Respondent	Comment	Response
	Shellfish and Seawater	
Scottish Water	**Chapter 2 – Scottish Water comments on 2013 Government Update** **Recommendation R6.2** **Investment Plans should take account of the impact on commercially important shellfisheries.** Scottish Water has invested significantly in improving discharges associated with Shellfish Waters. Overall this has not provided the general improvement in shellfish quality that was expected, due to other influencing factors. Investment in shellfish related projects will be completed in 2014, and there is no further investment programmed. Investment planning is governed via the Regulatory process shared with Scottish Government, SEPA and our Economic Regulator. We will promote an evidence based approach to future investment and would expect there to be clear evidence of SW impact on shellfish, coupled with clear benefits if Scottish Water were to invest. Where SW is clearly a major contributor, and a significant improvement can be delivered, we would expect projects to be prioritised via the Scottish Government's Quality and Standards process. This runs on a 12 year cycle with 6 yearly investment planning periods. Our next investment plan covers 2015-21. No specific needs have been identified for shellfish.	Thank you for your helpful update on the response to the recommendations from the 1998 Report.

	Recommendation R6.3 **Recommendation the Government develops a national policy for the reduction of pollution-related illness associated with shellfish consumption, containing the following elements** **– All classified shellfisheries to be designated as sensitive areas under the UWWTD** The Shellfish Waters Directive was repealed in December 2013. The Scottish Government decided to set the protection of shellfish waters within domestic legislation under the Water Framework Directive. 84 Shellfish Water Protected Areas were designated in December 2013, reflecting the areas with classifications under the Shellfish Hygiene Regulations. **-Formulate a policy to reduce the no of CSO spills to a minimum. Monitor and report annually** SEPA guidance and licensing is based on 10 or less significant (50m3) spills per annum discharging to shellfish waters. For SW investment projects, modelling has been undertaken to develop the required spill and storage solutions. CSO monitoring has been included for investment projects, and there are some reporting requirements depending on individual licences. It has not been provided for sites where the impact was not deemed sufficient to require further investment.	Thank you for your helpful update on the response to the recommendations from the 1998 Report.
	CSOs should not be directed into Class A or B harvesting areas SEPA advice is that designated areas can be used as buffer zones for the harvesting areas within them. SW investment has created some Combined Sewer Overflows (CSOs)/Emergency Overflows (EOs) within designated areas, where existing continuous discharges have been	Thank you for your helpful update on the response to the recommendations from the 1998 Report.

	replaced with pumping stations. This has to be seen in the overall context of improvement of the shellfish water by removing the continuous discharge. The impact of CSOs on harvesting areas has not been modelled as part of the investments **Water Companies should provide local Food Authorities with summaries of storm overflows and immediate notification of emergency discharges** The majority of CSOs and emergency discharges are not monitored. Scottish Water has developed an Environmental Pollution Incident reporting process for reporting pollution incidents to SEPA. This process has been amended to identify where assets are associated with shellfish waters and local Environmental Health teams will be informed. This process is manual and has been in place since April 2012. To date there have been very few incidents reported. A proposal for study into the use and value of CSO monitoring/reporting is to be included in our forward (SR15) investment programme.	Thank you for your helpful update on the response to the recommendations from the 1998 Report.
	The above proposals present a significant departure from current practice, with the potential for significant cost impacts. We would expect a full regulatory impact assessment to be conducted to evaluate the full costs and benefits of such an approach. We would seek further discussions with Scottish Government on this matter. Additionally, it must be acknowledged that SW has spent substantial sums investing to remove and reduce discharges from shellfish waters. This has not led to a significant improvement in class of water bodies and it is very apparent that quality is compromised by diffuse pollution. We are concerned that the proposals may risk driving investment to meet prescribed standards with little or no quality outcome in the environment.	

	Chapter 6 – Scottish Water comments on section 6.2 Shellfish, and recommendations **6.2.2 Faecal contamination of shellfish production areas** We agree that there are multiple sources of faecal contamination including sewerage systems. The general lack of improvement in shellfish quality following Scottish Water investment suggests that diffuse pollution is a significant factor. The risk factor associated with human enteric viruses increases with the presence of public sewerage discharges serving large populations, including treated sewage discharges and intermittent CSO spills, and we agree that prevention of harvesting in proximity to this discharge is sensible.	Thank you for your helpful comments noting your agreement with our commentary.
	6.2.3 Protection for shellfish waters against faecal pollution With the repeal of the Shellfish Waters Directive in 2013, the Scottish Government has issued domestic regulations to protect shellfish waters under the Water Framework Directive. This has led to the designation of 84 Shellfish Waters Protected Areas to match existing classifications under the Shellfish Hygiene Directive (SHD). A Faecal Indicator Organism (FIOS) classification system based on the SDH E. coli standards is being developed. Scottish Water discharges are regulated by the Controlled Activities (Scotland) Regulations 2011 (CAR), with the Scottish Environmental Protection Agency (SEPA) setting licence conditions to achieve compliance with FIOS limits and reduction of storm overflow events. While we agree that FIOS standards can be met by higher levels of treatment, dilution and dispersion, we do not agree that relocating discharges should be seen as a way of improving shellfish quality. Our experience has shown that relocation of discharges does not always lead to the assumed improvements. Assessment of the cost of investment	We note the progress on the designation of protected Shellfish Waters in Scotland. We agree that various sources, including diffuse, can contribute significantly to the faecal indicator burden in shellfisheries. However, diffuse agricultural pollution is not responsible for norovirus contamination. We reiterate our view that shellfish, and in particular oysters, should not be harvested in close proximity to sewer pipes. In general whether this is best achieved by relocation of pipes, or prevention of harvesting, is a matter for risk managers

	versus income and potential water quality benefits should be taken into account. For new harvesting sites, the planning system should be used to prevent harvesting in proximity to discharge pipes. Scottish Water would also recommend dilution and dispersal modelling of known inputs to assess the best areas for harvesting. Where Scottish Water has invested in the protection of Shellfish Waters, storm storage to limit CSO spills to <10 per annum has been included. Licence conditions, including CSO monitoring and reporting have been set as required under CAR. This does not include discharges associated with designated areas which have not been considered significant in terms of the risk posed. The majority of CSOs and emergency discharges are not monitored. Scottish Water has developed an Environmental Pollution Incident reporting process for reporting pollution incidents to SEPA. This process has been amended to identify where assets are associated with shellfish waters and local Environmental Health teams will be informed. This process is manual and has been in place since April 2012. To date there have been very few incidents reported. A proposal for study into the use and value of CSO monitoring/reporting is to be included in our forward (SR15) investment programme.	and likely to be site specific. For this reason we have recommended that Defra and FSA (and territorial equivalents) work together in formulating strategy. We accept that recommendation 6.5 did not fully cover the available options and have reworded. We note the absence of monitoring in Scotland and the variation across the UK in monitoring emergency discharges and CSOs We suggest in the absence of either monitoring or a formal reporting system these events are likely to be significantly under-recognised.
	6.2.5 Controls at primary production The Sanitary Survey programme is almost complete for Scottish shellfish harvesting areas. The surveys include details of Scottish Water and private discharges, as well as noting the presence of livestock, wild animals, sea mammals, birds, and other activities such as fish farming, boating, forestry and other industries. They include information on tides, currents and wind direction trends. This is used to determine the monitoring point for Food Authority sampling.	

	There is an assumption that the public sewerage system poses the biggest risk. Based on the history of non-improvement in shellfish quality associated with significant water company investment, we suggest that modelling the inputs identified by the Sanitary Surveys may provide a more evidence-based assessment of risk, and highlight more suitable areas for harvesting.	We note the response, but we are in no doubt that for norovirus, human sewage, including that discharged through the public sewerage system poses the greatest human health risk.
	6.2.6 Virus contamination in primary production We note the persistence of enteric viruses in comparison with *E.coli*, and the recommendation that virus control is included in EU food hygiene regulations. We would point out that although there may be different levels of virus reduction associated with different forms of wastewater treatment, there is no treatment system for the removal of virus. Therefore the only way to reduce the risk associated with sewage discharges is to ensure harvesting takes place at a safe distance. With the current lack of clarity on the significant level of norovirus in relation to illness, we believe that setting a standard will be a barrier to the industry.	We note the comment and agree that this is one of the options for mitigating virus risk. We have not made a recommendation about establishing a standard but note that discussions are taking place currently at EU level and those discussions are reflected in the Report.
	Recommendations that Inform Risk Assessments **R6.3 – Further research into the effectiveness of sewage treatment processes in reducing norovirus concentrations** We are interested in the outcome of any research, but advise that innovative treatment options will need to be funded within the usual investment constraints and subject to cost/benefit assessment. Additionally the benefit of any investment will need to be robustly demonstrated, and improvements will only be available in the longer term	Thank you for your comments which are noted.

	given the likely size of investment required for an overall improvement	
	Recommendations that impact on risk Assessments **R6.5 – environmental controls should be reviewed in the light of emerging evidence on norovirus contamination**	
	We agree that the focus of research on reducing the level of risk from norovirus contamination should focus on oyster harvesting areas.	We note these concerns and have amended the Report at Recommendation 6.6.
	We do not agree with the recommendation to remove sewage discharges. We believe that rigorous cost/benefit analysis should be applied which is unlikely to support water company investment.	
	Research to confirm tertiary or innovative treatment to be effective against norovirus will be needed	We note agreement with our recommendation 6.3.
	We support the recommendation that new CSOs should not be permitted to discharge to shellfish waters.	We thank Scottish Water for their support for this recommendation.
	As part of an improvement programme, the removal of a continuous discharge presents an opportunity to improve shellfish water quality, but the discharge point may need to be retained as a CSO provided the policy on limiting spills to <10 per annum is met.	We agree, provided the CSO meets regulatory requirements.
	Improvements to CSOs associated with shellfish waters should be prioritised within the investment process	We agree.
	A proposal for study into the use and value of CSO monitoring/reporting is to be included in our forward (SR15) investment programme. This may provide the basis for investment in these processes	We welcome this proposal and will be interested to hear the results in due course.

