.*
R6.5	*The environmental controls protecting shellfish waters should be reviewed by Defra and its equivalents in the devolved administrations in the light of emerging evidence on norovirus contamination:-* ○ *As a priority future sewerage infrastructure investment should be particularly targeted at controlling norovirus risk from permanent sewer discharges and storm overflows impacting oyster areas.* ○ *Permanent sewer discharges should be relocated away from oyster production areas and planning should ensure sufficient sewage dilution between the discharge point and the shellfish beds.* ○ *Other permanent discharges impacting designated shellfish beds should receive at least tertiary treatment – which need to be shown to be effective against norovirus.* ○ *New CSOs should not be permitted to discharge into designated shellfish waters.* ○ *The compliance of existing CSOs with Government policy on maximum number of spills permitted should be reviewed and action taken to improve those found to be non-compliant.* ○ *All existing and future CSOs potentially impacting designated shellfish waters should be monitored and spills reported such that prompt risk management action (e.g. area closure) can be taken.*
R6.6	*The FSA should review risk management measures for shellfisheries (particularly oyster fisheries) in regard to point source human faecal discharges:-* ○ *Prevention of harvesting in areas in close proximity to sewer discharges, or regularly impacted by CSO discharges, is a sensible preventative measure and should be introduced.* ○ *Policy should be formulated regarding preventative measures (e.g. bed closure periods, virus monitoring policy) following a*

	known spill event or outbreak.
R6.7	*Given the range of risk management options set out above, Defra and the FSA should work together to develop a unified strategy for managing the risk from raw bivalves.*
R6.8	*Prohibition of overboard disposal of sewage from boats should be mandatory under local byelaws in all water bodies and coastal areas with designated shellfish waters. Inshore Fisheries and Conservation Authorities (IFCAs) and the Marine Management Organisation (MMO) should take the lead on this.*
R6.9	*The FSA should review traceability and enforcement of sanitary controls for bivalve molluscs, particularly following outbreaks, to ensure that all regulatory requirements are being complied with at the local level.*

* The recommendations have been separated into those that we consider will ***inform risk assessments*** and those that will ***impact on risk assessments***. For recommendations that inform risk assessments we have identified the lead Department.

7. Fresh produce

7.1. UK fresh produce market

The total quantity of fruit and vegetables marketed in the UK decreased slightly by 1 per cent (88,400 tonnes between 2011- 2012, following consistent growth between 2009 and 2011. There was a 2 per cent decrease in vegetables marketed from 2011 to 2012, and an increase of 0.06 per cent in the fruit sector. Since 2000 the market volume has grown by 20 per cent. There is significant potential for the market to expand further to meet consumption targets, with the UK consumer only eating on average 2.5 servings of fruit and vegetables a day.

7.2. UK fresh produce production

Overall UK fruit and vegetable production decreased by 5 per cent to 2.8 mt in 2012, following a period of growth of 4 per cent from 2007 to 2011, with an overall decrease of 11 per cent since 2000. Home production of vegetables accounts for 56% of UK total supply, and home production of fruit is 10% of UK total supply. Self-sufficiency is around 35 per cent, and has been increasing steadily since 2007 (based on total volume, not solely on UK indigenous products).

7.3 UK fresh produce imports

Imports in fruit increased in 2012 by 1.7 per cent to 3.7 mt, and vegetable imports have remained almost static at 2mt. The UK imports 67 per cent of all its fresh produce, and the majority comes from other EU member states (around 56 per cent of imports).

The wholesale/food service sector accounts for approximately a third of overall sales of fresh produce in UK. (For more information see Annex 2).

7.4 Mechanisms for contamination of fresh produce

There have been several outbreaks of viral gastroenteritis and hepatitis globally, reported in the international peer-reviewed literature, in which consumption of contaminated fresh produce items such as berry fruits and leafy green vegetables was implicated (Table 6). In a review of outbreaks of foodborne norovirus in the US, between 2001 and 2008 365 foodborne norovirus outbreaks were reported annually. In 364 foodborne norovirus outbreaks (28%) that were attributed to a single commodity, leafy vegetables were implicated in 33% of outbreaks (Hall *et al*, 2012).

Table 6: Outbreaks of viral disease in which consumption of fresh produce items was implicated

Year	Country	Virus	Foodstuff implicated	Origin of foodstuff	Number of cases	Reference
1983	Scotland	HAV	Frozen raspberries	Scotland	24	Reid and Robinson (1987)
1988	Scotland	HAV	Fresh raspberries	Scotland	5	Ramsay and Upton (1989)
1997	USA	HAV	Frozen strawberries	Mexico	258	Hutin *et al*. (1999)
1998	USA	HAV	Salad onions	USA / Mexico	43	Dentinger (2001)
2002	New Zealand	HAV	Raw blueberries	New Zealand	19	Calder *et al*. (2003)
2005	Denmark	Norovirus	Frozen raspberries	Poland	~ 300	Falkenhorst *et al*. (2005)
2006	Sweden	Norovirus	Frozen raspberries	China	12	Hjertqvist *et al*. (2006).
2009	Australia	HAV	Semi-dried tomatoes	Australia	144	Donnan *et al*. (2012)
2010	Denmark	Norovirus	lettuce	France	< 264*	Ethelberg *et al*. (2010)
2010	Finland	Norovirus	Frozen raspberries	Poland	46	Maunula *et al*. (2009)
2010	France	HAV	Semi-dried tomatoes	Not identified	59	Gallot *et al.* (2011)
2010	Netherlands	HAV	Semi-dried tomatoes	Not identified	13	Petrignani et al. (2010)
2012	Germany	Norovirus	Strawberries	China	11,000	Maede (2013)
2013	4 Nordic countries	HAV	Frozen strawberries	Unknown at this stage	>150	Gillesburg Lassen *et al*. (2013)

*More than one disease agent was present in analysed samples of the foodstuff, and not all cases fulfilled the Kaplan criteria, indicating that some of them were due to infection by other pathogens.

Surveys of fresh produce which have been undertaken recently have found that enteric viruses could be observed contaminating a small percentage of the sampled foods. In Belgium, a survey of 30 soft red fruits conducted in April-May 2009 (Stals et al, 2012) found 10 (34.5%) samples positive for norovirus. Kokkinos *et al*. (2012) analysed lettuce sold at retail in three European countries, and found 2/149 (1.3 %) and 1/126 (0.8 %) samples positive for norovirus genogroups ggI and ggII respectively; HEV was also found in 4/125 (3.2 %) samples. Mattison *et al*. (2009) analysed 275 samples of packaged leafy greens sold in Canada between April and November 2009 for the presence of norovirus and found 148 (54%) were positive for norovirus, mostly genogroup I. These surveys were performed using RT PCR-based methods which cannot discriminate between infectious and non-infectious virus particles, and therefore the presence of viruses in the samples does not conclusively demonstrate that the food items would have been hazardous to health. However, the detection of the viruses *per se* demonstrates that the supply chains of these items were vulnerable to virus contamination, and that failure to prevent contamination had occurred at some point in the supply. Hitherto, no such survey has been undertaken in the UK, and the prevalence of virus contamination of fresh produce has not been estimated.

Contamination of fresh produce can occur through contact with the hands of virus-infected persons during harvesting, processing, or preparation for consumption. Poor hand hygiene, e.g. not washing thoroughly following use of toilet facilities and prior to handling of foodstuffs, is an important risk factor for contamination of food. Studies have shown that it is possible for a proportion of viruses contaminating a human hand or fingertip to be transferred to a food surface (Bidawid *et al*, 2000).

Water which has been contaminated with viruses, and is then used in food production, processing or preparation, can also cause contamination of fresh produce. Sewage-contaminated water used for irrigation or washing during primary production is a particular hazard. It has been shown that viruses can be transferred from water to the surfaces of berry fruit and leafy green vegetables (Baert *et al*, 2008).

Animal manure is prohibited in the growing of non-arable edible crops supplied globally to the main retail chains in the UK; however, if used as fertiliser for leafy green vegetable crops it may potentially be a vehicle for contamination of the produce. It is possible that HEV in pig manure or slurry may be able to contaminate fresh produce this way, although this has not been confirmed.

The possibility for virus contamination of produce items to spread via cross-contamination through contact with food processing or preparation surfaces exists (Escudero *et al*, 2012).

Enteric viruses will not multiply outside of a host, but they can persist on fresh produce items for several days or longer, and can survive in an infectious state up to the time when the items are consumed (Rzezutka, and Cook, 2004).

It is possible that viruses which contaminate irrigation water or manure-based fertiliser could enter the plant roots become internalised within tissues of berry fruits or leafy greens (Hirneisen *et al*, 2012), although the potential for this has not been fully examined.

7.5 Legislation

There is no legislation in the UK or elsewhere specifically directed to control of viruses in fresh produce, and no regulatory requirements specifying microbiological criteria with regard to virus contamination. The UK market is built on HACCP-driven Good Agricultural Practice (GAP) standards established by the industry from the 1990s onwards, which address all microbial hazards, to deliver microbiological food safety.

7.6 Controls at primary production

The Codex Committee on Food Hygiene has produced a code of hygienic practice for the control of viruses in food, entitled “Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food” (FAO/WHO, 2012). These guidelines follow the format of the Codex Recommended International Code of Practice - General Principles of Food Hygiene - (CAC/RCP 1-1969), and define hygienic practices during the production, processing, manufacturing, transport and storage of foods which are considered essential to ensure the safety and suitability of food for consumption. The Guidelines contain Annexes which are relevant to the soft fruit, salad vegetable, and shellfish supply chains; these give specific mention to HAV and norovirus. Contamination of the pork (or other supply chains) is not dealt with in the Codex guidelines.

The European Commission project "Integrated monitoring and control of foodborne viruses in European food supply chains (VITAL)" produced guidance sheets for preventing contamination of berry fruits and leafy green vegetables by viruses. These are intended for use in conjunction with the Codex guidelines, and are available at[17].

