

**Microbial water quality: Challenges to Blue Growth in Shellfish**

**Report of a workshop held at**

**Tŷ Cymru/Wales House, Brussels**

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Shellfish  
Association of Great Britain



*Microbial water quality: Challenges to Blue Growth in Shellfish*

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## ***Microbial water quality: Challenges to Blue Growth in Shellfish***

### **1. Executive Summary**

Shellfish aquaculture production makes up half of all aquaculture production in the EU, with a value of €1.12 billion, supporting more than 60,000 jobs. The sustainability of shellfish aquaculture is highly dependent on clean and healthy coastal waters and microbial water quality is of particular importance, especially with regard to minimising risk of transfer of human pathogens to consumers. Recently, there has been a move towards implementing an EU standard for norovirus (NoV) in shellfish production areas, however, the shellfish industry is concerned by the potential deleterious economic impact that its introduction may have. Estimates produced by SEAFISH suggest that it could result in closure of a large proportion of EU shellfish production areas. The workshop was therefore organised as an open forum to facilitate the exchange of information and views on this issue, with attendees including aquaculture producers, shellfish industry associations, national and EU regulatory and public health agencies and researchers. Invited speakers gave a series of talks covering the current status of shellfish aquaculture in the EU, the NoV standard and the evidence behind it, the human health risk from NoV, perspectives from the water industry, alternative approaches to integrated management of water quality and a review of research needs. These talks informed an open discussion of the issues raised.

NoV was characterised as a highly infectious but self-limiting virus that is passed from person to person through close contact, via contaminated surfaces, food and water. Unlike other microbial contaminants which can contaminate the marine environment, agriculture is not a source of human infectious NoV. The illness caused by NoV is not serious compared to other microbial infections that can be transmitted via food. Epidemiological evidence showed that human health risk of NoV from shellfish was very low. NoV cases associated with shellfish are extremely rare compared to general occurrence of the disease in the human population. There is a shortage of evidence confirming epidemiological links between outbreaks and shellfish. The effectiveness of the method of quantifying NoV in shellfish was questioned, as it does not distinguish between infectious and non-infectious virus particles. The evidence linking NoV outbreaks to shellfish using this method was circumstantial.

Water companies were concerned that the evidence for introduction of a NoV standard is not as robust as it should be and questioned whether the cost of closing down shellfish waters would be worth the benefit, when the Water Framework Directive (WFD) is set to have beneficial impacts over the next five to ten years. Approaches to integrated risk management using water safety planning, HACCP and sanitary surveys as an alternative to NoV limits have been shown to be effective and could be further developed.

Shellfish industry representatives were highly critical of the proposed NoV standard, highlighting the risk of loss of up to 80% of the industry, with severe damage to coastal and rural economies that would completely undermine the blue growth ambitions of the EU. The conflict between the strategic aims of different DGs and apparent lack of communication between them was highlighted and there was a call for a more unified approach to the problem.

There was overwhelming support for a halt in the process of setting the NoV standard, while views of stakeholders are consulted and the evidence base is enhanced/validated. Some significant knowledge gaps were clearly identified and it was agreed that a priority should be to undertake a critical review of evidence in a timely manner for dissemination to all interested parties including the EU Commission, Member States and their regulatory bodies. The workshop organisers are currently working towards securing funds to commission an evidence review to be completed in the next 3-6 months. The review will be carried out by a panel of independent experts and can be used to inform the consultation process. A draft scope of the evidence review has been based on the discussions from the workshop, with further refinement anticipated as a result of consultation with stakeholders before commissioning.

## **2. Background**

Shellfish aquaculture production (0.68 million tonnes) makes up half of all aquaculture production in the European Union, with a value of €1.12 billion, supporting more than 8000 companies and 60,000 jobs (2011 data, STECF-13-30). However, there has been no growth in overall EU aquaculture output over the last decade despite annual global increases averaging 7% and EU production currently only supplies 10% of seafood consumption within the EU. European Commission communications on Strategic Guidelines for the Sustainable Development of EU aquaculture (COM(2013) 229 final) and Blue Growth Opportunities for Marine and Maritime Sustainable Growth (COM(2012) 494 final) set out strategic aims of significantly increasing aquaculture production by 2020, through reducing administrative burdens, improving access to space and water, increasing competitiveness and exploiting competitive advantages due to high quality, health and environmental standards.