	R6.6 – review of risk management for shellfisheries (particularly oyster fisheries) Prevention of harvesting in areas in proximity to treated and intermittent discharges should be managed by the planning system, with input from Food Authorities, Environmental Agencies and Water Companies **R6.9 – FSA should review traceability and enforcement of sanitary controls, particularly following outbreaks, to ensure regulatory requirements are met at a local level** For Scottish Water, sanitary controls are set, and enforced, by SEPA under CAR	 We note the complexities in organisational terms but this does not affect our view that prevention of harvesting in areas in proximity to discharges is a sensible measure. We note this comment but would emphasise that our recommendation refers to food safety controls and have re-worded to make this clear.
Anglian Water	We welcome the opportunity to comment on the recommendations of this document. Our response is mainly limited to those areas relevant to the Water Industry although we have provided more general comments where we felt able to do so. It is important that the impact of proposed recommendations on both regulators and stakeholders is assessed. We would expect a Regulatory Impact Assessment to be undertaken before any decision about adoption of recommendations is made. We are pleased to see that the report considers a broad range of issues which may contribute to the risk of viruses in the food chain and with the exception of our specific comments below broadly support recommendations as part of a toolbox of measures to reduce the risk of illness associated with shellfish consumption. Anglian Water Services (AWS) is committed to investing and working with	We thank Anglian Water for their comments, but for those recommendations where a RIA would be required it is the responsibility of the relevant government department that this is undertaken. Noted. We note these useful initiatives.

	other stakeholders to improve shellfish quality as part of the Asset Management Programme (AMP). Investment in the current AMP5 period has focused on UV treatment of effluent and the creation of a Combined Sewer Overflow (CSO) Text Alert Initiative in conjunction with Seafish and associated harvesters. AMP6 investment will focus on extending Event Duration Monitoring (EDM) at our CSOs; data recorded by EDM could allow for more targeted investment in the future subject to being supported by customers through willingness to pay surveys.	We note these useful initiatives which should help improve public health protection.
	Our specific comments are limited to the recommendations (R) contained in the Contamination of Food (section 6) of the document. **R6.1 –** We agree broadly with this statement assuming that the monitoring is being conducted on the shellfish bed **R6.2 -** Agree **R6.3 –** Agree. There is a possibility that a greater proportion of viruses are being deactivated than is currently thought but this currently cannot be demonstrated as no methodology exists to show viability in viruses. **R6.4 -** Agree but this must be a balanced provision of advice. Other food products including salads carry a greater risk so the risks attributed to oysters must not be over stated Anglian Water Services Ltd response Pg 2 of 3 May 2014 **R6.5** Bullet 1 – it is not possible to target investment to control Norovirus (NoV) risk when there is no methodology available that indicates whether treatment has resulted virus deactivation or not. This research requires	Thank you for your support for this recommendation. Thank you for your support for this recommendation. Thank you for your support for this recommendation. Thank you for comment. We are sure the FSA will take this into consideration in reinforcing their food safety advice. We thank Anglian Water for this comment but note that sewage treatment is not the only option for reducing risk which is why the second bullet point has been included

	addressing first before investment options can be evaluated. Any additional treatment would need to be assessed on a cost benefit basis and subject to water company customer willingness to pay surveys.	(R6.6). We note the requirement for research (our 6.3) but acknowledge that it will be up to risk managers to decide upon the balance between research requirements and risk management action.
	NoV enters sewage from sickness in the community so controls need to be considered for establishments such as hospitals and other healthcare facilities as increased incidents of illness in the community will result in increased NoV loadings in waste water.	We note this point. However the evidence shows that the burden of NoV is greatest in the community. What occurs in hospitals is a reflection of what is happening in the wider community and there is no evidence that hospital discharges pose a greater risk than the community in general.
	The authors of the report may need to consider that treatment may not be a viable option based on the amount of missing information on NoV behaviour in the environment such as data on sediment association or on how far NoV can travel. For example, waters in the South of the Anglian region may be heavily impacted by NoV originating from London. This would require 'cross border' investment between water companies.	We agree. Pathogens do not respect administrative or geo/political boundaries.
	Bullet 2 – consideration needs to be given to whether such measures will be financially cost beneficial, technically feasible and supported by water company customers through willingness to pay. Research and Guidance is required to arrive at appropriate distance limits from shellfish beds to water company assets to allow for sufficient dilution. Marine modelling which considers factors such as tide and dilution and other factors should be used to inform guidance on a site by site basis.	We note these points and expect these would be taken into account in any risk management action.
	Raw water impacts are considered by the EA when setting effluent limits and this has resulted in UV treatment being provided at applicable sites therefore the impact on many shellfish beds has already been assessed.	We note this comment
	Bullet 3 – AWS has appropriate UV treatment on assets which discharge continuously to shellfish waters, these measures need to be applied to	Human faecal discharges, include those from private discharges containing NoV pose a risk to human health.

	private discharges. Bullet 4 – Agree. Bullet 5 – A forthcoming Task and Finish Group (TaF) with the Water Industry and EA has been set up to look at this issue. The number of spills will depend on a number of variables including weather, growth and changes to the upstream sewerage network. The outcome of the TaF needs to be considered along with government policy and it is important to note that it is not spill frequency that is important here but impact. Bullet 6 – Agree.	We note Anglian Water agree with our recommendation and are already treating some of their relevant assets with tertiary treatment. Noted. We note this initiative is under way. Noted.
Glasgow Caledonian University	Section 1, page 27 in 'considered' section of table, shellfish should be added as they have been evidenced to contain HEV RNA. Page 54, 6.2.1 and section 8.4; As mentioned, HEV is only 50% inactivated at 56^{o}C and 96% at 60^{o}C for 1 hr (consultation cites Feagins and Barnaud), however, it is also stable when exposed to tri-fluoro-tri-chloroethane and resistant to inactivation by acidic and alkaline conditions therefore, lightly steaming, preservation of shellfish by smoking and/or in acetic acid are also potential routes for viable virus to cause a risk to public health, this should be confirmed. It should also be noted that different strains may have different characteristics (http://jid.oxfordjournals.org/content/192/5/930.long)	We have noted this comment and amended the Report to remove "pork" from this sentence. We note this comment. We recognise there is a gap in knowledge but the epidemiological evidence in the UK points to pork consumption as the main risk to human health currently which is why we have focussed on pork in our report.
BRC	***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:- o *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.* o *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.* o *Other permanent discharges impacting designated shellfish beds should receive at least tertiary treatment – which need to be shown to be effective against norovirus.* o *New CSOs should not be permitted to discharge into designated shellfish waters.* o *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.* o *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.* We agree with the considerations for Defra when approving sewage and water treatment facilities/overflows. However, there is also scope when considering approvals for new catch areas to take account of the location of nearby sewage treatment works. This would give the opportunity to regulate proximity to these works.	We note your support for R6.5.
	R11.6 *Advice should be available at the point of consumption of the hazards of eating raw oysters.*	

	We support that point of consumption advice should be made available to increase awareness. However we would only support mandatory labelling with an agreed consistent message for all businesses. We would not support a voluntary approach which would lead to responsible businesses losing trade to those choosing not to provide labelling.	We note BRC support for our recommendation that advice should be available at the point of consumption for all consumers. How this is effected will be a decision for risk managers.
PHE	**Chapter 6. Contamination of food** **6.2.1 Bivalves** We suggest that this section be amended as follows: 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). *Although the results of an analytical study showed shellfish consumption to be linked to infection on board a UK cruise ship, it was not possible to establish the full provenance of the shellfish mix consumed. An epidemiological link with human illness has yet to be established for this transmission route in the UK* (Ijaz *et al*, 2005, Lewis *et al*, 2005; *Said 2009*).	Noted. The Report has been amended. We have also added a research recommendation regarding HEV and bivalve molluscs following several comments.
Aquaculture Initiative	<u>Potential impact on Aquaculture</u> Oyster farming is an area of Aquaculture that is expanding and has potential to contribute to the rural economy and the aims of the Common Fisheries Policy to increase seafood production from Aquaculture. It is recognised that the norovirus presents problems to public health and that oyster consumption has a role to play, however when looking at the norovirus problem it should be borne in mind to keep the scale of the problem posed by oyster farming into perspective.	We note these comments. Noted.

	A consequence of an over emphasis on oyster consumption is that more and more oyster farming is turning to selling oysters to the bulk market abroad, as it is becoming increasingly difficult to continue to perform commercially within the UK market. If Norovirus as an issue, which results in a high burden of testing and administration being passed onto producers, this will result in a sharp increase in the cost of production and those costs will be passed to the consumer – who then buys less oysters. Another knock on effect of reduced oyster sales in the UK, and higher exports made direct to the European market, is in reduced payments to the levy which funds Seafish.	
	<u>Level of problem posed</u> From the sales of oysters within the UK, it can be seen that oysters are not eaten regularly or widely by the UK public. The study, 'Comparing Aetiology and incidence Rates ' referenced in the consultation – shows that the incidence rates of overall infectious intestinal disease (IID) show that the rates of IID were highest in 0-4 year olds and high also in 5-14 year olds. It should be recognised that these are two groups that don't eat raw oysters, and that oyster's role in IIDs in quite low. Other results from this report show that less than 5% of cases who provided a specimen had an infection of more than one organism. Mixed infections are indicative of contamination from sewage – the origin of norovirus in the case of oysters. This shows that the overall problem represented by oyster consumption is not high in the list, considering that travel outside of the UK had a strong correlation with those presenting themselves to the GP (12%).	Noted but we would draw attention to conclusion on p65 (second bullet) and 98.

The first study of IID in the community (2001) – states that ‘’we found the consumption of very few specific foods to be associated with an increased risk of suffering from IID. – Infection is predominantly from person to person’’.

This is supported by the table in p53 of the consultation that shows that the estimated fraction of norovirus transmitted by Fish and shellfish to be 16% yet the level infected by humans / animals was 51%.

From a Northern Ireland Perspective, the CEFAS Prevalence and Distribution Study (2011), on the two NI sites studied over two years (samples n=24) shows that although the norovirus is present on sites, it is not at a sample frequency which would present a high risk to public health;

NI Site. Number.	Norovirus > 100 copies/g	Norovirus > 500 copies/g	Norovirus > 1000 copies/g
29	6/24	2/24	0/24
31	10/24	5/24	2/24

Lowther et al. 2011, indicates that Norovirus levels in outbreak related oyster samples had an average of 1,048 genome copies per gram. Also human volunteer studies show that there is a 10% probability of illness with a dose of 1,000 genome copies. If there is 10% chance of illness with this dose, and that this dose is found only twice out of 48 samples in NI over two years. This would mean that this risk is very rare in NI terms, and as there is a significant correlation between presence of norovirus and illness, this could be seen as a supportive finding for NI’s oyster sector.

We note this comment but would suggest such a small survey would not be powered to give a robust assessment of public health risk.