The United Kingdom Chilled Food Association has produced a guidance document for produce suppliers (Chilled Food Association, 2007) on the main microbial food safety hazards and their controls, particularly in relation to produce that is to be minimally processed and eaten without being cooked.

It is probable that the most critical factors influencing virus contamination of fresh produce, particularly at primary production, are the condition of water used for irrigation/washing and the hand hygiene of food harvesters/handlers. Compliance with pre-requisite programs such as Good Agricultural Practice during primary production, Good Manufacturing Practice during processing, and Good Hygienic Practice before consumption, combined with attention to the above guidelines, should considerably reduce the potential for contamination of fresh produce by enteric viruses.

[17] http://www.eurovital.org

7.7 Post-harvest controls

During many food manufacturing processes, various methods are commonly employed to eliminate microbial pathogens from foods. These include heat and chemical disinfection, or irradiation, or high pressure processing and may become more widely adopted in the future, but only if the intervention is acceptable to consumers.

Heating is generally unsuitable for fresh produce, which is mostly consumed raw or minimally processed. The most commonly used sanitizer for fresh produce is chlorine, of which the most effective form is hypochlorous acid (HOCl). A common current industry practice for treatment of fresh vegetables is to use 100 ppm hypochlorite, which yields 30 - 40 ppm free chlorine, depending upon the organic load, at 6.8 - 7.1 pH at 4^{o}C for a contact time of 2 min (Seymour, 1999); for soft fruit such as strawberries and raspberries, a quick spray with, or a short (10 sec) immersion in, 15 - 20 ppm free chlorine can be used (Seymour, 1999). The level of chlorine used in this treatment can inactivate 2-3 logs of contaminating enteric viruses, but the contact times may not be sufficient (Casteel *et al*, 2008).

Chlorine has environmental and health risks, which have led to efforts to replace it with less hazardous alternatives, such as ozone, ionised water and medium pressure UV. Increasingly there are novel forms of disinfection being used commercially to treat produce. Chemical disinfection, ionisation and UV may nonetheless be useful for removal of infectious viruses from food processing and preparation surfaces.

7.8 Standards and Guidelines - Codex, GLOBALG.A.P., Assured Produce, Retail standards

The Codex Alimentarius Committee (CAC) "Recommended international code of practice: general principles of food hygiene"[18] (2003) states that a HACCP-based assessment should be carried out and identifies that a number of pre-requisite procedures be in place at primary production to ensure the safety of the food produced. In 2006 CAC agreed to progress the development of commodity-specific annexes to its Fresh Fruit and Vegetable Code[19], which was initiated through a 2007 meeting of experts[20] and a 2008 FAO/WHO expert group[21], which reviewed potential

[18] Codex Alimentarius. Recommended international code of practice: general principles of food - CAC/RCP 1-1969, Rev. 4-2003 Accessible at: http://www.codexalimentarius.net/web/more_info.jsp?id_sta=23

[19] Code Of Hygienic Practice For Fresh Fruits And Vegetables CAC/RCP 53-2003. http://www.codexalimentarius.net/download/standards/10200/CXP_053e.pdf

[20] FAO. Microbiological hazards in fresh fruits and vegetables: JEMRA Meeting report Microbiological Risk Assessment Series, pre-publication version, 2008 Accessible at: http://www.who.int/foodsafety/publications/micro/MRA_FruitVeges.pdf

[21] FAO/WHO. Microbiological hazards in fresh leafy vegetables and herbs: Meeting report Microbiological Risk Assessment Series 14 (2008) (ISBN 978-92-5-106118-3) Accessible at: ftp://ftp.fao.org/docrep/fao/011/i0452e/i0452e00.pdf

microbiological hazards and their control in the production of fresh leafy vegetables and herbs.

That report concluded that emphasis needs to be on appropriate field standards rather than end-product testing.

Appropriate grower knowledge of hazards, control of the growing environment (including the need for specific site assessment prior to cultivation, appropriate use of soil amendments and fertilisers and especially the role of composting) were identified as being key, together with full implementation of existing GAP standards. These and other key principles were in 2010 included in Annex I of the Codex Code of Good Hygienic Practice for Fresh Fruit and Vegetables[22] and therefore are recognised by the World Trade Organization. A series of commodity-specific annexes are being developed by CAC although the basic GAP principles are common to all.

The European Chilled Food Federation (ECFF) in 1999[23] presented its international Expert Group's microbial hazard minimisation review to the European Commission, which resulted in a Scientific Committee for Food produce risk assessment in 2001.

To address the need for clear microbial control guidance, the Chilled Food Association (CFA) used information from the ECFF review to develop its Microbiological Guidance for Produce Suppliers to Chilled Food Manufacturers, first published in 2002, with a revision in 2007. The Guidance provides information on the main microbial food safety hazards (bacteria, viruses, protozoa) and their control in the field, particularly in relation to raw ready to eat (RTE) produce. It has been taken up by certain major UK retailers in their own GAP protocols with which their produce suppliers, including overseas, are required, as a condition of supply, to demonstrate continuous compliance and undergo monitoring and auditing.

Documents setting out more general agricultural controls include Assured Produce Scheme (APS – now Red Tractor) and GLOBALG.A.P. standards.

Given the range of commercial and professional standards and guidelines FSA commissioned a review (Project B17007[24]) of their scope in comparison with CAC requirements. The review confirmed that UK multiple retailers are driving implementation of QA schemes in the UK retail supply chain and that focus needs to be on greater uptake outside those supply chains.

[22] Codex Code of Good Hygienic Practice for Fresh Fruit and Vegetables. CAC/RCP 53-2003. Accessible at: http://www.codexalimentarius.org/standards/list-of-standards/

[23] VTEC and Agriculture, http://www.kaaringoodburn.com/images/VTEC_Agriculture_-_Final_-_address_updated_2002.pdf

[24] A review of the published literature describing foodborne illness outbreaks associated with ready to eat fresh produce and an overview of current UK fresh produce farming practices. FSA Project B17007 (2011). http://www.foodbase.org.uk/results.php?f_report_id=340

The project reviewed the coverage of non-statutory standards in use in the UK versus CAC requirements (Table 7).

Table 7: Relative content of QA schemes (including standards and guidance notes) addressing key areas that manage hazards and risks in the primary production of crops that are likely to be consumed without cooking

Potential risk	CAC section	GLOBALG.A.P.	APS (Red Tractor)	CFA	Retailer #1	Retailer #2
Site history	3.1	✓	✓✓	✓✓	✓	✓✓
Water for primary production	3.2.1.1	✓	✓✓	✓✓	✓✓	✓✓
Manure inputs	3.2.1.2	✓	✓✓	✓✓	✓✓	✓✓
Worker hygiene	3.2.3	✓✓	✓	✓✓	✓	✓✓
Wildlife / farm animal access	3.1	✓	✓	✓	✓	✓
Harvest equipment hygiene	3.2.4	✓	✓	✓✓	✓	✓
Handling, storage and transport	3.3	✓✓	✓	✓	✓	✓
Post-harvest treatment	5.2.2	✓	✓	✓✓	✓	✓
Training	10.0	✓	✓✓	✓✓	✓✓	✓✓

Key
✓ = Covered comprehensively
✓✓ = Covered
CAC = Codex Alimentarius Commission
GLOBALG.A.P. = Global Good Agricultural Practice (control points and compliance criteria)
APS = Assured Produce Scheme
CFA = Chilled Food Association microbiological guidance

7.9 Assessing compliance

Suppliers are audited by processors, retailers and independent third party auditing bodies in the case of retail own label foods. The standard approach to certification (retailer and third party) is:-

- Once certified the CB makes regular assessments.
- To maintain certification requires conformance to the relevant standard at all times.
- Once certified growers/processors may also be subject to random spot checks at short notice. This is in addition to customer and internal audits.
- All non-conformances against the standard must be put right (closed out) prior to certification being awarded.
- The CB reserves the right to suspend certification in the case of a large number of such non-conformances or in the event of the same non-conformance being found on successive assessment visits.

In the UK retail fresh and prepared produce industry there is a commercial imperative for growers/suppliers to comply with the required standards since not doing so will lead to loss of customer confidence and, ultimately, delisting. It is for this reason that suppliers to major UK retailers have adopted the various standards since doing so enables them to compete in the marketplace.

We conclude that:

- The contribution of contaminated leafy green vegetables, berry fruits and semi-dried tomatoes to foodborne norovirus and HAV is uncertain but the impact at population level could be significant given the consumption levels.
- Protection to the consumer relies on voluntary codes of practice.

We recommend that

	Recommendations that Inform Risk Assessments*	**Lead Department/s**
R7.1	There needs to be systematic surveys to estimate the prevalence of enteric viruses in fresh produce particularly those grown outside the retail Field to Fork schemes. This should include imports, wholesale, markets, food service and smaller farm shops “Pick your Own”. Ideally these studies should address the issue of infectivity (see section 3.4).	FSA
R7.2	Further research is needed to identify the most effective means of decontaminating produce post-harvest.	FSA

	Recommendations that Impact on Risk Assessments*
R7.3	*The FSA reviews the reliance on voluntary hygiene schemes to ascertain whether this provides adequate protection for the consumer, this should include the level of uptake of such schemes no matter the scale of production.*

* The recommendations have been separated into those that we consider will ***inform risk assessments*** and those that will ***impact on risk assessments***. For recommendations that inform risk assessments we have identified the lead Department.

8. Pork products

The application of mild heat treatments to short shelf life chilled foods as part or all of the food manufacturers cooking processes is designed to make them safe. In practice the cooking process carried out by food manufacturers pasteurises the product with the aim of eliminating harmful pathogens.