The sustainability of shellfish aquaculture is highly dependent on clean and healthy coastal waters, as set out in the Water Framework Directive and Marine Strategy Framework Directive. Microbial water quality is of particular importance, especially with regard to minimising risk of transfer of human pathogens to consumers. Food safety is strictly regulated and bivalve molluscs must be harvested from areas classified under the Food Hygiene Regulations, which use the number of faecal indicator bacteria such as *E. coli* to assess whether an area of shellfish can be harvested. However, *E. coli* numbers are used as an indicator of overall microbial pollution and shellfish may also potentially be affected by viral contaminants. Recently, there has been a move towards implementing an EU standard for norovirus (NoV) in shellfish production areas, based on molecular methods for determination of viral contamination based on an RT-qPCR technique which estimates the number of copies of the viral genome in shellfish tissue. One potential threshold limit for NoV which has been suggested is that of 1000 genome copies per gram and 200 genome copies per gram in harvested shellfish and end products, respectively. The shellfish production industry is concerned at the prospect of the imposition of a standard based on this method and with these threshold levels, these would result in closure of a large proportion of all EU shellfish production. Concerns have been raised about the apparent lack of consideration of the social and economic impacts this NoV standard will have, especially in comparison to (1) the actual human health risk posed by NoV in shellfish relative to other infection pathways, and (2) the validity of the proposed monitoring method, which cannot differentiate between infective and non-infective virus particles.

## **3. Aims and structure of the workshop**

The workshop was organised as an opportunity for exchange of information and views on issues relating to microbial water quality and shellfish production and specifically the implications of the proposed introduction of a NoV standard. Attendees included representatives from aquaculture producers, shellfish industry associations, national and EU regulatory agencies, laboratories and researchers in the field of shellfish and human health. The workshop was structured to provide an opportunity for proponents of the introduction of a NoV standard in shellfish to present the background and current status of the proposal to stakeholders and for a series of invited speakers to present their perspectives on the issue, together informing a moderated discussion in which all attendees had the opportunity discuss the information and evidence presented and to introduce their own information and views.

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### **4. Summary of the invited presentations**

PDF versions of the presentations can be accessed by visiting the news section of [www.shellpath.com](http://www.shellpath.com).

#### **4.1 Opening remarks - James Wilson (Deepdock Ltd)**

**James Wilson (Deepdock Ltd)** welcomed attendees to Tŷ Cymru/Wales House. He highlighted the importance of research and development to the success of the shellfish industry and the science-based nature of the sector. Microbial water quality was highlighted as a core issue to the sustainability of the industry, with emphasis on the importance of the workshop in addressing an urgent issue that threatens the continuation of the industry at its current scale and hence the European Commission's and member states' strategic ambitions for aquaculture as a key pillar of Blue Growth.

#### **4.2 Shellfish aquaculture in the Common Fisheries Policy - Richard Bates (DG MARE)**

**Richard Bates (DG MARE)** gave a presentation that gave background data on the significance of the shellfish production sector in EU aquaculture (0.68 million tonnes, €1.12 billion), making up half of all aquaculture production supporting 60,000 jobs and indicating the socio-economic importance of increasing production in terms of job creation in coastal and rural areas; every 1% increase of current EU consumption produced internally through aquaculture potentially creating 3000-4000 new full-time jobs. Information was given on support available under European Maritime and Fisheries Fund and research opportunities under Horizon 2020, with an update that there has been no specific research funded on NoV and shellfish in recent years and no EU or member state research could be found in Knowledge Gate which lists marine research projects and relevant knowledge outputs up to June 2014 ([www.kg.eurocean.org](http://www.kg.eurocean.org)). In summary, the integrated maritime policy has Blue Growth at its core and while there is little potential for fishing growth, increased seafood production is expected to come from areas such as aquaculture and ocean energy. However, the potential effects on the industry of introduction of a NoV standard is a concern.