	In other discussions 500 copies per gram is often discussed as a potential threshold that harvesting would be prevented, this level in the context of NI's sites from this study should be regarded as low risk sites. If enhanced risk management controls need to be instigated at high risk sites, clearly there is a case for NI not to be included from these initiatives. Although it does point out that gaps in the understanding of the levels of norovirus on our sites do need to be filled. It is also noted from the report that these figures are the Norovirus levels found on site and that post-harvest treatment, would potentially reduce further the levels found to some degree. Other parts of the consultation indicate that the overall the risk to the public by oyster consumption is low, after all the level of infection by food is uncertain and asymptomatic infection by norovirus is common. For many the norovirus from food is not a serious illness. Indeed only 4% of people with norovirus infection present to primary care because the illness is mild and self-limiting. Also only 2.7% of outbreaks of norovirus reported in the UK between Jan. 2001 and Dec. 2008 were judged to be food borne. The predominant mode of transportation tends to be identified as person to person.	The IID studies have shown significant under-reporting and under-ascertainment of NoV. Moreover, it is rarely possible to investigate outbreaks fully so a foodborne seeding event may well be missed. So 2.7% judged to foodborne is likely to be large under-estimate.
	<u>Chapter 6. Contamination of Food</u> This chapter recognised the role that sewage treatment works have in managing and reducing the risk posed by oyster consumption. 'for norovirus strains that infect humans, contamination of bivalves…is <u>*always*</u> associated with human faecal pollution in some form''. And ''it is fundamentally important to protect and improve the water quality of	

	coastal areas intended for the harvesting of shellfish for human consumption'' These are points often made by oyster farmers as they don't see themselves as being the source of the problem – although often made to feel that they are. Another issue often raised by the Aquaculture sector is to do with CSOs. The role that CSOs play and changing weather patterns has also been recognised in the consultation. The Government policy described in the consultation is that a designated shellfish water should not be impacted by more than 10 significant CSO spills per year is of interest and we would seek clarification if this is applied to NI – especially as there does not seem to be any record or notification kept of the frequency of overflow events. A recommendation from ACSMF 1998, that all shellfish production areas should be designated as 'sensitive' water' would potentially have reduced the risk from norovirus contamination. This is still the case. Figures from the consultation on p61 show that 40% of EU production areas fall into class A. Yet figures for the UK as a whole were less at 27%. From The FSA NI classifications of 2014 this figure in NI is 21%. Clearly, there is potential to further improve the water quality of NI's shellfish production areas. The Shellfish Waters Directive was replaced by the Water Framework Directive in December 2013 in NI. The review of the Shellfish Waters Directive was not popular with the Aquaculture sector, and a considerable response was made during the consultation held on this. Despite this from this review the objective's made, for NI were to aim for a 'B'	We thank Aquaculture Initiative for their comments on this chapter. In relation to the specific issue in Northern Ireland we refer them to NIEA who will be able to answer this question. Our recommendation 6.6 covers all UK waters.

	classification with a fall back to 'C'. This is in contrast to Scotland's review which aims for an 'A' classification with a potential fall back to 'B' in some cases. From this consultation the Recommendations R61 to R.9 to a large degree are all needed, and R6.5 should be amended to strongly encourage the devolved administrations and England, to follow Scotland and to make their own WFD policy objective's to aim for class ' A' water. It should be recognised that R6.4. i.e. advice on the risk of consuming raw oysters – should emphasize that the results from numerous studies show us that the risk with norovirus and oysters is seasonal, and is really only confined to the winter period. The advice should be clear on the seasonal nature of the risk. Another matter to be noted is that R6.6. - the proposed prevention of harvesting taking place, would not be welcomed by the established oyster farms – as many would find that there are sewage pipes in their location and potentially their farms could be put in jeopardy – on the other hand, this should be put into the context of R6.5. which recommends the relocation of sewer discharges from oyster production areas, this is a strategy more in tune with the producers.	Please note recommendation 11.5. We agree that these two recommendations (now R6.6 and R6.7) should be considered together.
	<u>Additional actions</u> From documents referenced. The FSA guidance on 'Managing Farm Manures for Food Safety', should be revised so that it can be used to minimise risk to oyster farming by agricultural manure use. As currently it does not take this into account. The Northern Ireland Aquaculture sector needs to be put into an informed position as to the level of Norovirus routinely present on the farms and also the level present in oysters sent to market. This gap in the knowledge makes it difficult to establish an informed	We anticipate that once our report is published risk managers will revise their guidance in the light of our recommendations. Recommendation 6.1 applies to the whole of the UK.

	position on the many norovirus related administrative plans as they are put out for consultation. Filling this gap could be in addition to the recommendations that inform Risk Assessments of R3.1-R3.6.	Recommendation 6.1 applies to the whole of the UK.
	<u>Further issues</u> Oyster consumption is a unique and special case in the food business and its unique characteristics should be taken into account. Oysters are traditionally eaten live and raw and by adults – who understand that there is a possibility of norovirus being present at a low level from the seawater environment. A zero risk oyster is not possible and should not be the aim of the recommendations. Oyster's situation is quite different to other foods such as raw vegetables, e.g. on p34 of the consultation, ''foodstuffs such as leafy green vegetables etc. – noroviruses should *under no natural circumstances be present*''. This isn't the case with oysters where a level of norovirus (preferably low) can be expected by the authorities and the consumer to be present, due to it being a filter feeder raised in open water. Relaying is highlighted as being a way of minimising risk, it has been noted that relaying is less widely used in the UK than elsewhere in the EU. NI at present does not have any designated relaying site. It would be a useful recommendation by the ACSFM to recommend the formation of a working group to locate a suitable site for relaying shellfish as that this could be a low cost way for producers to deal with an outbreak if it occurs.	We note these comments but our assessment is different. We note these comments but our assessment is different. We note this comment, but this will be for risk managers in NI to take a decision on.
Defra	Defra suggested editorial changes on the following pages 20, 22, 56, 57 and 58 in the report.	Thank you for your helpful editorial changes. The Report has been amended.

	Fresh and frozen produce, food handling	
Bakkavor	The document seems to make some broad statements and then follows them up by comments that suggest great uncertainty. This applies to the methodology, foodborne outbreaks associated with foods and reactions to positive detections. There is emphasis on developing methods and carrying out surveys and testing, but even if produce samples are found to be contaminated with viral RNA, effective controls are not known and there have been very few outbreaks associated with fresh RTE produce especially considering the size of the market. Food safety of fresh RTE produce is managed by a series of hurdles from the field to the finished product. The risk from animal manures, contaminated irrigation water, food handlers and harvesting and cooling equipment etc. is already controlled due to the risk from any foodborne pathogen, not just viruses. Due to the very low numbers of outbreaks caused by fresh RTE produce these hurdles could already be effective. In the industry we need to know about new intervention strategies e.g. effective treatments to inactivate viruses to add any necessary hurdles. Reference is made to potential issues with fresh produce; however the majority of outbreaks have been linked with certain processes e.g. freezing and drying. I would suggest that these types of produce have different supply chains and processing and there are very few outbreaks associated with fresh RTE produce. Unnecessary damage could be caused to the produce industry by carrying out surveys and taking a zero tolerance approach.	Thank you for your comments which we note.
	P11 What evidence is there that 200,000 cases of foodborne illness are associated with food. Fresh produce e.g. soft fruit has usually been	Thank you for this comment. The evidence is provided in the peer-reviewed reference.

	linked to frozen berries.	This is a quotation from Adak *et al*'s paper in 2005. The sentence at bottom of p11 has been amended to read "contaminated produce such as soft fruits, particularly those that have been frozen".
	P12 Food handlers and person to person spread are a major source of illness and we cannot be sure that the original source was food.	We note this comment. Given the way NoV circulates it is difficult to be sure in which direction transmission occurs.
	P16 The ISO 15216 is a technical standard and does not determine the ability of the virus to cause illness	We agree with this comment. In R3.4 we advise research determination of virus infectivity.
	P17 Research into effective measures should be a priority, as to identify a source when no effective processes have been defined does not aid in protecting public health.	We note this comment on the 1998 report's recommendation.
	P18 The exclusion period for food handlers following viral illness is 48hours, however 48hours and 72hours are stated at various points in the document. 48hours is recommended in the FSA guidance.	At the time of writing these were the exclusions in existing guidance which we accept were inconsistent. We have made a recommendation to update the FSA's 2008 guidance (R5.8.)
	P19 I support the approach for a review of the Fresh Produce Guide	Thank you for this comment. As previously recommended in the 1998 report there needs to be an update of the Fresh Produce Guide.
	P26 A wide range of viruses have the ability to cause human illness and therefore the focus should be on how these viruses could enter the food chain and develop interventions.	Noted.
	P27 200,000 cases per year stated, but only a few due to fresh produce (these are usually frozen) which may have a different supply chain.	See comment on p11.
	P30 When describing heat processes, what log reduction does this achieve? What log reduction is necessary to give food safety assurance?	As stated on P30 of the Report, it is not possible to define the log reduction of infectious HEV produced by a

	As the food industry uses 70˚C for 2 minutes, why have there not been more outbreaks?	heat process, as there is currently no quantitative infectivity assay which can be used to do that. As stated on P12, although the number of clinical cases may not be high (300-700 annually), the number of infections is likely to be considerable (at least 65,000 annually).
	P31 With potentially 16% of the population shedding the virus asymptomatically, the importance of hand washing and good hygienic practices must be communicated.	We agree. See our Recommendations 9.2 and 9.5.
	P32 Risk assessment and risk management needs to consider quantitative understanding of the infectivity. If this is not known why does the document suggest reacting to the presence of viral RNA?	This relates to the precautionary principle because there will not be further heat treatment. See also our recommendation 3.1.
	P33 Fresh produce is not routinely tested for positive RT-PCR signals and therefore to say that any positive signals should be interpreted as the produce being potentially infectious and a failure in good practice is a statement that has not been proven, nor is there evidence for this. If routine testing were to be introduced, this approach could greatly damage the fresh produce industry which has a good food safety record.	We note the comment but disagree with it. We have not advocated routine testing. Our recommendation 3.2 refers to surveys to understand better the burden of virus contamination in foodstuffs on the UK market.
	P34 Produce grows in a field environment and although controls can be put in place to control contact with livestock and animal manures, contact with wild animals cannot be eliminated. Therefore as stated above, to react to a positive signal and make a decision to reject large batches is neither practical nor improving food safety. Testing cannot be a control of food safety as very small samples are taken to represent large batches. Negative results cannot guarantee absence in the batch. Focus must be on prevention and testing to verify the controls. The controls for viruses must be the priority of research –	We have not made any recommendations on batch testing or release. We agree. Recommendations for methodologies in 3.1-3.3 could be used to verify the effectiveness of controls in place of primary production.