In short shelf-life chilled foods the most heat resistant vegetative pathogen is *Listeria monocytogenes.* If the factory cooking process eliminates all the *Listeria monocytogenes* then all other vegetative pathogens, such as *Staphylococcus aureus*, *Campylobacter*, *E. coli* and *Salmonella* should also have been destroyed. Historical scientific research has established that at 70°C it takes 0.3 minutes to achieve a 1 decimal reduction in the level of *Listeria monocytogenes.* To reduce the level of *Listeria monocytogenes* by 6 decimal reductions will require 6 x 0.3 minutes which equals 1.8 minutes at 70°C. In practice this time has been rounded up to 2 minutes and hence the 70°C for 2 minutes has been established as the minimum 'Pasteurisation Value' for *Listeria monocytogenes* in the chilled food industry (Table 8).

Table 8: Pasteurisation of short shelf-life chilled products

Type of cooked pork product	Typical Total Cook Length/Time	Typical Time held at >70°C	Typical Actual Core Temp achieved	Typical Pasteurisation value*	Volume Sold
Small Pork Pie	30 minutes	15 minutes	98°C	>100,000	91 million units
Large Pork Pie	60 minutes	20 minutes	98°C	>100,000	23 million units
Pâté containing pork	3hrs 5 minutes	2 hours	80°C	100	10.7K Tonnes
Sandwich ham	310 minutes	2 minutes	74.5°C	216	9.5K Tonnes
Whole muscle ham	7 hours	4 hours 24 minutes	>70°C	1004	159 million units
Cocktail Sausages	2.5 to 3.5 minutes	3 minutes	>80°C	23	34 million units
Scotch egg	7 to 10 minutes	5 minutes	>80°C	54	49.5 million units
Wiltshire Ham	5.5 hours	>70°C - 1 hour 30 minutes	74°C	150 - 200	4.5 million units

* "Pasteurisation value" can be explained as 70°C for 2 minutes which has been established as the minimum Pasteurisation Value of 2 for *Listeria monocytogenes*

(Campden Bri 'Pasteurisation – A food industry Practical Guide. (second edition) 2006)

The heat treatment delivered during the cooking process can quantified by monitoring the product temperature and then calculating the 'Pasteurisation Value'.

Cooking processes are designed to make a food product microbiologically safe however, the desire to achieve certain organoleptic standards of bake, colour, flavour and texture means that the cooking process typically achieves a significant number of decimal reductions of Listeria monocytogenes in excess of the minimum of 6 decimal reductions required, as can be seen in Table 8.

8.1 Hepatitis E virus and pigs

Hepatitis E (genotypes 3 and 4) has a high prevalence in the European pig herd (Berto *et al*, 2012a), and the virus has been detected in pork products at point of sale. HEV RNA has been found in ~2% of pig livers sold in grocery stores in Japan and 11% in the USA (Yazaki *et al*, 2003; Feagins *et al*, 2007). In the UK, HEV RNA was detected at each of three sites in the pork food supply chain, at the slaughterhouse, the processing plant and at points of retail sale (Berto *et al*, 2012b).

A multi-agency funded study of pigs slaughtered at abattoirs across the UK was carried out between January and April 2013, principally to establish baseline levels of some potentially zoonotic pathogens (including HEV) found in pigs. In total, just over 600 pigs were sampled, and samples were tested for presence of antibodies to HEV, and for the presence of viral RNA (assumed to represent viraemic pigs).

The results are still being analysed, but figures are expected to be available by the time the final report is published. However, it is anticipated that the outcome will be similar to other recent surveys carried out in France and Austria, showing a high proportion of pigs to be seropositive and a small percentage showing signs of viraemia at the time of slaughter.

8.2 Hepatitis E outbreaks linked to pork products

Several outbreaks have been linked directly to consumption of undercooked pork products. In a case of hepatitis E in the UK which was caused by an HEV strain very similar to pig strains, the patient had admitted to eating raw pork products, although this was not conclusively the cause of the infection (Banks *et al*, 2004). In USA 11% of the retail livers tested were positive for HEV RNA and, when inoculated into HEV free pigs they were able to infect the animals, implying the survival of the virus under storage conditions (Feagins *et al*, 2008). The Third National Health and Nutrition Examination Survey in the USA showed that HEV seropositivity was associated with consumption of liver and organ meats (Kuniholm *et al*, 2009).

8.3 Control of contamination

There are no official control policies regarding HEV in pigs, and at any given time, it is possible that pigs inside a herd have an active infection. Infected pigs normally appear healthy even to veterinarians, i.e. they do not show symptoms of disease, therefore, they can be sent for slaughter and contaminated organs and meat will enter the food supply chain. Control of HEV contamination in the pork supply chain is not dealt with in the Codex guidelines for control of viruses in foods (FAO/WHO, 2012).

HEV can be present in the faeces, urine, liver and gall bladder and bile of infected pigs in very high numbers, and can be spread within the slaughterhouse and processing plant and could cross-contaminate meat from uninfected pigs. The European FP7 project "VITAL" produced a guidance sheet for preventing cross contamination of pork products by HEV, which is available at[25]. Compliance with good practice at the slaughterhouse and during processing and storage should reduce the risk of HEV cross-contamination of pork meat.

8.4 Effect of cooking on Hepatitis E virus

HEV is difficult to grow *in vitro*, and there have been few studies to determine its survival characteristics or the effect of elimination procedures. Such information as is available appears to indicate that the virus may possess a degree of resistance to commonly used cooking procedures. HEV in contaminated pigs livers was completely inactivated after boiling or stir frying for 5 minutes, whereas, incubation of contaminated livers at 56°C for 1 hour, equivalent to medium to rare cooking conditions in a restaurant, did not inactivate the virus (Feagins *et al*, 2008). Heating to an internal temperature of 71°C for 20 minutes was necessary to completely inactivate HEV in experimentally contaminated foods (Barnaud *et al*, 2012).

We conclude that:

- Available evidence suggests that HEV is able to withstand the current minimum standard pasteurisation process of 70°C for 2mins in pork products contaminated experimentally. However, we note that typical industry pasteurisation practice for various pork products is variable but exceeds 70°C for 2mins.
- Cooking pig's liver medium or rare may not inactivate HEV.

We recommend that:

	Recommendations that Inform Risk Assessments*	**Lead Department/s**
R8.1	Further work is undertaken on heat inactivation of HEV in naturally contaminated raw, rare and ready to eat pork products and these studies should relate to industry practice.	FSA
R8.2	Further work is undertaken on the effect of curing and/or fermentation of pork products (e.g. salamis and dry cured	FSA

[25] http://www.eurovital.org

	meats) on HEV infectivity.	
R8.3	Work towards development of an ISO standard method for detection of HEV in foodstuffs (including pork products) should be encouraged.	FSA
R8.4	A structured survey of HEV contamination in pork products across the retail sector is conducted.	FSA

* The recommendations have been separated into those that we consider will ***inform risk assessments*** and those that will ***impact on risk assessments***. For recommendations that inform risk assessments we have identified the lead Department.

9. Contamination of the environment

9.1 Environmental contamination as a source of infection

Food preparation areas typically become contaminated with human enteric viruses when a food handler is acutely ill at work. Aerosolised vomit, in particular, can lead to contamination of food preparation surfaces with viruses. They can persist on materials found in kitchen or domestic environments for a sufficient time to be a source for secondary transmission of disease. Viruses can survive on aluminium, stainless steel, china, glazed tile, plastic, latex, polystyrene, cloth and paper (Sattar *et al*, 1986; Abad *et al*, 1994). Hands are frequently in contact with environmental surfaces and both HAV and rotavirus retain infectivity for several hours on skin and can be transferred as infectious virus from fingertips to environmental surfaces (Ansari *et al*, 1988; Mbithi *et al*, 1992).

Outbreaks of gastroenteritis associated with environmental contamination during the cultivation of foodstuffs, such as salad vegetables, are often characterised by the detection, in affected patients, of several viruses and/or bacteria and reflects faecal or sewage contamination during cultivation (Gallimore *et al*, 2005).

Contamination during harvesting is likely to be associated with agricultural workers and may be a result of an acute episode of vomiting in the vicinity of foodstuffs or poor hygiene practices.

Contamination during food processing may be associated with poor hygiene practices, cross contamination from foods contaminated during cultivation or harvesting or staff suffering an episode of vomiting in the work place.

Contamination at point of sale may be through inappropriate storage of foodstuffs, food preparation areas contaminated during the preparation of foods such as shellfish, food handlers with poor hygiene practices and staff taken ill at work or returning to work too soon after a gastroenteric illness. As non-enveloped viruses, such as HAV and norovirus, are resistant to many classes of disinfectant, ineffective cleaning or disinfection used in food outlets, will allow infectious virus to remain viable on environmental surfaces. There are some new biocides that have been developed that are successful in reducing virus on surfaces. However, they are more expensive than chlorine-based biocides which may slow their wider use.

Contamination in the domestic setting is likely caused by a reliance on ineffective decontamination and a lack of good hygiene measures including proper segregated food storage and good hand hygiene.

Transferability from contaminated food or ill food handlers to hands, environmental surfaces and kitchen implements and the persistence of infectious viruses on these surfaces may be key to the transmission of viruses in food outlets and the family home.

9.2 Persistence and transferability of viruses on and between foodstuffs and environmental surfaces

Viruses, outside their host, are inert. Transmission from host to host is dependent on them remaining infectious during their time in the environment and the conditions they meet (Table 9). The factors that affect virus survival in the environment are also relevant for their survivability on food products. High temperature is virucidal and is enhanced by acidity, whereas, they may resist thermal inactivation when salt or fat levels are high. The presence of faecal material and high relative humidity enhances virus persistence.

Contamination of food contact surfaces with viruses may be an important vehicle for the indirect transmission of foodborne diseases. Environmental contamination can arise following vomiting from which aerosol droplets could settle on foodstuffs or surfaces. Foodstuffs can be eaten, resulting in infection, or contamination on environmental surfaces may be transferred to the hands of food handlers who subsequently transfer the contamination to cooked or pre-prepared foods. Contamination of carpets by vomitus can result in prolonged exposure to viruses through inadequate cleaning and the subsequent re-suspension of infectious particles which can settle on other surfaces and subsequently be transferred by hand to foodstuffs.