#### **4.3 Implementing norovirus standards - Paolo Caricato (DG SANCO)**

**Paolo Caricato (DG SANCO)** spoke first about developments regarding biotoxin legislation and classification of shellfish beds. He referred to NoV in shellfish, particularly oysters, as the real current problem following scientific advice from the European Food Safety Authority (EFSA) in 2012 (following a request from the Food Safety Authority of Ireland). The advice said there should be a focus on avoiding contamination by either preventing human faecal contamination or restricting harvesting from affected areas and that risk managers should consider establishing an acceptable limit for NoV in oysters to be harvested and placed on the market. An earlier opinion on viruses in food had in 2011 recommended a focus on prevention of contamination and the introduction of microbiological criteria for viruses in live bivalve molluscs (LBM) unless they are labelled: -'to be cooked before consumption'. He reported that current legislation is not clear on this issue and there is a need for clarity regarding imports from outside the EU in addition to food safety in the internal market. Some possibilities for management of viruses in shellfish are being discussed by a restricted working group of member state experts, but there was still no agreement on a solution. However, for bivalve molluscs that cannot be labelled in this way, a limit for NoV is envisaged. To date, the focus has been more on the overall approach rather than the specific quantification of a limit. While the need to act may be accepted, this is not an easy topic as there are concerns regarding the testing methodology and its efficacy and some member states are asking for more data and others are opposed to the approach. He noted that some producers in Italy are already using 'to

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be cooked' labels on mussels and clams. The next meeting of the restricted working group is to take place with member states on 24 October, 2014.

### **4.4 Methods for detection of enteric viruses in food - Dr. David Lees, Director European Union Reference Laboratory (EURL) for monitoring bacteriological and viral contamination of bivalve molluscs**

**David Lees (EURL)** outlined work done on detection of enteric viruses over the last ten years. Research methods for detection of norovirus and hepatitis A virus in molluscs have now been available for >10 years. The EURL has conducted ring tests during this period which has clearly shown the need for standardisation of methods. Work on standardisation of methods recently culminated in the publication of ISO/TS 15216, the first standard method for detection of viruses in foodstuffs. The EURL, working with partner labs in Europe, has now completed technical validation of the method and the results are being analysed. The method has been reviewed by EFSA and found to be robust, appropriately quality controlled, and therefore suitable for use in a regulatory context. The EURL also highlighted the availability of standard virus reference materials which can support application of the method and are available from Public Health England. All PCR methods target nucleic acid and therefore cannot give definitive evidence of organism viability. However, since NoV cannot be cultured, and other methods lack sensitivity, this is the only methodology currently shown to be suitable for detection of viruses in molluscs. Given this limitation, EFSA recommended that the PCR assay be regarded as an indirect measure of risk. There is growing evidence of a dose response between measured virus genome copies per gram and health consequences, both in human volunteer studies and in bivalve molluscs. However, valuable additional information from outbreaks is scarce since they are often not fully investigated. Evidence from the 2012 EFSA report regarding norovirus levels found in oyster production areas was presented. In Europe, peak levels are found during winter months and EFSA recommended that risk managers should consider establishing virus limits for high risk live bivalve molluscs (i.e. those consumed raw). The conclusions and recommendation of the EFSA opinion were recapped and attention was drawn to its Table 8, the percentage of samples which would fail in UK, IE and FR during the winter (Jan to March) of 2010 at various minimum limits of genome copies per gram (between 100 and 10 000). However, it was also stressed that, in hindsight, the winter of 2010 now appears to be quite an extreme year for norovirus and that, by comparison, levels of norovirus in the community during 2014 were much lower. This suggests that year to year variation may also be significant regarding the impact of any given NoV limit. During discussion it was clarified that the possibility of NoV limits in production areas, for products intended to be consumed raw, was being considered as one approach to better control of the virus risk. In this case the approach could be considered analogous to that for algal biotoxins where areas are closed when monitoring shows exceedance of the regulatory limit and reopened when levels are again compliant. EFSA also highlighted the need for further work on validation of post-harvest treatments for effectiveness against viruses. However, the control of pollution would ultimately be the best solution.

### **4.5 Water Industry Perspective – Tony Harrington (Dŵr Cymru/Welsh Water)**

**Tony Harrington (Dŵr Cymru/Welsh Water)** said Wales has 22 designated shellfish waters. Historically these had been impacted by both point and diffuse sources of pollution. Dŵr Cymru/Welsh Water has invested over €1.1 billion to improve Coastal and Estuarine water quality, and Wales now has almost 100% compliance with the both the requirements of the new Bathing and transposed Shellfish Waters Directives. Dŵr Cymru/Welsh Water are to invest a further €3.1 billion, both in renewing and running their infrastructure between 2015-2020, with as much as €10 million invested in new coastal water quality predictive models which are to be made available to Welsh Government, its Agencies, and through their consultants to third parties. Protecting public health whilst