	these will improve food safety.	
	P35 Low levels of norovirus may not always present an acute illness risk. This suggests a quantitative method is required for infectious viruses.	We agree. Please see recommendation 3.3.
	P36 & 37 I support these areas of research, however until this work is carried out, conclusions must not be drawn from the current methods and assumptions that the detection of viral RNA makes food unsafe and therefore requires action as no further effective actions are known. Very few outbreaks have been caused by fresh RTE produce and field to fork controls already in place may already be effective.	We are pleased to note Bakkavor supports our recommendations and reiterate that we have not made any recommendations about batch testing and positive release.
	P41 Methods to quantify and detect infectious virus particles are required to carry out 4.1 and 4.2	In addition to 3.1-3.6 recommendations 4.1 and 4.2 concern epidemiological approaches to the assessment of the burden of illness and risk factor studies for Hepatitis E infection. We have amended the recommendations in 4.1 and 4.2 to clarify this.
	P46 The issue of infected food handlers is already covered in the FSA guidance for food handlers and return to work procedures. These should be communicated better to all food manufacturing and catering establishments.	We agree. Please see recommendations 9.2-9.5.
	P50 It would be extremely useful for the industry to be regularly communicated with any learning's from ALL foodborne outbreaks – not just ones associated with viruses. This way the industry can check adequate controls are in place to prevent a reoccurrence and identify areas where more guidance or research is required.	We agree, see recommendation 5.4. However, all foodborne outbreaks were outside the scope of this report.
	P53 Quoted percentages of norovirus transmitted by food commodity should be given more detail – what type of fruit / vegetables and how	This information was not available.

	were they processed or sourced?	
	P68 & 69 Many of the outbreaks are associated with frozen or dried produce. This should be noted as more detail may be required on the supply chain and traceability of these products. Considering the size of the market there seem to be very few outbreaks. The learnings from these outbreaks would useful to try and prevent reoccurrences	We agree this is an important point and to avoid confusion the Report has been amended to “Fruit and vegetables”. Viruses, particularly NoV are hugely under-reported. Therefore this impacts on the ability to detect outbreaks, most of which are likely to be hidden. We agree learning from outbreaks is useful for preventing reoccurrences. Please also see recommendation 5.4.
	P70 If surveys are to be carried out on fresh produce, there should be caution about how the results are interpreted. Conclusions will be drawn about the safety of these products which could damage the industry which has a good food safety record. Is it known how widespread viruses are in the environment? The report shows that they can survive well and with produce being grown outdoors there is a likelihood that viral RNA could be present.	We agree. We stand by our conclusion that viral RNA should not be present. If it is present, somehow contamination by infected people has occurred.
	P72 Chemical disinfection of produce will not eliminate microbial pathogens. This is why a field to fork approach is taken to reduce the risk, however risk cannot be eliminated. Heat treatment, irradiation and high pressure processing is not an option for many fresh RTE produce products.	We agree.
	P81 The issues regarding the food handlers return to work and staff taken ill at work should be covered in the FSA food handler guidance. This document may need updating with further guidance in these areas	We agree. See recommendations 9.2-9.5.

	P83 This is the kind of information that the industry need to be able to manage the risk. More details are required on the minimum parameters for these factors that affect the persistence of viruses. Also to what extent are the viruses affected.	We agree that this information has value to risk managers. It is incomplete for the viruses discussed here. See recommendation 9.1.
	P93 11.1 Information on washing leafy green vegetables and soft fruit is not required. Efficacy of the washing against viruses is not known. Viruses must be controlled from field to fork and washing alone will not remove the risk. This information is therefore not required for prepared produce that is sold already as RTE. As previously stated there are very few outbreaks associated with fresh RTE produce. The outbreaks are mainly associated with alternative supply chains.	We note the comment but disagree as not all leafy green vegetables and soft fruit are ready-to-eat.
	P94 The ability to detect virus RNA in foods does not assist in risk management as the decontamination processes may already be inactivating any virus particles. Control measures are initially required and a quantitative method for infectious virus detection is needed to verify these controls.	We disagree. We think these methods will assist in risk assessment.
The Fresh Produce Consortium	**The Fresh Produce Consortium** is the UK's trade association for the UK fresh produce industry. FPC welcomes the review by the FSA's Advisory Committee on the Microbiological Safety of Food to review foodborne viral infections, assessing the risk to consumers and highlighting any research and surveillance gaps. We are concerned that the ACMSF's conclusions in relation to fresh produce could be taken out of context with a resulting negative impact on consumption of fresh produce. The report states that there is an unknown	

	level of risk arising from the consumption of fresh produce, and that consumer safety is reliant on a '*voluntary* code of practice', implying that this is somehow inferior to any regulatory requirement. The report does not put into perspective the extremely low level of risk to UK consumers from eating fresh produce, the high standards maintained by the industry and its strong record of food safety.	Voluntary Codes of Practice are a fact. We disagree with the inference drawn that voluntary codes are inferior. Our concern would be that they are not universally applied rather than that they are inferior. Recommendation R7.3 has been amended.
	FPC agrees that there needs to be a better understanding of foodborne viral disease by investigating the correlation between infective dose and genome titre. The fresh produce industry would welcome the development of methodology to assess norovirus infectivity in food sampling which can be applied in a practical cost-effective way to routine monitoring. As the report states: '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' (Page 34).	We agree.
	However, detection of a virus is no indicator that a virus presents an infectious risk. On this basis, great care needs to be applied to any requirement for widespread industry testing if there is no clarity with regard to what action should be undertaken by the food industry (Recommendation R7.1).	We have recommended systematic surveys but this does not equate to "widespread industry testing".
	The industry carries out extensive regular monitoring, over and above any regulatory requirements. Testing for testing's sake will merely result in increased costs to be passed on to the UK consumer and will provide no additional surety for food safety. In addition, this is not in line with the UK Government's strategy to avoid a disproportionate burden on industry.	See above response.
	We note that the ACMSF Committee recommends that research is needed to identify the most effective means of decontaminating fresh produce post-harvest (Recommendation R7.2). This is a complex task,	We agree.

	given the wide range of highly perishable products with short shelf lives. The fresh produce industry is coming under increasing pressure with the scrutiny by the European Commission on **reducing levels of residues of disinfectants** in fresh produce. The safety and quality of fresh produce is paramount to the industry and we are concerned that any reduction in a range of effective products for cleaning fresh products and surface areas in production could result in a potential increase in the level of risk of foodborne virus on products beyond the industry's control. We would welcome the Committee and the Food Standards Agency to participate more effectively in this debate with the European Commission to ensure that food safety remains the key driver for any recommendations by EFSA to change Maximum Residue Levels and subsequent action by the European Commission. The ACMSF is not required to undertake an assessment of risk, and therefore this report fails to take into account the overall benefits of including fresh fruit and vegetables as part of a healthy diet with the risk from microbiological issues. We believe that it is essential that the Food Standards Agency takes this up.	We note this comment, but this is outside the scope of this Report. We note this comment, but our remit is microbiological food safety.

	UK Market The total quantity of fruit and vegetables marketed in the UK decreased slightly by one per cent between 2011 and 2012, to around eight hundred and forty-nine thousand tonnes. This followed a period of consistent growth between 2009 and 2011. There was a two per cent decrease in vegetables marketed from 2011 to 2012, and a very small increase (0.06 per cent) in the fruit sector. Since 2000 the overall 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 two and a half servings of fruit and vegetables a day, way below the recommended 5 A DAY.	
	We are concerned that elements of the ACMSF report could easily be taken out of context to infer that there is a significant risk to the UK consumer from eating ready-to-eat fresh produce when there is substantial evidence to demonstrate that this is not the case, given the large volumes consumed throughout the year in the UK. For example, the UK has consumed more than five billion packs of prepared salads in the last ten years, with only extremely rare occurrences of any issues.	We note the comment. The report does not highlight any specific market data for the 'Ready to Eat Fresh produce'
	EFSA opinion on microbiological risk of food of non-animal origin In 2012 the European Food Safety Authority published its opinion on the microbiological risk of food of non-animal origin. The report identifies the main risk factors and specific mitigating measures for priority categories of fresh produce identified by the European Commission.	We note the comment and reviewed EFSA's findings during the course of our deliberations.
	The panel developed a multi criteria analysis model aimed at risk ranking combinations of food of non-animal origin and specific pathogens. Using all the seven criteria in the model, the top ranking groups of food/pathogen combinations in the following decreasing order of priority:	Noted.

Ranking	Pathogen	Category
1	*Salmonella* spp.	Leafy greens eaten raw as salads
2	*Salmonella* spp.	Bulb and stem vegetables
	Salmonella spp.	Tomatoes
	Salmonella spp.	Melons
	Pathogenic *E.coli*	Fresh pods, legumes and grain
3	Norovirus	Leafy greens eaten raw as salads
	Salmonella spp.	Sprouted seeds
	Shigella spp.	Fresh pods, legumes or grain
4	*Bacillus* spp.	Spices and dry powdered herbs
	Norovirus	Bulb and stem vegetables
	Norovirus	Raspberries
	Salmonella spp.	Spices and dry powdered herbs
	Salmonella spp.	Leafy greens mixed with other fresh non animal products
	Shigella spp	Fresh herbs
	Pathogenic *E.coli*	Sprouted seeds
	Yersinia spp.	Carrots
5	Norovirus	Tomatoes
	Norovirus	Carrots
	Salmonella spp.	Nuts and nut products
	Shigella spp.	Carrots

This model was based upon reported outbreaks in the EU between 2007 and 2011. The model has been used by the Commission to identify which food and pathogen combinations should be given priority for addressing risk factors, mitigation options and possible microbiological criteria.
In the course of 2013 we provided further input through Freshfel, the European fresh produce trade association, to a series of workshops run by the European Commission to develop more detailed analysis for leafy greens (Salmonella, Norovirus), bulb & stem vegetables and carrots (Salmonella, Yersinia, Shigella, Norovirus), tomatoes (Salmonella, Norovrius), berries (Salmonella, Norovrius) and melons (Salmonella).
The EFSA scientific opinion on leafy greens was published in April 2014, serving as a reference for the other opinions which are expected to be released during 2014. The opinion focused on improving current monitoring efforts by regulatory authorities and industry, as well as conducting further research on Norovirus detection. There were no concrete suggestions to develop new microbiological criteria. The EU

	Commission will start discussions with Member States later this year on any future recommendations from the next suite of reports; however, concrete proposals are unlikely to be presented before the end of the year.	We note these comments but are not suggesting implementation of microbiological criteria.
	2. **Review of previous ACMSF report** Within the report the comments from the Ad Hoc Group refer to the FPC's **Guide to Good Hygiene Practice – Fresh Produce'**, stating that '..*There appears to be no current version'* (page19). This is incorrect. The current Guide was published in 2009 and is available from the Fresh Produce Consortium. We intend to review the current edition of the FPC Guide after the completion of EFSA's work. This will enable us to take into account any recommendations arising from the review and subsequent proposals by the European Commission. Following the E.coli outbreaks in central Europe in 2011 the Food Standards Agency approached the FPC to develop '**Guidance for food business operators on the hygienic sourcing, production and safe handling of ready to eat sprouts'**. This guidance sets out minimum standards and best practice for this sector, and was revised to take into account EU Regulations coming into force in July 2013. The Guide covers primary production of seeds for sprouting and production of sprouts. It includes advice on microbial analysis, information on legal requirements and advice on microbiological sampling and testing regimes. It's important to keep in perspective the relative risk from fresh produce in comparison with animal products. Between 2007 and 2011 food of non-animal origin was associated with 10% of all EU reported outbreaks. Outbreaks associated with fresh produce remain extremely rare.	The report has been corrected on p19. We understand that the latest version is 2009. We would say that outbreaks are rarely reported.