In model experiments in which mouse norovirus (MNV) was used to contaminate stainless steel coupons virus infectivity rapidly decreased by >2 log MNV/ml followed by a slow decline and complete loss at day 30, whereas, MNV in food residues, including lettuce, cabbage and ground pork, resisted inactivation and decreased by only 1.4 log MNV/ml by day 30. Also, sodium hypochlorite at 1000ppm was sufficient to inactivate virus in the absence of food residues, whereas, 2000ppm had little effect on MNV infectivity on stainless steel coupons with food residues *(*Takahashi *et al*, 2011).

Cleaning cloths are able to remove viruses from food contact surfaces but can also transfer viruses back to these surfaces (Gibson *et al*, 2012).

Table 9: Factors that affect the persistence of viruses in the environment

Factor	Effect
Virological factors	
Type of virus	In general, enveloped viruses are less stable than non-enveloped viruses in the environment and are more susceptible to inactivation by disinfectants and solvents
Physical factors	
Heat	Inactivation is directly proportional to temperature
Light	UV light is virucidal
Desiccation	Enteric viruses transmitted through contact with faecally-contaminated surfaces can survive desiccation
Pressure	High pressure inactivates viruses
Absorption	Viruses readily absorb onto suspended solids in sewage resulting in their protection from inactivation
Chemical factors	
pH	Viruses are inactivated at extremes of pH although ingested enteric viruses survive pH 2-3 as food transits the stomach
Divalent cations	Protect enteric viruses from thermal inactivation
Salinity	Increased salt concentrations are virucidal
Ammonia	Virucidal
Free chlorine ions	Virucidal
Organic matter	Protects from inactivation
Enzymes	Proteases and ribonucleases contribute to inactivation
Microbiological factors	
Microbial and protozoal activity	Contributes to inactivation and removal of viruses
Biofilms	Absorption protects from inactivation although microbial activity may be virucidal

9.3 Infected food handlers and prevalence of norovirus in the catering environment

Food handlers can be involved in growing, manufacturing, producing, collecting, processing, packing, transporting, displaying, storing and thawing or preserving food. Food handlers also handle surfaces that come into contact with food including storage and preparation areas, cutlery, plates and bowls. Food handlers should endeavour to prevent food becoming unsafe or unsuitable for people to eat.

Symptomatic food handlers are frequently implicated in foodborne outbreaks of norovirus. Surveillance data from England and Wales show that infected food handlers were implicated in 40% of all outbreaks. Attributing transmission to infected food handlers is likely to be underestimated because it is claimed that food handlers are often reluctant to report their illness to investigators or agree to have specimens taken. Epidemiological investigations of a large outbreak of infection associated with the Fat Duck Restaurant in 2009 showed that although the restaurant served oysters that were linked to other outbreaks the main disease burden in the outbreak was attributable to food handlers working while infectious contaminating a wide range of dishes on the menu (HPA Report Foodborne Illness at the Fat Duck Restaurant[26].) In a review of foodborne norovirus outbreaks between 2001 and 2008 in the US a food handler was specifically implicated as the source of contamination in 473 of 866 outbreaks (53%) in which contributory food handling/hygiene factors were provided (Hall *et al*, 2012).

In outbreaks associated with transmission via a food-handler, the same strain is often found in all involved, including the food-handler (Daniels *et al*, 2000; Sala *et al*, 2005; Vivancos *et al*, 2009). A food handler who develops symptoms at work such as vomiting, diarrhoea, sore throat or fever should report to their supervisor and not handle any food. The burden of foodborne transmission could be reduced if professional food handlers infected mainly through person to person spread adhered to public health guidance and refrained from working while infectious.

Estimates of norovirus prevalence in the catering environment range from 4.2% (Boxman *et al*, 2011) (Table 10) to 40% (Miren Iturriza-Gomara – personal communication).

[26] http://www.hpa.org.uk/web/HPAweb&HPAwebStandard/HPAweb_C/1252514872830

Table 10: Prevalence of norovirus in catering environments during outbreaks in the Netherlands

Type of catering company	Number visited	Norovirus positive	%
Restaurant	446	15	3.4
Lunchroom	112	8	7.1
Snack Bar	77	1	1.3
Cafeteria	23	1	4.3
Takeaway	22	1	4.5
Elderly Home	18	4	22.2
Bakery/Patisserie	16	1	6.3
Canteen	14	2	14.3
Hotel/Guest House	6	2	33.3
Total	832	35	4.2

In a study in the Netherlands the prevalence of norovirus on surfaces in catering premised during outbreaks was found to be very high (Boxman *et al*, 2011), (Table 11).

Table 11: Prevalence of norovirus in catering environments during outbreak investigations, The Netherlands 2006-8

Year	Kitchens samples +ve (%)	Bathrooms samples +ve (%)
2006	30	79
2007	55	63
2008	35	63
Total	40	67

Infected food handlers who display symptoms shed virus throughout illness and may continue to shed virus for at least 3 weeks after recovery (Moe 2009). Furthermore, as discussed in section 4.1, asymptomatic shedding in the population in general is fairly common, although the public health significance is uncertain.

9.3.1. The importance of hand hygiene

Food handlers should do whatever is reasonable to prevent unnecessary contact with food or food contact surfaces and are expected to wash their hands whenever their hands are likely to contaminate food. This is particularly important before working with ready-to-eat foods after handling raw food and immediately after using the toilet. Hands should be cleaned using soap and warm running water and dried with a single use towel or warm air hand drier. Non-hand contact taps could reduce the risk of expose from touching contaminated surfaces.

In a Cochrane Systematic Review that included 14 randomised controlled trials, Ejemot *et al.* (2008) demonstrated a 29% reduction in diarrhoeal disease episodes in institutions in high-income countries (IRR 0.71, 95% CI 0.60 to 0.84; 7 trials) following hand washing with soap and water and a 31% reduction in communities in low- or middle-income countries (IRR 0.69, 95% CI 0.55 to 0.87; 5 trials). Their conclusion, based on robust analyses, was that hand-washing can reduce diarrhoea episodes by about 30%. However, in two studies in the US amongst people in the catering sector the barriers to compliance with hand-washing were enlightening. In Kansas Howells *et al.* (2008) investigated barriers to hand-washing, using thermometers and cleaning work surfaces. The barriers revealed included time constraints, inconvenience, inadequate training and resources, no incentive to do it, inconvenient location of sinks and dry skin from hand-washing. In Oregon in a study of hand-washing only, Pragle and colleagues (2007) found that lack of accountability, lack of involvement of managers and co-workers and organisations not being supportive of hand-washing were all important disincentives.

9.3.2 Vaccination and immunotherapy

9.3.2.1. Hepatitis A vaccination and post exposure prophylaxis

Four monovalent vaccines are currently available, prepared from different strains of the hepatitis A virus; all are grown in human diploid cells (MRC5). Three (Havrix®, Vaqta® and Avaxim®) are absorbed onto an aluminium hydroxide adjuvant. The fourth, Epaxal® vaccine, contains formalin-inactivated hepatitis A particles attached to phospholipid vesicles together with influenza virus haemagglutinin derived from inactivated influenza virus H1N1. These vaccines can be used interchangeably.

Hepatitis A vaccination may be considered under certain circumstances for food packagers and handlers, although in the UK they have not been associated with transmission of hepatitis A sufficiently often to justify their immunisation as a routine measure.

If a food handler develops acute jaundice or is diagnosed clinically or serologically with hepatitis A infection a risk assessment should determine whether other food handlers in the same food preparation area could have been exposed and should be considered for post-exposure prophylaxis. Rapid serological confirmation and notification of hepatitis A infection will allow an assessment of the possible risks to any customers who can be traced and offered prophylaxis.

Hepatitis A vaccine should be given to previously unvaccinated contacts of cases of hepatitis A with the onset of jaundice within the last week. When the interval is longer, human normal immune globulin (HNIG) should be used, particularly for older people, given the greater severity of disease in this age group.

HNIG is prepared from pooled plasma derived from blood donations. Use of HNIG should be limited to situations where it may have a definite advantage over vaccine. HNIG can provide immediate protection, although antibody levels are lower than those eventually produced by hepatitis A vaccine. There have been no studies directly comparing the efficacy of HNIG with vaccine for prophylaxis in contacts of cases. HNIG licensed for use for prophylaxis must have a hepatitis A antibody level of at least 100IU/ml.

HNIG has a proven record in providing prophylaxis for contacts of cases of acute hepatitis A. HNIG will protect against hepatitis A infection if administered within 14 days of exposure, and may modify disease if given after that time. Protection lasts for four to six months.

9.3.2.2. Hepatitis E vaccine

No hepatitis E virus vaccine is currently licensed for use in Europe. A recombinant bacterially-expressed hepatitis E virus (rHEV) vaccine, HEV 239, has been licensed for use in China. In a randomised, double blind, placebo-controlled phase 3 clinical trial conducted in adults aged 16-65 years with a three dose vaccine regimen (0, 1 and 6 months) the vaccine efficacy after three doses was 100% (95% CI 72.1 – 100.0), (Zhu, Zhang *et al*, 2010). Adverse effects attributable to the vaccine were few and mild and no vaccine-related serious adverse events were noted.

Similarly, a phase 2, randomised, double-blind, placebo-controlled trial of a baculovirus-expressed genotype 1 rHEV vaccine (US Army and GlaxoSmithKline) in 61 Nepalese Army units recorded a vaccine efficacy of 88.5% (95% CI 77.1 – 94.2), (Shrestha, Scott *et al,* 2007).