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very important, must be balanced with supporting a vibrant and sustainable aquaculture and tourist industry. To this end he questioned the need to set a new shellfish flesh standard for NoV as no one could articulate what the public health benefits could be. There has been no regulatory or socio economic impact assessment undertaken or published for review. He questioned whether the cost of closing down as much as 80% of shellfish waters across the EU would produce any substantive public health benefits. He noted that the Water Framework Directive (WFD) would drive further improvements to water quality when effective controls on diffuse pollution were formulated and enforced. In the absence of the necessary evidence to support the imposition a new NoV standard, he called for a full and balanced debate on the issue as the public health risks associated with eating raw shellfish seemed small yet the impact of such new standards could be devastating on the Shellfish Industry. Given the impact of such new standards, these should be set through the EU parliamentary process and subject to public debate.

### **4.6 Norovirus, epidemiology, shellfish and the public health ‘hazard’. John Harris (Public Health England)**

**John Harris (Public Health England)** is an epidemiologist working in the gastrointestinal, emerging and zoonotic infections department Public Health England. He outlined the characteristics of NoV, which is so small that it cannot be seen under an electron microscope and cannot be cultured. The NoV reservoir is humans (although it may pass through animals), with an incubation period from 10-72 hours and the symptoms, nausea and vomiting (which is a major route to spreading infection), last from one to two days. The route of transmission is person to person and it contaminates surfaces where it can lodge for long periods without growing. It is one of the most infectious viruses but is not zoonotic, i.e. it is not transmitted by food organisms *per se* but as a contaminant on food. NoV has five different geno-groups with many different genotypes, and hence it is very difficult to make a vaccine. John reported that one of the key uncertainties and information gaps is the lack of quantification of NoV in the human population and the lack of evidence confirming the cause of gastrointestinal disease outbreaks. The big question is how much testing needs to be done to confirm NoV as the cause of an outbreak, e.g. differentiating from Sapovirus, which is a Calicivirus from the same family as NoV and is responsible for a million outbreaks a year in the UK.

Public Health England, with 22 years of quantification of gastrointestinal infection, has the most comprehensive records in the world. NoV reporting became more accurate from 2008 due to increased use of PCR for detection. Laboratory reports for England and Wales from 2008-2014 showed a peak in 2009 of 700 reports and a much-reduced number in the last two years. For each laboratory report there are an estimated 288 unreported cases. A GP presentation study of 1254 cases of infectious intestinal disease gave a result of only 12% positive for NoV. Only a very small proportion NoV outbreaks have been attributed to shellfish. In the 22 years to 2013, some 280 outbreaks have been attributed to seafood; 176 to crustaceans/shellfish with 4153 people affected and 120 outbreaks to oysters with 2064 affected and no more than 12 per year except for 2009. This is not significant compared to the estimated total of 3 million cases of NoV illness per year in the UK. The human population is the reservoir of the virus and 12% of the population are asymptomatic carriers. Attributing any source to a NoV outbreak is difficult as many outbreaks go unreported due to it being a mild illness which is short lived and self-limiting. Investigation is difficult as there is often no product remaining to substantiate the cause of the illness which in most cases can be attributed to person to person transmission as opposed to the food consumed and often that food handling is a cause of outbreaks.

NoV is a relatively mild illness; in contrast, for example, *Campylobacter* is a much more serious infection with symptoms lasting from 5-7 days. It can cause reactive arthritis and a type of paralysis which can be

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life threatening. This is found in raw meat particularly chicken and there are half a million outbreaks per year in the UK.

The speaker was firmly of the opinion that the evidence does not exist that there is a significant public health risk from NoV in bivalve shellfish and NoV outbreaks from oysters are claimed without epidemiological evidence. The introduction of a NoV standard will have no significant effect on the overall number of cases per year. The PCR detection methodology that has been used for the proposed standard by EURL is flawed in that it detects parts of the genome but cannot identify whether or not the material is infectious or non-infectious. Therefore a standard based on this test would have inherent inaccuracies built in. Illness is mild and self-limiting, with no long term consequences and a shellfish limit will be set without evidence for effects on public health