	6.1 Food chain management **Table 4: Estimated fraction of norovirus transmitted by food commodity.** We are not sure why the ACMSF report uses this data when the EFSA report provides a more comprehensive review of foodborne outbreaks associated with a wider range of food products. A total of 5,363 food-borne outbreaks were reported in the European Union during 2012. These resulted in 55,452 human cases, 5,118 hospitalisations and 41 deaths. According to the latest EFSA/ECDC report, in 2012 the number of food-borne outbreaks decreased by 5% compared with 2011. Most of the reported outbreaks were caused by *Salmonella* (28.6%), bacterial toxins (14.5%), viruses (14.1%) and Campylobacter (9.3%). *Salmonella* continued to be the most frequently reported cause of food-borne outbreaks with known origin. Vegetables and juices accounted for just 2.6% of Salmonella 'strong evidence 'outbreaks. The largest outbreak in 2012 occurred in Germany, affecting 10,950 people, and was caused by norovirus associated with frozen strawberries from China. This outbreak accounted for the overall increase in the number of outbreaks associated with viruses.	We have used data from recently completed research funded by the Food Standards Agency. This is the most recent, relevant, i.e. UK-based, estimate of foodborne disease in the UK. Tam CC, Larose T, O'Brien SJ (2014). Costed extension to the Second Study of Infectious Intestinal Disease in the Community: Identifying the proportion of foodborne disease in the UK and attributing foodborne disease by food commodity (FS231043). Available at http://www.foodbase.org.uk//admintools/reportdocuments/866-1-1609_IID2_extension_report_-_FINAL_25_March_2014.pdf Furthermore, reliance on outbreak data alone can provide a skewed picture since the majority of cases of foodborne disease do not occur as part of outbreaks.
	7.4 Mechanisms for contamination of fresh produce The Committee refers to incidents which have occurred in the US and other countries (Table Six, Page 69), but does not carry out a robust evidence based assessment to compare differences in the production processes here in the UK. A number of the incidents included were associated with frozen soft fruit and dried products, not fresh produce, yet	The report has been amended in chapter 7 to clarify and a new paragraph added on frozen products.

	these are included under the title 'fresh produce items' which is misleading.	
	Sewage contaminated water and use of animal manure as fertiliser (Page 70) Untreated or raw sewage sludge cannot be applied to land which is used for growing crops. There are stringent requirements with regard to the application of treated sewage sludge to land which is used to grow vegetables. At least 12 months must elapse between application and harvest of a vegetable crop. In the case of ready-to-eat salads which may be eaten raw, a harvest interval of at least 30 months must be adhered to. This report does not put into perspective that any **accidental** contamination of water by sewage is extremely rare. Potable water is usually required in produce washing operations, with separate facilities for washing produce and equipment.	We agree and have modified the text of the report at paragraph 7.4.
	7.8 Standards and Guidelines The report implies that imported fresh produce may carry a greater risk to the UK consumer which is totally unfounded. Overseas suppliers have to meet the same standards of those of UK growers, with contracts set in advance for the supply of fresh produce which include full specifications and traceability.	We disagree. We have not implied this and indeed state that "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." (p 73).
	Reliance on 'voluntary codes of practice' (page 75) Good Agricultural Practice is critical to ensure the elimination of potential routes of infection in the production of fresh produce. Industry standards are often higher than regulatory standards and have been responsible for maintaining the strong record of safety which we have in the UK. No sector of the industry is complacent about food safety and strict standards relate to all sectors, not just for those companies which trade	See earlier comment – we have not inferred voluntary schemes are inferior. Recommendation 7.3 has been amended to clarify.

	with multiple retailers. It is misleading to infer that these standards may somehow be weak or inferior compared with any regulatory requirements (Recommendation R7.3). Moreover, any fresh produce company which wishes to trade in the UK, whether in the retail, foodservice or wholesale sector, has to comply with these standards to secure customers and remain competitive. With regard to assurance schemes, membership of such schemes includes regular independent inspections to ensure that production methods comply with scheme protocols. Such schemes often go above and beyond what is required by law, and Produce Marketing Organisations can review and check that their contracted growers are in possession of all the appropriate controls and documentation. The FSA has already undertaken some research on the assessment of internationally recognised food assurance schemes in relation to food safety with its long-awaited research into the application of Assured Trader status, recognising the high standards of reputable UK fresh produce companies.	We note this research has taken place.
	Annex 2 – Fresh Produce Market Sectors (Page 106) Please note that this data is sourced from the Fresh Produce Consortium, not the Chilled Food Association. The fresh produce industry must never be complacent and absolute priority is given to food safety. We must always be conscious of the impact which food borne outbreaks can have. Yet at the same time we mustn't lose sight of the immense contribution which fresh produce can make as part of a healthy diet, something which we cannot take for granted that the UK consumer understands fully today. We believe that it is important for the FSA to target its limited resources to	Thank you for pointing this out. The report has been amended. This is outwith the remit of ACMSF.

	areas which pose the greatest risk to UK consumers. The ACMSF gives no prioritisation for its series of recommendations yet bears a duty of care for the public impact of its recommendations. This will be critical for the FSA in making any assessment of the overall benefits of future research to both the food industry and the consumer.	As with all ACMSF reports the FSA will take into account its prioritisation and taking into account the best use of science.
	As the ACMSF report states 'The most commonly recognised outbreaks of foodborne norovirus cases are also thought to result from contamination of food by infected food handlers'. We believe that the recommendations R9.1 – R9.5 are critical to improve food safety, particularly where food products are the carrier and not the source of an outbreak. Any recommendations on personal hygiene must be translated to the UK consumer, where the majority of outbreaks arise according to the EFSA report.	We thank the Fresh Produce Consortium for their support for recommendations 9.1-9.5.
BRC	**P16 Ad hoc group's comments** It is unclear whether the guidelines for safe use of sewage sludge on agricultural land (which represent the good practice referred to on page 34) are effective against viruses. We would welcome clarity on whether the research been done to determine whether the sewage sludge guidelines produced for industry are effective. However, we note that even if sufficient to inactivate viruses, we're unsure whether the nucleic acid will degrade or could still persist resulting in a positive (presence) on the finished product whilst not being infective. We believe there is scope to expand on this in the report or include recommendations for further investigation.	We thank BRC for their comments. Please see our response to the FPC on page 32 and amendment to the report in paragraph 7.4.

	Section 7 Fresh Produce The committee may want to consider the title given to this section as the content sways between fresh and frozen references. We note that produce is considered a 'risk' but the current evidence has only shown an association with frozen produce. We're unclear on the reason for this, it may be because of the different supply chains. However, the difference leads us to query whether discussions on produce should separate fresh from frozen. ***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 use of third party schemes introduces a point of difference between accredited and non-accredited suppliers by prescribing implementation of best practice as a condition of business. Accredited third party schemes stipulate compliance to conditions above the legal minimum and are independently verified. A number of reviews have already been undertaken and we query the need for this recommendation.	Thank you for these comments. The title of chapter 7 and text has been changed to "fruit and vegetables". Recommendation 7.3 has been amended to: The FSA assesses the level of take up of voluntary hygiene schemes at all scales of production to determine sector coverage and whether or not this provides adequate protection for the consumer. We recognise the BRC does this but we wish the FSA to assure themselves that this addresses the risks across *all* scales of production.
	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.*	

	We are supportive of the recommendation and suggest that there is opportunity to go further and recommend that funding should be made available for research into effective alternatives to alcohol wipes.	Thank you for your support for this recommendation. We have amended this recommendation to include current best evidence which is "with soap and warm running water and drying".
Red Tractor	We would have to say that Chapter 7 of the draft report: ▪ Is mistaken about the regulatory background ▪ Confuses 'schemes' and 'codes of practice' and fails to understand critical differences between the two ▪ Shows little understanding of the FSA's interface with schemes So we cannot accept that the report has a proper basis for the second conclusions at p75 nor the recommendation R7.3. It is a pity that the working group made no contact with us. We would have been more than happy to assist a better understanding.	
	Legislation: (Para 7.5) The first sentence presents an incomplete picture of the legal background. The overall legislative approach to hygiene is to mandate certain controls that will be broadly relevant to any pathogen in any food. It might be true to say that there are no specific criteria for viruses but this is hardly unusual. Specific micro-criteria for specific foods are still the exception rather than the rule and in any case the HACCP approach focuses on control at critical points having regard to hazards relevant to the particular case.	We note this comment but this is a report on viruses.
	This paragraph is completely wrong to say that in the absence of micro (virus) standards the only back up is industry GAP standards, a theme which is repeated in the second conclusion and R7.3.	We have not said this, but to clarify we have amended the report.