9.3.2.3. Norovirus vaccine

No norovirus vaccine is currently licensed or in use throughout the world. The expression of the norovirus capsid protein in recombinant systems such as insect or plant cells yields virus-like particles (VLPs) (Green, Lew *et al*, 1993; Tacket, Mason *et al*, 2000), that mimic the antigenic structure of the virion and have the potential to be used as intranasal or oral vaccines. Also, possible subunit vaccines, such as the norovirus P particle (Tan, Huang *et al*, 2011), which comprises the antigenic protruding domain of the virus capsid, expressed in bacterial cells have been devised as potential vaccine candidates.

A randomised, double-blind, placebo-controlled, trial to assess the safety, immunogenicity and efficacy of an intra-nasally delivered norovirus VLP vaccine (Atmar, Bernstein *et al*, 2011) showed protection against illness and infection after challenge with a homologous virus, but many challenges lie ahead for the development of an effective norovirus vaccine. Antibody responses following vaccination were much lower than those induced following natural infection, the immunity after natural infection is short-lived and the duration of protection after vaccination remains to be determined. A multivalent vaccine, regularly re-formulated, will most likely be required as natural infection does not generate cross protective antibodies and the predominant norovirus strain worldwide, GII-4, undergoes antigenic drift similar to that seen among influenza viruses.

We conclude that:

- Our current understanding is that symptomatic infected food handlers constitute the single most common source of foodborne norovirus. However, the public health relevance of asymptomatic carriage is not well understood.
- General guidance on food and personal hygiene is widely available but translating it into reliable control measures within small scale outlets especially those with a transient workforce, has not been accomplished.
- Alcohol wipes/gels are not effective against enteric viruses.

We recommend that:

	Recommendations that Inform Risk Assessments*	Lead Department/s
R9.1	Further studies to understand the role of environmental contamination in transmission of enteric viruses would be valuable.	FSA with PHE

	Recommendations that Impact on Risk Assessments*
R9.2	*The FSA should ensure that the industry guide to good hygienic practice in catering is completed and published.*
R9.3	*The FSA should work with training providers to highlight and promote good practice to assist improved understanding and compliance.*
R9.4	*There needs to be better engagement with the smaller catering establishments to ensure adequate awareness of enteric viruses and their control.*
R9.5	*Hand hygiene needs to be highlighted better as a critical control measure. EHOs should consider investigating the effectiveness of a targeted campaign to tackle hand washing as a norovirus control method. Alcoholic wipes are not effective against enteric viruses.*

* The recommendations have been separated into those that we consider will ***inform risk assessments*** and those that will ***impact on risk assessments***. For recommendations that inform risk assessments we have identified the lead Department.

10. Drinking water

In countries with well organised adequately chlorinated drinking water systems, viral infections related to water consumption are not a risk. There have been a large number of outbreak reports linking Norovirus infection to water consumption, but in all cases these were due to problems with the water control systems, leading to sewage contamination of the drinking water supply.

In countries with less well controlled water supply, outbreaks are frequent and widespread and water plays a significant role in the transmission of enteric viruses and Hepatitis A and E (Riera-Montes, 2011, Arvelo, 2012; Hewitt, 2007; and Brugha *et al,* 1999).

There is no evidence that bottled water has been associated with viral infection.

11. Consumer awareness

There are a number of sources which provide information on viruses for consumers. These mainly cover general issues around food preparation and hygiene in the home.

Current FSA guidance can be found on the NHS Choices website[27] with guidance also available on the HPA's[28] website. Although the FSA does produce a biannual public attitudes tracker survey which includes questions on the awareness of hygiene standards and other food related concerns[29], it does not specifically include questions on viruses.

Currently, the sources of information for consumers offer varied messages (footnotes 35-45), and this has an impact on consumer awareness of viruses and the risks associated with them. Information for consumers does not go into detail about individual viruses, and does not identify those viruses which tend to be foodborne, rather than spread by other means. There is also no information on which are the peak months of the year for viral disease incidence.

The importance and the impact of consumer awareness on foodborne viral illness should be considered as it is likely that better informed consumers are at a lower risk of illness. It is important that information provided to improve consumer awareness is consistent across all sources as this can reinforce messages of hygiene and food preparation. Currently, advice on viruses from different sources shows a lack of consistency, with some websites not even mentioning the possibility of virus transmission through food preparation processes. It would be helpful to draw consumers' attention to food preparation activities as well as good hygiene practises. There is a lack of specific advice on what do in relation to food preparation in the event of contracting a viral infection such as norovirus.

The advice on the NHS Choices website covers how to prepare food safely[30], providing general advice on food preparation and kitchen hygiene however; it does not mention risks associated with different foodstuffs, specifically shellfish which is one of the greatest risks. One information page on fish and shellfish highlighted the nutritional benefits of eating fish and shellfish, but did not mention the need to cook shellfish[31]. However, a separate page[32] made it clear that eating raw shellfish while pregnant was a risk and that it should be cooked thoroughly. Advice and tips were also provided on how to prevent the spread of norovirus[33] both through the

[27] http://www.nhs.uk/Pages/HomePage.aspx
[28] http://www.hpa.org.uk/
[29] http://www.food.gov.uk/science/research/ssres/tracker-may2013
[30] http://www.nhs.uk/livewell/homehygiene/pages/foodhygiene.aspx
[31] http://www.nhs.uk/livewell/goodfood/pages/fish-shellfish.aspx
[32] http://www.nhs.uk/chq/pages/can-i-eat-shellfish-during-pregnancy.aspx
[33] http://www.nhs.uk/Conditions/Norovirus/Pages/Prevention.aspx

foodborne and environmental routes. NHS Choices does also provide a general advice page on household germs[34] which includes some information on viruses. The guidance produced by PHE was more focussed on hygiene and hand washing in the home, but does include a general background to norovirus[35], shellfish consumption and the risk of norovirus infection[36] and a "norovirus – frequently asked questions" page[37]. The Group was not able to find any advice on the consumption of shellfish, which is specific to the elderly and those who are immunocompromised, This is an important area that the FSA should address.

To better improve consumer awareness of foodborne disease and to inform the public about the risks associated with viruses, and how these may differ from bacteria, the FSA may wish to consider social science research. This will investigate the best methods to use in order to get information on hygiene across to the consumer. Research should also examine the public perception of risk through popular sayings, such as oysters should only be eaten when there is an "r" in the month (i.e. September to April). This can mislead the consumer as this saying is presumed to derive from historical consumption of the European flat oyster which spawned, and consequently lost edible quality, during the warmer summer months. However, the majority of the UK market is now based on cultivated pacific oysters which are available all year round and, from the norovirus contamination perspective, the warmer months are the safest seasonal time of the year to eat oysters. The consumer would benefit from clear and consistent advice on such beliefs.

The consumer also needs to be made aware of the impact on risk from different preparation and cooking times of shellfish, as the risks attached to eating raw, cooked and smoked oysters, raw and cooked prawns and raw, cooked and smoked mussels will all be different. Currently, consumers generally rely on food labels for advice which most food manufacturers and retailers provide on food preparation, for example, there is now distinct advice on the cooking of oysters, mussels and cockles. However, the FSA should consider the need to target its advice and not assume all shellfish have the same risk as raw oysters. The term "shellfish" could be too vague to some consumers and making this clear would be helpful.

Overall, the information available on NHS Choices and PHE websites does provide the consumer with information on viruses, however, this is limited and not always consistent. It is recommended that the FSA should take the lead in ensuring there is consistent advice for consumers so that risk communication is improved. This should include advice on the need to maintain good hygiene in the home as this is the most important advice for consumers.

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[34] http://www.nhs.uk/livewell/homehygiene/pages/common-household-germs.aspx
[35] http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/Norovirus/
[36] http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/Norovirus/oysterconsumptionnorovirus/
[37] http://www.hpa.org.uk/Topics/InfectiousDiseases/InfectionsAZ/Norovirus/GeneralInformation/norovFrequentlyaskedQuestions/

We conclude that:

- Authoritative information on risks associated with different food stuffs and definitive cooking instructions is hard to find on Government websites.
- There is a lack of information about the public understanding of risk as applied to foodborne viruses, particularly for specific groups at higher risk such as the immunocompromised.
- There is a lack of clear and consistent advice on recommended food preparation and cooking advice to reduce risk.

We recommend that:

	Recommendations that Impact on Risk Assessments*
R11.1	*There should be clear, consistent and coordinated Government advice on viruses for all consumers in relation to food preparation and hygiene in the home. For instance, there should be advice on cooking shellfish and pork products as well as information on washing leafy green vegetables and soft fruit.*
R11.2	*The Government should identify the lead organisation responsible for developing and delivering clear and consistent advice on viruses for all consumers.*
R11.3	*There should be specific advice produced by Government for groups at high risk such as the immunocompromised.*
R11.4	*The Social Sciences' Research Committee should consider what further research is needed on public understanding of foodborne viruses. This might involve specific questions in the next FSA biannual public attitudes tracker.*
R11.5	*The Group reiterates Recommendation 6.1 from the 1998 FVI report that the Government should remind members of the public of the risks from eating raw oysters, of the potential dangers from collecting molluscan shellfish from beaches, and of the need to cook molluscan shellfish thoroughly. This should include the fact that the risk of norovirus, associated with eating raw bivalves from seawater, is higher during the winter months.*
R11.6	*Advice should be available at the point of consumption of the hazards of eating raw oysters.*

* The recommendations have been separated into those that we consider will ***inform risk assessments*** and those that will ***impact on risk assessments***. For recommendations that inform risk assessments we have identified the lead Department.

12. Summary of conclusions and recommendations

For ease of reference, this Chapter summarises the conclusions we have reached throughout this report and the recommendations we have made. These are listed by chapter heading.

We have endeavoured to prioritise the recommendations by separating these into recommendations that we consider will ***inform risk assessments*** and those that will ***impact on risk assessments***. For those recommendations that inform on risk assessments we have undertaken to identify the lead Department that should take these forward.