### **4.7 Norovirus diagnosis in bivalves - Willem van Leeuwen & Arjan Gittenberger (GiMaRIS/Toplab)**

**Willem van Leeuwen (GiMaRIS/Toplab)** a medical microbiologist from Netherlands, made similar points to the previous speaker (John Harris) and said that the human health risk from NoV in bivalve molluscs is low. Transmission is only from human sources and requires active living particles of virus; in 50% of cases diarrhoea and vomiting occur. The distribution of NoV within bivalve molluscs is unknown. As it is an RNA virus, validation and interpretation of results is very difficult and clinical validation is needed. As there is no real reference material, as the virus cannot be cultured, there is no method for quantifying results for infective viral counts. He questioned the value of using quantitative PCR results (i.e. genome copies per gram) which may be highly artificial, recommending instead the use of semi-quantitative Cq (quantification cycle) values. His laboratory can carry out pre-harvest testing on bivalve molluscs with semi-quantitative qPCR with results available within 24 hours allowing the customer (who is the only one to receive the report) to make rapid decisions about whether to harvest or not. However, there is a need to link the results of molecular amplification techniques (PCR) from different laboratories with standard material from a production lab (verified by 2-3 reference laboratories), as there is currently no cross-referencing as labs are using different protocols, with or without modifications. By using standard material, results from each lab can be harmonized. He concluded that the clinical relevance of NoV as a human health risk does not seem to be very high.

### **4.8 Safe and sustainable shellfish production - toolbox approach, alternatives to limits – Beverly Perkins (SAGB/FSA/SEAFISH)**

**Beverly Perkins (SAGB/FSA/SEAFISH)** presented a tool-box approach to safe and sustainable shellfish production based on water safety planning, HACCP, sanitary surveys with cooperative reporting as an alternative to virus limits. This model has been trialled with oyster producing areas in the UK and can be used for risk assessment and management with input from all stakeholders. In principle this appears to be similar to the French ‘SUMO’ mollusc surveillance system, which was reported in ACFA WG II in 2007 and which European Mollusc Producers Association (EMPA) reported at the workshop to be operational and functioning well in France. She concluded that this was a viable approach that requires further trialling to record and promote best practice and research to fill knowledge gaps and develop improved tools. Even though a viral standard may only result in seasonal (winter) closures, this will be enough to disrupt business and will result in permanent closures of up to 80% of UK shellfish production. Concerns had been raised in June (2014) regarding knowledge gaps and methods for NoV testing, but the response from the EURL had been that the methodology is a good basis for legislation. Up to the current meeting, DG SANCO has suggested that the new draft will be effectively the same as in June, and that the commission was unaware of any other proposals, despite that proposed by the UK FSA. The tool box approach has demonstrated that industry-led management and testing can be effective at risk reduction, allowing



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producers to act on this risk, but there was concern that there is no funding support for developing approaches such as this as alternatives to a viral standard.

### **5. Research needs – Dr Shelagh Malham, Bangor University**

**Shelagh Malham (Bangor University)** presented a summary of current research relating to shellfish and microbial water quality including problems associated with not being able to detect infective versus non infective NoV, transport and persistence of viruses in the coastal environment and looking at integrated risk assessment for management of shellfisheries. This led to some discussion and identification of priorities that are listed in Section 7 below.

### **6. Open discussion of issues raised**

After the presentations, each speaker gave a summary of the main points of their talks, reflecting also the other views and information presented by other speakers. The workshop was then opened up for comments and discussion by all participants.

One set of questions was taken separately, immediately after Paolo Caricato's presentation, as the speaker could not stay for the open forum session of Workshop, and the following points were clarified.

- It is envisaged that shellfish to be cooked would not also be subject to site criteria and testing for NoV would not be at batch level.
- The current A, B & C classifications based *E. coli* bacterial levels would not be replaced by a NoV standard.
- Audience members, representing the production industry, criticised the Rapid Alert System for Food and Feed, as lacking editorial control or moderation and for its potential to cause national or regional damage to non-affected producers.
- The “to be cooked” labelling approach was criticised as not saying anything about bivalve molluscs consumed raw and it was questioned whether it applied to industrial cooking only.

In response to concerns raised by the audience, the speaker called for practical suggestions for possible solutions. While water quality is likely to improve in the future, he said that it is not good publicity for producers to have virus illness outbreaks in the meantime. He said that the European Food Standards Agency (EFSA) opinion is that the risk manager (DG SANCO for COM) needs to act. Overall, it is a very difficult situation and the direction to take is not yet clear, as there is a lack of agreement between member states.