	Annex I of The General Food Hygiene Regulations (EC 852/2004) which came into effect in 2006 lays out hygiene requirements for the primary sector. This provides a complete framework of hygiene controls that will be equally relevant to viral hazards as other pathogens or contaminants. And there is an obligation in Regulation 882/2004 on Member States to ensure implementation of these controls by FBOs. It is a pity that Table 7 did not also include, as a key benchmark, a column of requirements from Annex I of EC 852/2004. In passing one might comment that it is slightly bizarre that hygiene was never regulated on farm (with the exception of dairy farms), either in the UK or EU, prior to 2006. Had this draft report taken a more charitable stance it might have commended the industry for filling this void with robust self-regulatory programmes for at least a decade before the legislation began to catch up.	We note this comment about the Food Hygiene Regulations. However, they are very broad and general and the UK market is built on HACCP-based standards which go beyond the legal requirements. What is not clear is what the uptake of these HACCP-based schemes is, at all scales of production. We note this comment and have mentioned that the industry has established standards from the 1990's onwards.
	Table 7 The analysis in Table 7 is wrong. We say this for two reasons. First the footnote 24 at p 73 suggests the project B17007 was completed in 2011. This is not true. The FSA website states that the project was completed between September 2007 and March 2008. I cannot speak for CAC, CFA or retailer schemes but both Red Tractor and GlobalGAP standards have changed since then and more than once. Our standards are just about to change again. It seems to us inadvisable for the ACMSF to publish a Table which is nearly 7 years out of date. Secondly we complete a regular, rigorous and highly formalised benchmarking exercise between the Red Tractor fresh produce	We note this comment but the analysis in the table is that of the authors of the report. The date of publication has been corrected to 2009. This was the most recent state of knowledge at the time of writing the report. The focus of our recommendation was not on the quality of the schemes themselves but on the need for wider

	scheme and GlobalGAP. The supposed differences between Red Tractor and GolbalGAP criteria in Table 7 are simply not credible and can only be explained by a misinterpretation of one or other of the standards.	uptake of the schemes across the industry. To avoid confusion we have removed Table 7. We have also referenced a more recent report on comparison of third party assurance schemes.
	Certification Schemes and "Voluntary Codes of Practice" The report is wrong to characterise formal certification schemes such as Red Tractor and GlobalGAP as 'industry Codes of GAP'. Throughout these 9 pages 'schemes', 'standards', 'codes' and 'guidelines' are used as if synonymous but this is misleading. Then paragraph 7.9 talks generally about 'assessing compliance' with the implication that the information in 7.9 applies equally to all the schemes mentioned in 7.7 and Table 7. Again this is wholly misleading. Some of the codes mentioned have no compliance assessment, some have very formalised assessments and some lie in between In short there is a substantial different between a formal accredited certification scheme and a voluntary code of practice which implies an advisory code, to be consulted by FBOs as they see fit but with no mechanism to verify the conformance to the code. Red Tractor and GlobalGAP are ***not*** voluntary Codes of Practice. Both are formal certification schemes whose certification bodies are accredited to ISO17065 (previously EN45011). *Accredited certification* is strictly regulated by international agreements and Regulation 765/2008 establishes a legal framework within the EU. Accredited Certification is itself used as the basis for a number of EU regulations, notably the validation of organic food. Accreditation means that there is oversight from the National Accreditation Body (UKAS) of the work of the work of the Certification Bodies against the standard ISO17065 to ensure competence, impartiality and	We have amended our conclusion in 7.9 to clarify. We note this comment but disagree. However, to avoid confusion, we have replaced the term "voluntary" with "non-statutory". 7.9 refers to a certain type of arrangement and we have checked with industry concerned and they are content it is a fair reflection of an example of an approach to certification. We note this comment.

	reproducibility. Red Tractor assessors inspect every grower every year. This is a comprehensive assessment against all of the requirements of the certification standard. Growers must conform to every requirement. If they do not they must demonstrate correction of the non-conformance within a defined timescale and if non-conformance is significant their certification will be suspended pending correction. In short accredited certification is wholly different to an FBO's use of a Code of GAP. Indeed it is a significantly more regularised and comprehensive approach than most regulatory inspections.	We note Red Tractor's approach to inspection which broadly reflects the generic approach we have described in 7.9.
	FSA's 'reliance on voluntary hygiene schemes' Finally the report appears not to have taken any evidence from the FSA itself as to what extent it 'relies on' voluntary schemes, which schemes and how any selection is made. From our perspective when the FSA does have regard for schemes in its own risk prioritisations the process is highly selective and rigorous. We would suggest that without this information from the FSA, and without a fuller understanding of schemes and the distinction between formal accredited certification schemes and 'voluntary codes of practice' the committee has little basis either for the second bullet point in the conclusions at p75 or the recommendation R7.3. More broadly, we say that the report underestimates the levels of responsible industry self regulation at play within the UK fresh produce sector. SPECIFIC POINTS Animal Manures (p70). The report might have commented on the FSA's own guidance. Our fresh produce standards are consistent with the FSA guidelines 'Managing Farmyard Manures for Safety'. Indeed	The FSA's 2013 report (project FS245006) has been referenced in the report. We have amended the second bullet and the wording of recommendation 7.3. We disagree. We have acknowledged on page 71 the UK industry has been doing this since the 1990's. The wording of paragraph 7.4 has been revised.

	the extended harvest or planting intervals specified in the Table at p10 of the FSA guidelines were specified in the Red Tractor standards well before the FSA guidance note. Although we would point out that the FSA guidelines do not themselves have any particular reference to viral hazards. At paragraph 3 the FSA text refers to bacteria and protozoan pathogens only; and there is no comment about the particular risks from pig manures or slurry.	
FDF	With respect to other viruses which could be included, there are other viruses that could be mentioned briefly and then cite other reports that deal with these in more detail e.g. ILSI document on zoonotic viruses (2009, http://www.ilsi.org/Europe/Publications/AnimalBorneVirusesReport.pdf) or other recent articles. However, the main viruses of concern are addressed e.g. Norovirus & Hep A / E. Page 19, R5.6 could be more strongly worded, e.g. updating of guides should be essential, and not just "encouraged". It is important to recognise the current limitations for some testing methods, such as those for norovirus. Page 33, 3rd paragraph, suggests risk managers treating RT-PCR signals as potentially infectious. For some methods, a positive signal in a RT-PCR could lead to destruction of the product as a precautionary measure and due to current uncertainties in interpretation. This testing, if adopted widely outside of outbreak situations, may lead to large volumes of product being destroyed without good evidence of a public health threat. Due to the limitations of current methods, the emphasis should be placed on the main contamination factors during primary production (e.g. irrigation water for fresh produce and proximity of contaminated water sources for oysters etc) and then by handling by humans. GAP / water controls, employee training and	Thank you for your comment. We acknowledge that other zoonotic viruses exist, but these are either not endemic or not mainly transmitted via contaminated food. We note your agreement that we have included the main foodborne viruses in our report. Thank you for your comments on this recommendation from the previous report. We thank FDF for their comments. In our view a positive RT-PCR result suggests that virus contamination has occurred. However, we have not recommended whole-scale testing and positive release schemes. See recommendation 3.3.

	provision of effective hand washing and toilet facilities and procedures should be the major areas of focus. For fresh produce, key concerns are farm workers not having access to toilets and appropriate hand-washing out in the fields – this could be added to section 7.6 (page 71).	The wording of paragraph 7.6 has been amended.
	Page 84, 3rd paragraph refers to prevention of infected individuals handling foods. In many food manufacturing facilities, individuals with symptoms are excluded from work altogether or at least restricted from entering areas where foods are handled, and would only return after recovery and clearance from medical practitioners. Additional training for staff in cleaning & GMP, and wearing gloves can also provide extra measures to reduce the risk of viruses coming into contact with foods in these situations.	We note this comment.
	Section 3.2.1 is missing some information on persistence of norovirus, in comparison to other sections on other viruses. It would be helpful if more data could be provided in this section, supported with relevant citations.	We agree this would be helpful, but since NoV cannot be cultured there is limited/no direct evidence to draw upon.
	Table 9 contains information about treatments and their efficacy. There is additional information that could be included here e.g. information contained in an article by Koopmans and Duizer (International Journal of Food Microbiology, 2004, 90, 23–41). The information on High Pressure Processing should be carefully worded, as the efficacy of this depends on conditions used (see Grove et al., Journal of Food Protection, 2006; 69(4):957-68).	We have modified the wording concerning High Pressure Processing and amended the title of Table 9 to make clear that the table provides a summary.
	The conclusion at the bottom of page 88, that alcohol wipes/gels are not effective against viruses could be supported by some additional wording and citations in the main text prior to this e.g. Tung et al. (Journal of Food Protection, 2013; 76(7), 1210-1217). That is also reflected in the Codex Alimentarius draft guidelines. control of viruses in food, cleaning section.	Thank you for this helpful suggestion. Additional wording has been added to section 9.3.1. to reflect these comments.

	These are the main technical points. We also understand that there was a recent presentation at the IAFP Europe meeting, which may be of interest to you, entitled "Potential for Norovirus Transmission by food handlers: reported behavior knowledge and awareness in relation to the prevalence of Norovirus" Ingeborg Boxman, Dutch Food & Consumer Safety Authority, NL. This paper described results from a survey, where a number of respondents indicated their willingness to return to work shortly after vomiting and suffering illness. There are a few typographical errors which have spotted, but I assume you will be checking through before finalising the report, but I just wanted to flag up the below sentence, which we feel there may be some words missing from: Page 44, 1st paragraph in section 5.3, 3rd sentence	Thank you for this information. We agree that this will have been an interesting presentation, relevant to our work, but unfortunately the work has not appeared yet in the peer-reviewed literature so we have been unable to assess it. We have added a comma in para 5.3 to clarify.
Uren	I attended the Norovirus/Hep A workshop in January and the Campden seminar more recently and have been privy to some other discussions on this topic. What strikes me at the moment is how little is really known about the topic of Hep A & Norovirus in IQF fruits and yet how jumpy people have become about a product range which in my opinion of nearly 25 years in the business is at the lower risk end of the food business. In other words it hasn't become high risk overnight and the number of reported outbreaks, which have not necessarily been proven to any particular source, is by comparison to some other issues low. Some very valid good questions/points have been raised in the document however the general theme from a scientific/ factual point of view is the	We agree.