Foodborne viral disease

Conclusions

- We conclude that the public health significance of viral contamination as indicated by PCR results is an important issue for the food producing sector that requires:
- Effective, quantitative tools for detecting viruses in the foodstuffs are now available. These methods are based on the direct detection of viral nucleic acid by PCR and viral nuclei does not necessarily equate to infectious virus, for example virus may be inactivated. However preliminary evidence suggests a dose-response relationship between viral RNA and subsequent illness at least in oysters.
- Validated quantitative methods are available for Noroviruses and Hepatitis A in molluscs. Methods have been described for other viruses such as Hepatitis E and for other food matrices as part of research studies, but these are not yet suitable for control purposes.
- A major change since the last review by ACMSF is the ability to detect viruses in food matrices and the existence of standardised methods suitable for use in a risk management context.

Recommendations

	Recommendations that Inform Risk Assessments*	**Lead Department/s**
R3.1	Wider use of food and environmental testing should be employed to support outbreak investigations this will need to include methodological refinements targeting characteristics indicative of viable virus eg. intactness of genome or protein coat.	PHE and devolved equivalents

R3.2	Molecular diagnostics, typing and quantification should all be used more systematically to understand the burden of virus contamination in foodstuffs on the UK market to help identify the potential control points this might include validation of potential virus indicator organisms.	PHE and devolved equivalents
R3.3	Further work is undertaken on the correlation between infective dose and genome titre (as measured by PCR) in order to help develop risk management criteria that will adequately protect public health without imposing disproportionate burdens on the food industry. This might include food consumption studies focussing on infection outcomes related to virus titre.	PHE lead with FSA support
R3.4.	Further research is undertaken on the development of methods for assessment of norovirus and Hepatitis E infectivity in food samples to inform surveys and that could potentially be applied to routine monitoring.	FSA
R3.5	Further research is undertaken on appropriate surrogates in other food matrices to help identify suitable control treatments.	FSA
R3.6	Research is undertaken on processing methods that are effective for virus decontamination and appropriate for the food product.	FSA

Burden of illness

Conclusions

- Although the IID2 Study provided valuable information on the overall burden of norovirus, the proportion of norovirus transmitted by food is still uncertain.
- Pork products have been implicated in foodborne hepatitis E infection in the UK and abroad. However, the burden of HEV transmitted by food, including pork and pork products, is still uncertain.

Recommendations

	Recommendations that Inform Risk Assessments*	**Lead department/s**
R4.1.	Further research is undertaken to estimate the contribution of foodborne transmission to the burden of enteric virus disease and to identify the most important foods	FSA/PHE Joint

R4.2.	Further studies are undertaken to identify sources, and risk factors for HEV infection and the role of the food chain in transmission.	PHE

Routine surveillance and investigation of foodborne viruses

Conclusions

- Currently the burden of foodborne illness associated with norovirus is likely to be an under-estimate. The impact of foodborne transmission in health and social care settings, in particular, may be higher than is currently recognised because the possibility of foodborne transmission in these settings is likely to be under-investigation. Variation in the extent to which potential foodborne outbreaks are investigated also militates against a good understanding of the scale of foodborne transmission.
- Next generation sequencing may provide further insight into foodborne and environmental routes of contamination.
- Multiple agencies at local, regional and national level across the UK are responsible for public health surveillance but other organisations also hold relevant data and this information needs to be coordinated.
- Current legislation appears not to be applied by all food business operators e.g. in relation to notifying suspected foodborne enteric virus outbreaks immediately to allow the relevant statutory authorities to perform a thorough public health investigation.
- Failure by any food business operator to report immediately to the competent authority "when it has reason to believe that a food it has placed on the market is injurious to human health" constitutes a criminal offence[38].
- In almost all incidents where a viral aetiology is suspected proper investigation is not performed.

Recommendations

	Recommendations that Inform Risk Assessments*	**Lead Department/s**
R5.1	Reliable methods for Norovirus WGS should be established so its use to track transmission of norovirus and attribute potential food vehicles/sources in outbreaks should be investigated. The value of WGS to link food	PHE with FSA support

[38] See http://food.gov.uk/enforcement/regulation/foodlaw/ and Regulation 4 of the General Food Regulations 2004, SI 2004 No.3279.

	stuff, infected cases, food handlers for Norovirus, Hepatitis A, and Hepatitis E should be defined.	
R5.2	Public health agencies need to work together and with other relevant organisations to develop a single, integrated outbreak reporting scheme, (this was previously recommended in the 1998 FVI report) involving all aspects of enteric virus transmission through the food chain. In the meantime we reiterate recommendation R3.1 from the 1998 Report that all relevant authorities who maintain outbreak records (PHE and equivalents in devolved administrations, FSA, local authorities, other Government laboratories and agencies) should contribute to an annual reconciliation and consolidation of outbreak records. PHE, and equivalent authorities in devolved administrations, should take the lead on this activity. In the absence of a reconciled system the impact of food related viral illness and outbreaks will continue to be under-estimated.	PHE, with Defra and FSA
R5.3.	Studies are required to investigate the best way(s) of gathering and analysing information from sporadic cases of suspect food poisoning to ensure public health benefit without wasting scarce resources. For example, the FSA should consider funding a local or regional pilot study to elicit the costs and benefits of developing a sentinel surveillance system for investigating foodborne enteric viruses.	PHE with FSA
R5.4.	Viral foodborne outbreaks should be reviewed periodically (e.g. annually) to evaluate lessons learned, to identify any reoccurring problems or issues, and to review the effectiveness of control measures and potential improvements.	PHE with Defra and FSA
R5.5.	National surveillance of foodborne viruses should include the foodborne component of hepatitis A and hepatitis E.	PHE

	Recommendations that Impact on Risk Assessments*
R5.6	*The FSA reviews its guidance to local authorities and all food business operators, including caterers, to clarify their legal obligations to notify immediately "when it has reason to believe that a food it has placed on the market is injurious to human health".*

R5.7	*All food business operators, including caterers, need to be reminded of their duty to inform competent authorities immediately (Local Authorities and, when appropriate, the FSA) they suspect a foodborne virus outbreak so that appropriate public health investigations are not hampered by destruction of evidence before EHOs have been alerted to a problem.*
R5.8	*The FSA's 2008 Guidance on the management of foodborne illness[39] should be updated and the latest information on norovirus incorporated. These Guidelines need to ensure that investigations of suspected foodborne outbreaks are consistent. They should incorporate advice on the use of new virological tools to detect viruses in the environment and in food matrices. The Guidelines need to define when it is appropriate to investigate a potential foodborne virus outbreak and, if investigation is performed, the minimum dataset of evidence required for recording a foodborne outbreak in national surveillance systems.*

Contamination of food

Conclusions

- Many bivalve mollusc production areas in the UK are subject to significant human faecal contamination as evidenced by the low percentage of the highest quality (class A) areas and the high percentage of samples found to be contaminated with norovirus during surveillance studies.
- Consuming raw bivalves (e.g. oysters) is generally accepted as an important foodborne risk for enteric virus infection. The direct impact at population level is likely to be small, given that the people who eat raw bivalves are probably relatively limited in number. Assessing exposure is hampered by lack of consumption data. However, the contribution of raw bivalves to the overall burden of norovirus through seeding of the community, introduction of new strains through trade, opportunities for recombination events within multiply infected cases, secondary and tertiary cases, might be important.
- Whilst cooking provides effective health protection the available post-harvest treatment processes for bivalves sold live (particularly depuration) have limited effectiveness for control of norovirus.
- Norovirus testing of bivalves is now available, which can contribute significantly to risk assessment and risk management for producers and for Government.

[39] Management of outbreaks of foodborne illness in England and Wales. FSA 2008. http://www.food.gov.uk/multimedia/pdfs/outbreakmanagement.pdf

Recommendations

	Recommendations that Inform Risk Assessments*	Lead Department/s
R6.1	The potential value of routine norovirus monitoring for better risk management during primary production should be evaluated by the FSA.	FSA
R6.2	There is a need for further research into the effectiveness of depuration and relaying in reducing the viral content of shellfish species commercially harvested in the UK to try and establish ways of improving the performance of this commercial process for removal of norovirus.	Defra
R6.3	There is a need for further research into the effectiveness of sewage treatment processes in reducing the norovirus concentrations in sewage and the effectiveness against norovirus of disinfection treatments.	Defra

	Recommendations that Impact on Risk Assessments*
R6.4	*The FSA should reinforce its advice on the risk of consuming raw oysters and that cooking of shellfish reduces the risk of exposure to human enteric viruses as stated in the 1998 Report.*
R6.5	*The environmental controls protecting shellfish waters should be reviewed by Defra and its equivalents in the devolved administrations in the light of emerging evidence on norovirus contamination:-* ○ *As a priority future sewerage infrastructure investment should be particularly targeted at controlling norovirus risk from permanent sewer discharges and storm overflows impacting oyster areas.* ○ *Permanent sewer discharges should be relocated away from oyster production areas and planning should ensure sufficient sewage dilution between the discharge point and the shellfish beds.* ○ *Other permanent discharges impacting designated shellfish beds should receive at least tertiary treatment – which need to be shown to be effective against norovirus.* ○ *New CSOs should not be permitted to discharge into designated shellfish waters.* ○ *The compliance of existing CSOs with Government policy on*

	maximum number of spills permitted should be reviewed and action taken to improve those found to be non-compliant. ○ *All existing and future CSOs potentially impacting designated shellfish waters should be monitored and spills reported such that prompt risk management action (e.g. area closure) can be taken.*
R6.6	*The FSA should review risk management measures for shellfisheries (particularly oyster fisheries) in regard to point source human faecal discharges:-* ○ *Prevention of harvesting in areas in close proximity to sewer discharges, or regularly impacted by CSO discharges, is a sensible preventative measure and should be introduced.* ○ *Policy should be formulated regarding preventative measures (e.g. bed closure periods, virus monitoring policy) following a known spill event or outbreak.*
R6.7	*Given the range of risk management options set out above, Defra and the FSA should work together to develop a unified strategy for managing the risk from raw bivalves.*
R6.8	*Prohibition of overboard disposal of sewage from boats should be mandatory under local byelaws in all water bodies and coastal areas with designated shellfish waters. Inshore Fisheries and Conservation Authorities (IFCAs) and the Marine Management Organisation (MMO) should take the lead on this.*
R6.9	*The FSA should review traceability and enforcement of sanitary controls for bivalve molluscs, particularly following outbreaks, to ensure that all regulatory requirements are being complied with at the local level.*

Fresh produce

Conclusions

- The contribution of contaminated leafy green vegetables, berry fruits and semi-dried tomatoes to foodborne norovirus and HAV is uncertain but the impact at population level could be significant given the consumption levels.
- Protection to the consumer relies on voluntary codes of practice.