Terrence O'Connell asked for views on the issue of a rapid alert for NoV associated with oysters, as the system currently used implicates all the oysters of the region leading to a huge impact on the farmers as they will be audited and with all EU documentation examined. The Irish Food Standards Authority will attempt to test the oysters for a clear link between them and the ones implicated in the outbreak. The oyster farm can be closed for month or even years. NoV is a small risk but the impact is huge.

Willem van Leeuwen suggested that the only way to do this was to type the strains and compare with the stool sample of the patient. However, John Harris stated outbreaks usually occur when there are already high levels of NoV within the community. There are large numbers of NoV genotypes in shellfish so it is difficult to match with patients due to gross contamination with sewage in their environment. Epidemiology is not being carried out properly in order to investigate outbreaks properly and this is a key evidence gap. David Lees agreed with John Harris that there needs to be a greater degree of evidence,

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however with budgetary crisis there are less and less quality investigations being carried out. We no longer have the quality of information that we used to have in outbreak situations.

David Jarrad asked why are we trying to trying legislate for the ‘don’t knows’ as we do not have the evidence for the health risk posed by NoV. David Lees responded that legislation is required because there are some outbreaks.

Richie Flynn further reinforced the fact that rapid alerts do cause rumors that in the end impact upon the producers who may be closed and no one has ever talked about a limit to reopen the producers not told when they can reopen. After closure due to potential viral contamination of an area there is no time set to reopen and no mechanism for determining when oysters can be put back on the market with no health risk. The PCR techniques are not robust enough to determine this.

Richie Flynn raised the question of what monitoring procedures would be for NoV and what level of sampling would be required. David Lees responded that he envisaged a system similar to that used for biotoxin monitoring. Richie Flynn pointed out that this would be complex and very costly – and asked who would fund the sampling and reporting costs.

John Harris commented that the setting a limit for NoV in shellfish is not aligned with the public health impact that it will have. There is no way to guarantee that if a limit is set that anyone eating oyster from an area recorded as being below that limit will not get ill. To suggest that this is possible is simply not truthful as there is no hard and fast evidence to suggest that the limit is good, bad or indifferent because the evidence for the degree of public health risk at a particular level of NoV as currently measured is highly inconclusive; we do not really know what the public health impact is of consuming oysters at different level of contamination. Despite the hard work that David Lees and EURL have done, he was not convinced that the evidence is there and he disagreed with setting a limit or standard when the science behind it is a so uncertain. David Lees responded that microbiological standards are the best estimate that we have come up with to control the risk. John Harris responded that NoV is a transient infection for which it is difficult to get the epidemiological data to quantify risk and that to set a limit to attempt to reduce cases is very difficult and based on incomplete science, unlike *E.coli*.

David Jarrad noted that he was very disappointed that Paolo Caricato was unable to stay for the afternoon open session and hoped that the discussion is relayed back to him. He commented that he was struggling with the proportionality of the argument and questioned what the driver was for rushing through a NoV standard and where was the supporting data. He also questioned the information presented by Paolo Caricato that a NoV standard was required in order to support quality control of 3<sup>rd</sup> country import/export standards – and asked if we should be sacrificing the EU industry for the sake of imports.

Richard Bates commented that he had given a presentation about marine aquaculture in 2004 where the view was that all water quality issues were to be solved by 2015 under the WFD. Clearly this was not the case, and from evidence presented by Bangor University at a previous seminar at DG Mare, current research suggest that even very substantial investment in sewage treatment improvements will still not solve the problem.

The question of the specificity of the PCR primers was raised and specifically whether presence of animal NoV could be misreported as a positive human NoV test. David Lees responded that only specific strains are detected using specific qPCR primers. In addition, John Harris stated that only if cross-testing had been positively demonstrated would it be reported in the literature. David Lees stated that there was a vast amount of information on NoV humans and very little on animals. Arjan Gittenberger suggested that this was an important area for research and requested publications on primers and testing from David Lees.

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Hans Bal stated that even if there are a very large number of negative NoV tests in a supply of shellfish, the food safety authority tend to ignore these results if there is even a single positive test in a person (i.e. there is no checking of evidence of the source). Even when food handlers are implicated there is no batch by batch recall but an entire recall on the product.