	degree of uncertainty at present.	
	The concerns for me are: 1. The fact that testing for the Norovirus is inconclusive even if a positive result is detected and if a wider testing programme is implemented as a regulation and a few positives are detected, chaos could ensue, This could have a huge consequence for the industry with potentially fruit being wasted and all the social/environmental/supply issues this can bring. 2. Norovirus is present in our environment, there are humans and therefore there are viruses. Farming on a global basis on the IQF side of the business is generally small scale with typically plantations being less than 0.5 hectares producing very little fruit per grower. This commonly gets composited to form bigger quantities and over the medium term this will not change. The understanding of the supply chain for the IQF fruit business is not understood widely outside of the immediate industry and is treated by those buying the product more as a commodity and totally unlike the fresh produce industry. Therefore this needs to be considered within the consultation. 3. Research needs to be carried out about the consequence of freezing fruits on such viruses, where the shelf life of such products can be 24 months plus. 4. Globally a joined up approach needs to be considered perhaps under CODEX to reflect the intricacies of the supply chain.	We have not recommended whole-scale testing and positive release. We acknowledge this helpful information on the complexity of the IQF berry supply chain. Additional wording on freezing has been added to paragraph 7.4. Thank you for this suggestion. However, in the light of the EFSA Opinion we have chosen not to include this as a research recommendation.
AFBI	With respect to the consultation exercise AFBI has provided some comments below for consideration. These have been limited to the areas where AFBI would have expertise and potentially be involved in	

	key control points for certain viruses such as HEV, HAV, Norovirus and horizon scanning through molecular diagnostic testing, next generation sequencing and virus strain typing for phylogenetic analysis in disease outbreak tracing (animal, food or environmental contamination), monitoring of divergent strains and control through food processing treatments. In particular AFBI has extensive experience in molecular virology and experience in food processing technologies which could play a key role in developing future control strategies (eg detection methods, high pressure sterilization and microwave volumetric heat treatments). With more frequent flooding and disaster zones around the world, detection and control of virus inactivation in disaster situations would be of great importance for supply of clean drinking water. As already mentioned in the report new diagnostic methods (particularly molecular diagnostics) are of great importance for detection and strain typing as many of the food borne illness due to viruses are probably vastly under-reported due to the difficulty of detecting them through traditional virus detection methods. Therefore it may be of benefit:- • To ensure that any national programmes to control viruses in the food chain fully consider the role of primary agricultural production systems and control points to reduce the pathogen burden in animals (surveillance in animals and introduction of vaccines in the future with respect to HEV). • To align with disease detection and control in livestock to ensure that the diagnostic methods and sample collections tools are optimised to ensure detection in different sample types • To assess agricultural run-off from livestock fields, discharges from slurry pits and manure spreading – contamination of waterways and fresh produce in different geographical locations. • To develop food processing and treatments to reduce or remove	Thank you for your helpful comments in relation to risk management. Thank you for your useful comments in relation to standardisation of methods. In relation to HEV we agree that alignment of methods across veterinary and public health applications would be beneficial. Thank you for your comment. It was unclear if this refers to HEV or all viruses. We refer you to the various recommendations throughout the report on reducing viral contamination throughout the food supply chain, specifically recommendation 7.2. We have also added a recommendation regarding HEV and bivalve molluscs.

	contamination (high pressure treatment, or volumetric microwave treatment of water to sterilize before washing of fresh produce?) and to ensure the best detection diagnostic tools work along with disinfection methods.	
CFA	• Need to ensure berries are included in fresh produce and Hep A research work as many questions are asked around what time and temperature of processing or washing will remove the virus • GAP/field to fork efficacy evaluation should be covered – what methodologies for doing so though? • Concerns about how long it will take for practically useful information to emerge from research and data will be managed into the public domain and communicated within risk analysis	We have amended R7.2 to make it clear that we mean viral decontamination. Please see amended paragraph 7.8. Thank you for this comment which we will refer to the Food Standards Agency.
Elizabeth	With regard to the consultation on The Update on Viruses In The Food Chain: There does not appear to be any proposal to undertake any research with regard to the introduction and survival of enteric viruses on frozen produce, especially soft berries. Most of the references are to fresh produce, catering establishments and food businesses but there is no real reference to large scale industrial fruit processing operations. Most retailers and brands use frozen fruits in desserts, cakes, pies, spreads, sauces, etc as these are available all year round owing to their preservation method and long shelf life.	We agree but until there is a reliable way of determining infectivity, research is unlikely to results that will inform risk management for NoV. In relation to HAV R7.2 includes survival in frozen produce. See additional text added to paragraph 7.4

	As there is nationwide distribution of these consumer products, which also have a long shelf life, there is the potential that outbreaks may not be localised by distance and/or by time and valuable data may be lost which could potentially be useful to the research as a whole.	We agree and have made several recommendations about outbreak surveillance in section 5.
Tesco	The report states on page 34: ". . . 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." On page 16, its unclear whether the guidelines for safe use of sewage sludge on agricultural land (which represent the good practice referred to above) are effective against viruses: "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." Has the research been done to say whether the ADAS sewage sludge guidelines produced for industry are effective against viruses? The comment on page 16 suggests not? If the guidelines remain effective for inactivating viruses, do we know whether the nucleic acid will degrade as quickly, or could it persist resulting in a positive on the finished product (that could in essence be non-infectious particles - safe product). I feel clarity is needed on this to ensure we don't see "false positive" results on crops from growers	Thank you for commenting on p16 which refers to the 1998 report. We agree that assays for infectivity would be desirable, hence our Recommendations 3.1, 3.3 and 3.4 concerning molecular methods.

	following good agricultural practices.	
Glasgow Caledonian University	Section 7, HEV has been detected in soft fruits (http://www.ncbi.nlm.nih.gov/pubmed/22427499?dopt=Citation) and it is clearly present in sewage/slurry which may be used as irrigation/feeding solutions to grow crops in the UK (http://www.ncbi.nlm.nih.gov/pubmed/18757902?dopt=Citation).	Thank you for your comments. We have included an additional recommendation on more research for HEV.
	Pork Products, HEV, HAV	
PHE	**Hepatitis E.** **P8, last sentence.** We suggest that this section be amended as follows: The thermal stability of hepatitis E was considered with data presented on the increasing occurrence of the disease *particularly* in older UK males and the recent case control study on *the association with processed* pork products. **P9, para 7.** We suggest that this section be amended as follows: With the emerging risk of *h*epatitis E in pigs the Group recommends work is undertaken to investigate the heat inactivation of *h*epatitis E in 'pork products'. Research on the effect of curing and fermentation on *h*epatitis E in pork products is also recommended. We suggest removal of references to UK pigs in the above section as it is not only pigs bred in the UK or UK pork products that carry the virus.	Thank you for these amendments which we have incorporated into the report.
	Background, Page 12 Para 1. We suggest that this section be amended as follows: In England and Wales, there are currently systematic seroprevalence studies underway to determine the true incidence and burden of hepatitis E infection. However, early *modelling* studies suggest that there could be as many as 65,000 unidentified cases in the UK each year.	Thank you for your comment. We have inserted the word "modelling".

	Chapter 3. Foodborne viral disease Page 26 We suggest that this section be amended as follows: Hepatitis E is an increasingly recognised foodborne illness associated with the consumption of processed pork *and has also been associated with the consumption of game meat and shellfish*.	Thank you for your amendment. We have amended the report at para 3.2 to read "and has been associated with the consumption of game meat and potentially shellfish".
	Page 27, Table 2. We suggest that the table content be amended as follows: Hepatitis E/ *Clinical presentation:* acute hepatitis/*Epi routes of transmission:* recently recognised zoonoses in UK *and around the world*. Genotypes 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./*Burden of foodborne illness:* Detected in *processed* pork products *(Said 2013), outbreak* linked to shellfish (*Said et al 2009*) /*Considered:* because potential to cause severe *disease* and presence in pork food chain. A general comment regarding the above paragraph is that there are 4 genotypes: GT1 and GT2 are human only and associated with epidemics, whereas GT3 and GT4 are zoonotic, associated with sporadic cases. In the UK GT3 is the indigenous virus.	Thank you for your comments. We have amended the report. Thank you for your comments. We have amended the report.
	3.2.3 Hepatitis E virus Second paragraph Page 30. 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. Our comment regarding the above mentioned section is that the disease is endemic throughout most of the world and is hyper-endemic or highly endemic in tropical and sub-tropical regions. See	Thank you for your comment. We have amended the relevant paragraph.

	http://wwwnc.cdc.gov/travel/content/yellowbook/2014/map_3-06.pdf	
	Third paragraph Page 30 We suggest that the following section be amended as follows: Recently, sporadic cases of hepatitis E have been reported in individuals *with no history of travel to highly endemic* areas (Ijaz, 2005). These cases are caused by HEV genotype 3 strains closely related to the virus found in the European pig population. *Genotype 3 infections are sporadic and tend to be milder than infection with Genotype 1 HEV. Cases of hepatitis E caused by genotype 3 virus* are typically observed in older men and have been related to various animal reservoirs including swine, wild boar, deer and rodents.	Thank you for your comment. We have amended this paragraph.
	Chapter 5. Routine surveillance and investigation of foodborne viruses **Recommendations that inform risk assessments R5.1** We suggest that this section be amended as follows: ….The value of *whole genome sequencing (WGS)* to link food stuff, infected cases, food handlers for ….hepatitis E should be defined.	Thank you for your comment. We have amended the report.
	Hepatitis A **Recommendation R4.2, Ad Hoc Group comments, Page 16** "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." Regarding the above paragraph, blood samples are used for testing	We note this comment, but disagree.

	hepatitis A at PHE Centre for Infectious Disease Surveillance and Control. Facilities are not available to test food and faeces, however, these may be available in local laboratories. In addition, there are standard methods to test for norovirus in some foods, but not all as the document implies. We recommend that the laboratories where testing for hepatitis A in food and faeces are listed in the document.	The ISO standard specifies the foods to which it applies. We have chosen not to provide a list of testing laboratories which would date quickly.
	Page 29 3.2.2. Hepatitis A virus "It is resistant to acid and elevated temperature (60ºC for 10 minutes)." A comment regarding the above is that the CDC website indicates that the virus is killed by heating to >85 degrees C for one minute. It may be useful to state that the virus is inactivated by high temperatures but may survive more gentle heat treatments.	Thank you for your comment. We have amended the report.
	Page 87, 4th,5thand 6th paragraphs Sections of these three paragraphs are incorrect in relation to current guidance as follows: Unvaccinated contacts aged 1 to 50 years of cases should receive one dose of hepatitis A vaccine within 14 days of exposure to a case. A second dose of hepatitis A vaccine at 6-12 months after the first dose should be given to ensure long-term protection. Current UK guidance advises that HNIG is only used for contacts of cases who are aged over 50 years or for those who have chronic liver disease, chronic hepatitis B or C infection or are immunosuppressed. Patients with chronic liver disease, pre-existing chronic hepatitis B or C infection or HIV infection and those aged over 50 should be offered HNIG in addition to hepatitis A vaccine if they are contacts of cases. The patient should be referred to their GP for a second dose of hepatitis A	Thank you for these comments. We have amended the report.

	vaccine at 6-12 months after the first dose to ensure long-term protection. A link to the current Guidance for the Prevention and Control of Hepatitis A Infection is available at: **http://www.hpa.org.uk/webc/HPAwebFile/HPAweb_C/1259152095231.** Please accept this letter as my formal response on behalf of Public Heath England.	
BRC	**R5.5.** National surveillance of foodborne viruses should include foodborne hepatitis A and hepatitis E. In discussion with members, there was feeling that the reference to "foodborne component" is not clear and we suggest the following alternative: National surveillance of foodborne viruses should include investigation to determine the main food contributors to transmission of hepatitis A and hepatitis E. ***R5.8*** *The FSA's 2008 Guidance on the management of foodborne illne should be updated and the latest information on norovirus incorpo These Guidelines need to ensure that investigations of suspected foodborne outbreaks are consistent. They should incorporate adv the use of new virological tools to detect viruses in the environme in food matrices. The Guidelines need to define when it is approp investigate a potential foodborne virus outbreak and, if investigati performed, the minimum dataset of evidence required for recordir foodborne outbreak in national surveillance systems.* We support this recommendation and suggest that the advice on virological tools be expanded to include specific reference to the use of rapid test methods.	Thank you for this comment. The Report has been amended. We agree that if available rapid test methods would be useful. We would expect that as new validated methods emerge the guidance should be updated.
	Pork and products	