Recommendations

	Recommendations that Inform Risk Assessments*	Lead Department/s
R7.1	There needs to be systematic surveys to estimate the prevalence of enteric viruses in fresh produce particularly those grown outside the retail Field to Fork schemes. This should include imports, wholesale, markets, food service and smaller farm shops "Pick your Own". Ideally these studies should address the issue of infectivity (see section 3.4).	FSA
R7.2	Further research is needed to identify the most effective means of decontaminating produce post-harvest.	FSA

	*Recommendations that Impact on Risk Assessments**
R7.3	*The FSA reviews the reliance on voluntary hygiene schemes to ascertain whether this provides adequate protection for the consumer, this should include the level of uptake of such schemes no matter the scale of production.*

Pork products

Conclusions

- Available evidence suggests that HEV is able to withstand the current minimum standard pasteurisation process of 70°C for 2mins in pork products contaminated experimentally. However, we note that typical industry pasteurisation practice for various pork products is variable but exceeds 70°C for 2mins.
- Cooking pig's liver medium or rare may not inactivate HEV.

Recommendations

	Recommendations that Inform Risk Assessments*	Lead Department/s
R8.1	Further work is undertaken on heat inactivation of HEV in naturally contaminated raw, rare and ready to eat pork products and these studies should relate to industry practice.	FSA

R8.2	Further work is undertaken on the effect of curing and/or fermentation of pork products (e.g. salamis and dry cured meats) on HEV infectivity.	FSA
R8.3	Work towards development of an ISO standard method for detection of HEV in foodstuffs (including pork products) should be encouraged.	FSA
R8.4	A structured survey of HEV contamination in pork products across the retail sector is conducted.	FSA

Contamination of the environment

Conclusions

- Our current understanding is that symptomatic infected food handlers constitute the single most common source of foodborne norovirus. However, the public health relevance of asymptomatic carriage is not well understood.
- General guidance on food and personal hygiene is widely available but translating it into reliable control measures within small scale outlets especially those with a transient workforce, has not been accomplished.
- Alcohol wipes/gels are not effective against enteric viruses.

Recommendations

	Recommendations that Inform Risk Assessments*	**Lead Department/s**
R9.1	Further studies to understand the role of environmental contamination in transmission of enteric viruses would be valuable.	FSA with PHE

	Recommendations that Impact on Risk Assessments*
R9.2	*The FSA should ensure that the industry guide to good hygienic practice in catering is completed and published.*
R9.3	*The FSA should work with training providers to highlight and promote good practice to assist improved understanding and compliance.*
R9.4	*There needs to be better engagement with the smaller catering establishments to ensure adequate awareness of enteric viruses and their control.*
R9.5	*Hand hygiene needs to be highlighted better as a critical control measure.*

	EHOs should consider investigating the effectiveness of a targeted campaign to tackle hand washing as a norovirus control method. Alcoholic wipes are not effective against enteric viruses.

Consumer awareness

Conclusions

- Authoritative information on risks associated with different food stuffs and definitive cooking instructions is hard to find on Government websites.
- There is a lack of information about the public understanding of risk as applied to foodborne viruses, particularly for specific groups at higher risk such as the immunocompromised.
- There is a lack of clear and consistent advice on recommended food preparation and cooking advice to reduce risk.

Recommendations

	Recommendations that Impact on Risk Assessments*
R11.1	*There should be clear, consistent and coordinated Government advice on viruses for all consumers in relation to food preparation and hygiene in the home. For instance, there should be advice on cooking shellfish and pork products as well as information on washing leafy green vegetables and soft fruit.*
R11.2	*The Government should identify the lead organisation responsible for developing and delivering clear and consistent advice on viruses for all consumers.*
R11.3	*There should be specific advice produced by Government for groups at high risk such as the immunocompromised.*
R11.4	*The Social Sciences' Research Committee should consider what further research is needed on public understanding of foodborne viruses. This might involve specific questions in the next FSA biannual public attitudes tracker.*
R11.5	*The Group reiterates Recommendation 6.1 from the 1998 FVI report that the Government should remind members of the public of the risks from eating raw oysters, of the potential dangers from collecting molluscan shellfish from beaches, and of the need to cook molluscan shellfish thoroughly. This should include the fact that the risk of norovirus, associated with eating raw bivalves from seawater, is higher during the winter months.*

R11.6	*Advice should be available at the point of consumption of the hazards of eating raw oysters.*

Annex 1

List of those who assisted the Group

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Annex 2

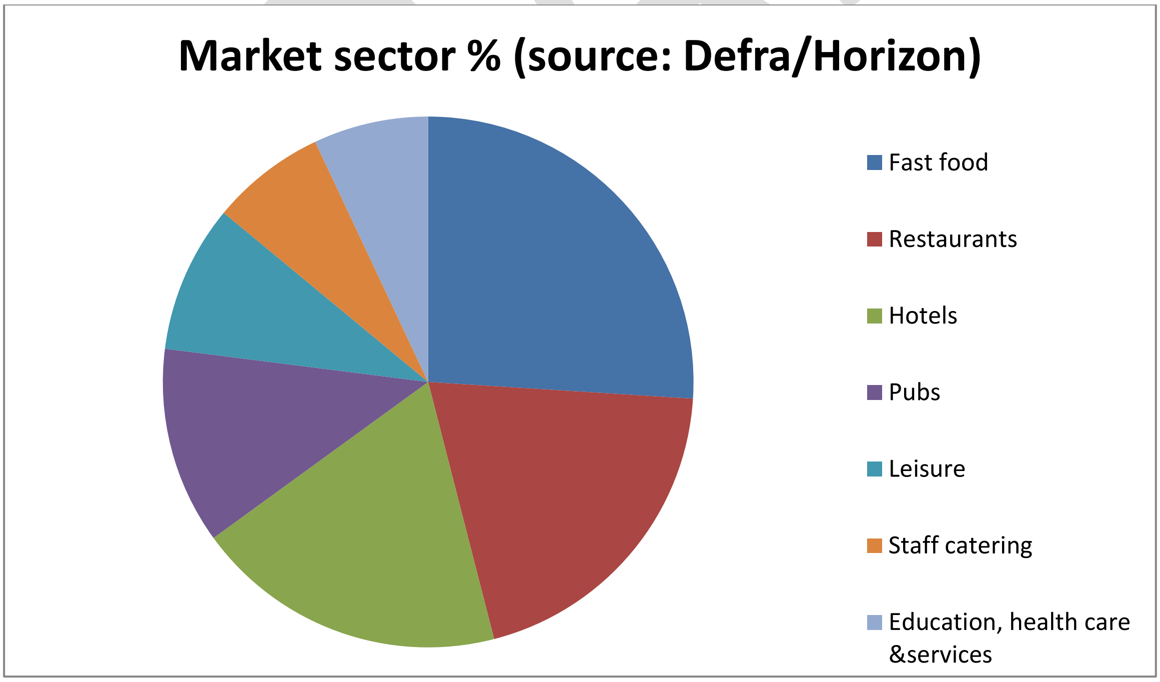
Fresh Produce Market Sectors

Market Share Profile 2010

Market Sector	Value (£ billion)	Market Share (%)
Multiple retail Estimated cost price equivalent *	7.54 4.97	68
Wholesale/food services	2.42	32
TOTAL	7.39	

*retail less 30%

Food Service Sector 2012



Source: TNS/CFA/KantarWorldPanel – www.chilledfood.org/market.asp

Annex 3

List of Tables and Figures

Tables

Figures

Annex 4

Glossary

This glossary is intended as an aid to the reading of the main text and should not be regarded as definitive

Acute disease	A disease which has rapid onset and lasts for a relatively short period of time. It can also refer to a very severe or painful disease.
Adenoviruses	Viruses which do not contain an envelope and have a double stranded DNA genome. Can cause illness of the respiratory/ intestinal systems.
Aerosol	The suspension of particles in airborne water droplets.
Aetiology	The study of the causation of disease.
Antibody	A protein formed in direct response to the introduction into an individual of an antigen. Antibodies can combine with their specific antigens e.g. to neutralise toxins or destroy bacteria.
Antigen	A substance which elicits an immune response when introduced into an individual.
Assay	The determination of the content or the concentration of a substrate.
Astroviruses	Viruses which look like stars under an electron microscope.
Asymptomatic infection	An infection with a microorganism where the person infected does not suffer any resulting symptoms or disease.
Avian influenza	Influenza virus subgroup which can be found in birds, but can also infect humans.
Bacterium	A microscopic organism with a rigid cell wall – often unicellular and multiplying by splitting in two – which has the ability to live freely.

Biocide	Biological/chemical means of controlling or destroying a harmful organism.
Bivalve molluscs	Filter feeders with two shells that process large amounts of seawater to obtain their food.
Campylobacter	Gram-negative bacteria with a characteristic spiral shape.
Capsid	The protein coat of a virus particle.
Coxsackie viruses	Single-stranded RNA viruses which are linear and do not contain an envelope. Two types have been identified - group A and group B.
Deoxyribonucleic acid	The genetic material of humans, bacteria, some viruses, etc. It is a polymer of nucleotides connected by sugars.
Depuration	A commercial treatment process used for shellfish. Harvested animals are transferred to tanks of clean seawater where they continue to filter feed for a period during which time sewage contaminants are purged out by normal physiological processes.
Electron microscopy	Microscopy that uses a beam of electrons as the radiation source for viewing a specimen.
Enteric virus	Any virus which enters the body through the gastrointestinal tract, multiplies there, and is usually transmitted by the faecal/oral route.
Enterovirus	Any virus which enters the body through the gastrointestinal tract, multiplies there, and has a tendency to invade the central nervous system.
Enzyme	A protein which acts as a highly efficient and specific biological catalyst.
Enzyme-linked Immunosorbent	An assay in which an enzyme is used (as a marker) to indicate the presence of specific antigens or antibodies.