Bruno Guillaumie summarised his views on the presentations and discussion. He was concerned about the confusion between the various EC DGs – it is like driving a car with three drivers, one for DG Environment, one for DG SANCO and one for DG MARE. The Commission (DG MARE) has set the direction towards blue growth, and we are happy to follow that route, which is clearly concerned with the economy, cost-benefits and competition. The member states have been required to write strategy plans to achieve this, to simplify the way forward to growth, but what we have now is a very complicated situation – when even 10 years ago we proposed and implemented a system for integrated risk assessment as a simple and effective way to manage shellfish water quality. He pointed out that there is an (unused) mechanism to quantify gastrointestinal outbreaks, using data from pharmacies dispensing or selling medicines for so that in real time information could be collected and disseminated on gastric viral disease levels in the general population. In real time, a measure of the level of diarrhetic illness, whatever the source, could be produced that can be used to assess and manage the risk in a particular shellfish production area. In his view, shellfish water quality should be protected as a requirement of Article 5 of the Water Framework Directive even though it appears that no member state had done this for 30 years. He suggested that we should not just set the indicator standards that are to be measured to show that we have reached the objective and not confuse between results and indicators. Bruno stated that indicators are very important but working on the underlying causes is essential and hoped that DG Mare will take leadership of the subject and that this meeting is all reported back to DG MARE.

### **7. Feedback in relation to research needs.**

Tony Harrington suggested that work needs to be done on whether the shellfish and water industries across Europe recognise and understand the social and economic consequences of NoV standards. Does this need researching or do we have it already and just need articulation in a cost-benefit analysis? An evidence review is needed.

Richie Flynn agreed that is needs to be done. There is an obligation to have an assessment of impact on regulations that would have this kind of impact on any economy, or industry or on the EU in general and that would have to be funded by the EU before regulation was put in place. But as a number has already been suggested then the press have picked up on it and Scotland has even started using it in negotiations already.

Arjan Gittenberger suggested a study of producers who comply with a NoV standard and compare with some that don't. Is there a significant difference in disease over 3 years? Although David Lees stated that there is some data available it may not be consistent between producers. In addition Bruno Guillaumie reiterated that in France there is data available within such a framework but as every lab follows different protocols the results are difficult to compare. It was suggested that a study could be made of alleged shellfish-associated outbreaks across Europe further to the information already gathered by EFSA.

Integrated risk assessment such as SUMO in France and the Toolbox in the UK can be effective and there is a need for research to further develop such approaches.

Microbial water quality indicators (such as *E. coli* and NoV) are important but actual health risks in shellfish and pollution levels in the environment are important knowledge gaps.

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Further work is needed on protocols for quantification of viruses in shellfish.

A better understanding of the relative importance of food handling versus environmental contamination of shellfish in viral disease outbreaks is needed.

Lewis Le Vay commented that given the timescale of the decision on whether to introduce a NoV standard, the normal process of applying for, commissioning research projects and reporting results would not be rapid enough to inform the debate. He reiterated a point made by Tony Harrington that an evidence review was urgently required to collate available data and to identify critical knowledge gaps. The current meeting has identified some of these gaps and an evidence-based review could build on the evidence collated by EFSA and should include economic cost benefit analysis of the human health risk and the effects of introduction of viral standards.

### **8. Closing remarks - Richie Flynn (Irish Shellfish Association)**

**Richie Flynn (ISA)** closed the meeting with some summary remarks from an industry perspective. He agreed that regulation is necessary and that food safety is the primary concern. The shellfish industry has educated consumers and government agencies about link between a healthy environment and safe food. The industry is not anti-regulation but it is the producers that will be impacted by restrictions, not the regulators who choose to impose them and it also seems that the polluters have no sanctions on their activity. Imposing a viral limit on producers is not the right way forward. The principal questions to ask are: Why are we doing it and in whose interest? The industry is going to suffer from the limits and is not standing still waiting for the answer, but is funding research already. Science is the backbone of the industry; science is fundamental to aquaculture, especially shellfish aquaculture. The Commission's purpose is to write legislation and they need numbers (i.e. limits and standards) to do this. However, in this case they are asking the industry to gamble everything on this one number, without enough information on the methods used to determine it nor the impacts it will have. If the industry is given no choice in this, then the process is anti-democratic. However, there is now sufficient awareness of the proposed viral standard that the door is open and there must be a pause in the process for review and consultation. This number may be the death of us, we don't know what the ultimate effects will be but it definitely won't be the start in the next big stage of blue growth. There is a political movement across Europe against the proposed standard and this will continue to grow from today.