	Throughout the report there are various references to links between HEV and pork consumption with specific references made to HEV genotype 3 strains being closely related to virus found in the European pig population. Results from the recently published UK pig monitoring survey suggest that the strains identified in pigs are not the same as found in humans. We would welcome a clearer reference to this in the report and recommendations for further research if needed.	Additional text referring to the pig monitoring survey has been added to the report at paragraph 8.1.
	R8.3 *Work towards development of an ISO standard method for dete HEV in foodstuffs (including pork products) should be encourag* The lack of robust methodology is a limiting factor in determining pathogenicity of viruses. We thoroughly support the development of better methods to detect and identify infective virus particles. Robust work in this area is imperative to successful completion of R8.4.	Thank you for your supportive comment.
	R8.4 *A structured survey of HEV contamination in pork products across the retail sector is conducted.* As stated above in the absence of the methodology recommended in R8.3 there is no value in undertaking these surveys. The results give no indication of pathogenicity and any funding earmarked for surveys is better invested in method development. Given the limited understanding of the organism test results would not give food business operators sufficient information to inform follow-up.	We note the comment but disagree that a survey would be of no value. PCR based methods provide sequence data and therefore information on the origin of contamination, e.g. UK versus non-UK production.
AFBI	With respect to the consultation exercise AFBI has provided some comments below for consideration. These have been limited to the areas where AFBI would have expertise and potentially be involved in key control points for certain viruses such as HEV, HAV, Norovirus and horizon scanning through molecular diagnostic testing, next generation sequencing and virus strain typing for phylogenetic analysis in disease	Please see response to these comments on page 44 above.

	outbreak tracing (animal, food or environmental contamination), monitoring of divergent strains and control through food processing treatments. In particular AFBI has extensive experience in molecular virology and experience in food processing technologies which could play a key role in developing future control strategies (e.g. detection methods, high pressure sterilization and microwave volumetric heat treatments). With more frequent flooding and disaster zones around the world, detection and control of virus inactivation in disaster situations would be of great importance for supply of clean drinking water. As already mentioned in the report new diagnostic methods (particularly molecular diagnostics) are of great importance for detection and strain typing as many of the food borne illness due to viruses are probably vastly under-reported due to the difficulty of detecting them through traditional virus detection methods. Therefore it may be of benefit:- • To ensure that any national programmes to control viruses in the food chain fully consider the role of primary agricultural production systems and control points to reduce the pathogen burden in animals (surveillance in animals and introduction of vaccines in the future with respect to HEV). • To align with disease detection and control in livestock to ensure that the diagnostic methods and sample collections tools are optimised to ensure detection in different sample types • To assess agricultural run-off from livestock fields, discharges from slurry pits and manure spreading – contamination of waterways and fresh produce in different geographical locations. • To develop food processing and treatments to reduce or remove contamination (high pressure treatment, or volumetric microwave treatment of water to sterilize before washing of fresh produce?) and to ensure the best detection diagnostic tools work along with	

	disinfection methods	
Glasgow Caledonian University	Section 3.3.3 page 32, in the section on clinical diagnostics, it would be worthwhile to reiterate the importance of HEV diagnosis. There are several papers in the literature comparing the sensitivity and specificity of a number of serological and molecular methods, in particular, it is worthwhile to note this for diagnosis of individuals too (during outbreaks) as frequency can vary significantly dependent on the test used. Could mention that use of WHO standard for infectious titre is requirement for any study. (http://www.ncbi.nlm.nih.gov/pubmed/23886501; http://www.ncbi.nlm.nih.gov/pubmed/21307208). This is also important in the use of harmonised methods for extraction from various materials.	Thank you for this comment. Paragraph 3.3.3 has been amended.
	R4.2 – devolved equivalents should also be considered given the increase in HEV case reports in Scotland. 15 cases vs 72 (2011 vs 2012; http://www.hps.scot.nhs.uk/ewr/article.aspx) and 48 reported in first half of 2013 (http://www.hps.scot.nhs.uk/ewr/article.aspx). There is evidence of clustering which may suggest a foodborne route that should be investigated.	ACMSF advises the UK. We have amended to include the devolved administrations in the lead departments.
	One additional point, is the geographical variation in sero-prevalence in the UK (Scotland 4.7%, SE England ~16%, Wales etc 11%). It is not clear why this is so, however, in France, it is suggested to be due to the increased consumption of raw pork sausage in this particular area.	Thank you for this interesting observation.
Royal College of Pathologists	Page 31: If you are retaining the whole section on emerging infections covering SARs, influenza and simian agents, please add “simian” before herpes viruses. I would suggest that this whole section on emerging infections does not add much to the document. We consider that it would suffice to have this information presented within a table.	Thank you for this comment. We have amended the paragraph accordingly.

	Page 79: Mention is made of HEV in pigs, however no mention is made of its presence in blood and therefore in meat. Recent evidence on HEV infection from PHE/DEFRA/FSA studies suggests that many pigs are actively infected and viraemic at the time of slaughter, so there is a need to expand information on where the virus is found in pigs, also to note at what ages pigs are infected and therefore the risk in various pig meats.	Thank you for this comment. Paragraph 8.1 has been amended.
	Table 2: Suggest that 'Adenoviruses Group F' replaces the current term 'Adenoviruses'. Nipah virus is included in Table 2 as 'considered because of potential risks'. However, it does not appear to be included in the text of the report.	Table 2 has been amended. Additional text has been added at paragraph 3.2.4.
	General	
Royal College of Pathologists	We note that the reports contains very little on sapovirus. This doubtless reflects the low numbers of documented food-associated outbreaks. However, given its high incidence in the community, its similarity in behaviour to norovirus, and its potential for foodborne infection with evidence of its presence in some shellfish and water, it might be desirable to give it some discussion in its own right.	We note this comment and have added a short paragraph (3.2.2 on page 29) to acknowledge that sapovirus can be foodborne and that its epidemiology is very similar to that of norovirus.
Glasgow Caledonian university	Page 94 onwards, reiteration of recommendations etc., may not be necessary at end of document as clear throughout. Could just refer back to relevant section.	Noted, but the format is consistent with other ACMSF reports.
BRC	We welcome the opportunity to comment on the draft report and are supportive of the emphasis within the document on the need for further research into the aetiology and detection of viruses. Further development of methods to identify infective virus particle is needed to assist businesses, regulators and health protection teams in making firm	Thank you for your supportive comments. With respect to guidance and research please see Recommendations 3.6 and 7.2.

	conclusions and interpretation of results on infectivity. This said we feel there is also the opportunity to include more of a focus on controls including guidance/research on preventative measures and efficacy of disinfectants.	
AFBI	It may be of benefit to have some linkages to what is happening in different EU countries to manage and address these issues, particularly due to the global food supply chains.	Thank you for this comment which we will refer to the FSA to take into consideration in its risk management response.
PHE	The disease hepatitis is capitalised in some parts of the document and not in others. The correct use is that it should not be capitalised unless at the beginning of a sentence.	We note the comment and have amended the report accordingly.
PHE	**Supplementary information for consideration by the FSA and ACMSF.** There are some important differences in terms of control of hepatitis E which are not addressed by the review in that the virus is embedded within pork meat as well as being present in faeces, urine, liver and gallbladder and bile. This is different from norovirus and hepatitis A which are largely human contaminants of food. As a consequence improvements in hygiene will not per se have any impact on HEV contamination of porcine sourced human food. Nearly 20% of pigs have evidence of active HEV G3 infection at the time of slaughter in the UK (129/629). However, nearly three quarters of last year's human G3 infections in the UK were in a group of viruses (G3 group 2) not previously seen in humans prior to 2010 and virtually absent from UK pigs sampled in 2013 indicating that the majority of G3 infections are currently coming from an unknown source. Evidence provided by the	Noted. The report has been amended at paragraph 8.3. Thank you for this comment. At the time of drafting, these results were not available. Since these data are now in the public domain, they have been included in the final version of the report.

	national case-control study indicates that G3 infection in the UK is associated with consumption of pork meat. Occupational hazards may be of importance but data more likely reflect poor serological techniques and inadequate assays and is unlikely to be the source of most G3 infections in the UK.	We agree, and this is reflected in paragraph 4.3.
	There is an urgent need to explore the epizoology of HEV G3 on the continent. Broadly speaking the prevalence of antibody in pigs at slaughter is considerably lower across the continent than in the UK where there is a susceptible seronegative group at slaughter of somewhere between five and seven percent. Published data for Holland is 25% susceptibility and for France and Germany as high as 35 to 40% susceptibility. This provides ample opportunity for the acquisition of acute HEV closer to the time of slaughter. Changes in animal husbandry practices on the continent may also be of importance, particularly the introduction of food supplements containing freeze-dried plasma from pigs at slaughter given to weanlings very early in life. One postulate is that this has shifted the force of infection from very young pigs such that there may be a higher viraemia at the time of slaughter. This feeding practice was introduced around 2010, about the same time as G3 group 2 started to impact in this country in humans. Collaborative surveillance is needed across Europe of both medical and veterinary colleagues to determine the intrusion of porcine G3 into the human population. The magnitude of the zoonosis in the UK, corresponding probably to in excess of 100,000 infections last year, and likely to be much higher this year if the figures are anything to go by, is of concern. It is not so much the damage which G3 does in the UK population but the magnitude of acquisition of an animal virus by dietary means which is of prime concern.	Thank you for these interesting data and the hypothesis concerning viraemia in pigs at slaughter in Europe. Our recommendation 4.2 is relevant to this.
	Very good protocols exist in medical laboratories for the measurement,	We agree with this comment which will have to be taken

	detection and characterisation of HEV in human materials. Protocols for extraction from flesh of HEV, in particular when seeking plasma borne virus is somewhat challenging and will be quite different from protocols used for hepatitis A and norovirus where these two viruses are excipients to the foodstuff whereas HEV is endogenous to the food.	into account when methods are developed in addressing Recommendation 8.3.
	Pan European surveillance and phylogenetic analysis of HEV in food from porcine sources, from live pig herds or those at slaughter, and from patients should be urgently considered in order to better understand the epizoology of European HEV infections.	We agree with this statement. Recommendations 4.2 and 8.4 go part way to addressing this point in people, pigs and pork in the UK. We agree that the European context is important and that this needs to be drawn to the attention of EFSA but this is beyond the scope of ACMSF.