Assay	
Epidemiology	The study of factors affecting health and disease in populations and the application of this study to the control and prevention of disease.
Escherichia coli (E. coli)	Gram-negative, rod-shaped, non-sporing bacteria.
Foodborne disease/illness	Disease/illness which is attributed to the eating of contaminated/infected food and drink.
Gastroenteritis	Inflammation of the stomach and the intestine, usually due to infection by bacteria, viruses, or food poisoning toxins, causing vomiting and diarrhoea.
Genome	The genetic material of an organism (e.g. the DNA or RNA of a virus).
Genotype	The genetic constitution of an organism (i.e. the organism's content of genetic information).
Gram stain	Method of using dyes to categorise bacteria
Hepatitis	Inflammation of the liver
Hepatitis A virus	A Hepatovirus with a genome of ssRNA of 7.5kb. It is non-enveloped, 27nm in diameter and has an icosahedral structure.
Hepatitis E virus	A Hepevirus, 32-34nm in diameter, calicivirus-like in morphology and has a genome of ssRNA of 7.5kb.
Herd immunity	The collective immunity or resistance to a given disease exhibited by a community or population (human or animal) in the setting of its own environment.
Human normal immune globulin	A solution which contains antibodies derived from the plasma of donated blood
IgA, IgG, IgM	Different types of immunoglobulin found in body fluids.
Immunity	The body's ability to resist infectious disease, afforded by the presence of circulating antibodies and white blood cells.

Immunoassay	Any procedure in which the specificity of the antigen-antibody reaction is used for detecting or quantifying antigens, antibodies or substances.
Immunoglobulins	A group of structurally-related proteins which are antibodies found in body fluids.
Immunotherapy	Suppression, enhancement or induction an immune response to treat an illness.
In vitro	Literally “in glass”, i.e. in a test tube, plate etc. Used to describe biological processes made to happen in laboratory apparatus, outside a living organism.
Incubation period	The time interval between the initial entry of a pathogen into a host, and the appearance of the first symptoms of disease.
Infectious dose	The amount of infectious material, e.g. number of viruses, necessary to produce an infection.
Jaundice	The yellowing of the skin, or the whites of the eyes, indicating excess bilirubin (a bile pigment) in the blood.
kaplan’s criteria	Criteria (clinical and epidemiological) for norovirus outbreaks developed by Kaplan in the 1980s.
Listeria monocytogenes	Gram-positive anaerobic, pathogenic bacteria which causes the listeriosis infection.
Micro-organisms	Very small organisms which can only be seen under a microscope. Examples include bacteria, fungus and viruses.
Molecular diagnostics	A method of analysing patterns in DNA/RNA that may provide information about disease.
Monovalent vaccine	A vaccine which contains one type of substance which can elicit an immune response when introduced into an individual.
Multivalent vaccine	A vaccine which contains several different types of substance which can elicit an immune response when introduced into an individual.

Mycotoxins	A group of naturally occurring chemicals produced by certain moulds.
Nipah virus	Emerging zoonotic virus with a large genome, capable of infecting various different types of host.
Norovirus	A member of the Caliciviridae with a genome of single stranded (ss) RNA of approximately 7.5kb. The virus is non-enveloped, 30-35nm in diameter and has an icosahedral structure.
Oligonucleotides	Short length polynucleoside chains, usually less than 30 residues long.
Organoleptic	Qualities of food experienced by the senses, such as taste and smell.
Outbreak	Two or more cases of disease linked to a common source.
Pasteurisation	A form of heat treatment which kills vegetative pathogens and spoilage bacteria in milk and other foods.
Pasteurisation value	Time taken, at a given temperature, for the pasteurisation process to take place, ensuring that the number of microbes present is reduced to a safe value.
Pathogen	Any biological agent which can cause disease.
pH	An index used as a measure of acidity or alkalinity.
Phylogenetic	Relating to the evolutionary history of a species or taxonomic group.
Picornaviruses	Group of positive-stranded RNA viruses which do not have envelopes, but do have an icosahedral capsid. Viruses in this group include Coxsackie group A and B and Enteroviruses.
Plasma	The fluid part of the blood in which the cells are suspended.

Polymerase chain reaction	An *in vitro* technique which enables multiple copies of a DNA fragment to be generated by amplification of a target DNA sequence.
Prophylactic	Treatment, usually immunologic, designed to protect an individual from the future development of a condition or disease.
Recombinant	DNA which contains sequences from different sources, brought together as a single unit to form a DNA sequence that is different from the original sources. Commonly used specifically for DNA molecules which have been constructed *in vitro* using various genetic engineering techniques.
Reverse transcriptase	An RNA-dependent DNA polymerase which synthesises DNA on an RNA template.
Reverse transcription polymerase chain reaction	A sensitive technique used in molecular biology studies to detect and measure mRNA expression levels in samples.
Ribonucleic acid	The genetic material of some viruses in the absence of DNA. Involved in protein synthesis in bacteria, humans, etc.
Rotavirus	A virus which contains double-stranded RNA and can cause gastroenteritis. It particularly affects young children and infants with the symptoms of severe diarrhoea and dehydration.
Salmonella	Gram-negative, rod-shaped bacteria.
Salmonellosis	Attacking of the stomach and intestines by salmonella bacteria.
Sapoviruses	Viruses which belongs to the Caliciviridae family which can cause acute gastroenteritis.
Sensitive waters	Estuaries, bays and other coastal waters where there is poor water exchange with the ocean and which are therefore susceptible to eutrophication.
Serodiagnosis	Identification of a micro-organism by means of serological tests.

Serology	The study of antigen-antibody reactions *in vitro*.
Seronegativity	Negative blood serum reaction to a particular pathogen.
Seropositivity	Positive blood serum reaction to a particular pathogen.
Seroprevalence	The persistence of serotype-specific serum antibodies, following infection with a given pathogen (e.g. virus), which are capable of protecting against challenge with the same virus type (but there will be no protection against an antigenically different virus).
Serum	Essentially similar to plasma (the fluid part of the blood), but lacking fibrinogen and other substances active in the coagulation process.
Severe acute respiratory syndrome (SARS)	Viral disease that affects the respiratory system which is caused by the severe acute respiratory syndrome coronavirus.
Sewage sludge	Residual sludge from sewage plants treating domestic or urban waste waters.
Small round structured viruses	The viral agents most commonly associated with foodborne viral infections. Distinguished from other viruses by their distinctive ragged surface morphology.
Species	A classification or organisms within a genus which have similarities and can be further sub-divided into sub-species.
Staphylococcus aureus	Small, round, non-motile bacteria that is commonly found in clusters.
Strain	A population of organisms within a species or sub-species distinguished by sub-typing.
Subclinical infection	Infection without illness symptoms.
Symptomatic	Displaying symptoms of a disease.

Vaccination	Administration of a biological preparation to stimulate the immune system to develop immunity against a particular pathogen.
Vaccine adjuvant	Agent combined with a vaccine which allows the host's immune response to be enhanced.
Viral gastroenteritis	Inflammation of the stomach and the intestine due to infection by viruses.
Viral hepatitis	Inflammation of the liver due to infection by viruses.
Virion	An infectious particle responsible for transporting the viral genome from cell to cell.
Virus	A sub-microscopic organism which is only capable of replication within living cells.
Virus-like particle	Particles that do not contain any viral genetic material and so are not infectious, despite having a likeness to viruses.
Zoonoses	Vertebrate animal host infections that can be transferred to humans naturally.

Annex 5

Abbreviations and acronyms

ACMSF	Advisory Committee on the Microbiological Safety of Food
APS	Assured Produce Scheme
CAC	Codex Alimentarius Committee
Cefas	Centre for Environment, Fisheries & Aquaculture Science
CB	Certification Body
CFA	Chilled Food Association
CSOs	Combined sewer overflows
Defra	Department for Environment, Food & Rural Affairs
DNA	Deoxyribonucleic acid
EA	Environmental Agency
ECFF	European Chilled Food Federation
EFSA	European Food Safety Authority
EHO	Environmental Health Officer
ELISA	Enzyme-linked immunosorbent assay
EM	Electron microscopy
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FBO	Food business operator
FPC	Fresh Produce Consortium
FSA	Food Standards Agency (also referred to as the “Agency” in the report
GAP	Good Agricultural Practice
HACCP	Hazard analysis and critical control points
HAV	Hepatitis A virus
HEV	Hepatitis E virus
HNIG	Human normal immune globulin
HOCl	Hypochlorous acid
HPP	High pressure processing
HPT	Health Protection Team
IID	Infectious intestinal disease
IID Study	Infectious Intestinal Disease Study
IID2 Study	Second Study of Infectious Intestinal Disease in the Community

ISO	International standard method
LRTI	Lower Respiratory Tract Infection
MNV	Mouse norovirus
NoV	Norovirus
PCR	Polymerase chain reaction
PHE	Public Health England (formerly the Health Protection Agency)
QA	Quality assurance
RNA	Ribonucleic acid
RT	Reverse transcriptase
RTE	Ready-to-eat
RT-PCR	Reverse transcription polymerase chain reaction
SARS	Severe acute respiratory syndrome
SRSVs	Small round structured viruses
SWD	Shellfish Waters Directive
UV	Ultra violet
UWWTD	Urban Wastewater Treatment Directive
VLPs	Virus-like particles
WHO	World Health Organization

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