### **9. Recommendations and actions**

The workshop highlighted a range of concerns from industry about the proposed imposition of a NoV standard for shellfish. There was overwhelming support for halt in the process of setting the standard, while views of stakeholders are consulted. Some significant knowledge gaps were clearly identified and it was agreed that a priority should be to undertake a critical review of evidence in a timely manner for dissemination to all interested parties including the EU Commission, Member States and their regulatory bodies.

Bangor University is currently securing funds to commission an evidence review to be completed in the next 3-6 months. The review will be carried out by a panel of independent experts and can be used to inform the consultation process. A draft scope of the evidence review, based on the discussions in the workshop, is listed below, with further refinement anticipated as a result of consultation with stakeholders before commissioning.

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### ***Evidence review – draft scope***

What is scale of the human health risk posed by norovirus in shellfish?

What would be the costs and benefits to the shellfish industry from the imposition of the proposed NoV standard, under a range of scenarios (e.g. viral limits imposed, methods of monitoring, requirements for reopening)?

What would the wider socio-economic consequences be in coastal and rural areas where shellfish production takes place?

What would be the costs and benefits to the water industry from the imposition of the proposed norovirus standard?

What are the options for mechanisms of implementing a virus standard? What would the costs of monitoring and implementation options?

What are the limitations of the proposed assay method in quantifying risk to human health from norovirus contamination of shellfish? Is the test fit for purpose?

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**Appendix 1: Attendees**

<b>Name</b>	<b>Organisation</b>
Arjan Gittenberger	Gittenberger Marine Research Inventory and Strategy
Berwyn Davies	Welsh Higher Education Brussels
Beverley Perkins	Shellfish Association of Great Britain
Bruno Guillaumie	European Molluscs' Producers Association
Chris Leftwich	Fishmongers Company
Craig Burton	SEAFOOD Scotland
David Alexander	Food Standards Agency UK
David Jarrad	Shellfish Association of Great Britain
David Lees	Centre for Environment, Fisheries and Aquaculture Science
Elaine Connolly	Department for Environment, Food and Rural Affairs
Erik Stalmans	Societe Generale de Surveillance (SGS Belgium)
Gerald Viaud	Comité National Conchylicole
Hans Bal	Krijn Verwijs Yerseke BV
Helen Duggan	SEAFISH
James Wilson	Deepdock Ltd.
Jasmine Sharp	Bangor University
John Harris	Public Health England
Jonathon King	Seafare
Karen Tuson	Bangor University
Kim Mould	Myti Mussels
Lewis LeVay	Seafare / Bangor University
Liz Cassidy	Welsh Government EU Office
Mark James	Marine Alliance for Science and Technology for Scotland
Marta Iglesias	Directorate General for Research and Innovation
Martin Flanigan	Bord lascaigh Mhara
Paolo Caricato	Directorate General for Health and Consumer Affairs
Paul Hagan	Welsh Higher Education Brussels
Philip Flanerty	Foreign & Commonwealth Office
Richard Bates	Directorate General for Maritime Affairs and Fisheries
Richie Flynn	European Molluscs' Producers Association/ Irish Shellfish Association
Shelagh Malham	Bangor University
Terrance O'Carroll	Bord lascaigh Mhara
Tony Harrington	Dŵr Cymru
Tristan Hugh-Jones	Loch Ryan Oyster Fishery Co. Ltd / Association of Scottish Shellfish Growers
Willem van Leeuwen	Toplab - Hogeschool Leiden
William Baker	Blackwater Oystermen's Association

## ***Microbial water quality: Challenges to Blue Growth in Shellfish***

### **Appendix 2: Agenda**

09:30 Welcome (James Wilson)  
09:40 Presentation DG MARE (Richard Bates)  
10:00 Presentation DG SANCO (Paolo Caricato)  
10:20 Presentation EURL (David Lees)  
10:40 Coffee  
11:10 Presentation Dŵr Cymru/Welsh Water (Tony Harrington)  
11:30 Presentation from Public Health England (John Harris)  
11:50 Presentation from Shellfish Industry (Willem van Leeuwen)  
12:10 Presentation Beverly Perkins (Tool Box approach)  
12:30 Lunch  
14:00 Presentation Reviews by speakers (5min)  
14:40 Open discussion  
15:30 Coffee  
15:45 Priority on ways forward – Research and Funding  
16:30 Summary of the meeting and outputs (Richie Flynn)  
17:00 Finish

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