**Food Standards Scotland bivalve mollusc classification and monitoring: consultation on changes to the official control programme**

# **Background and summary of proposals**

* 1. Bivalve shellfish, such as mussels, oysters, scallops (pectinidae) and razor clams, are filter feeders and can accumulate dangerous toxins and pathogens quickly. Shellfish toxins, which can be fatal, are heat stable which means that, unlike microbiological and viral contaminants, they cannot be removed through cooking. These toxins are produced by naturally occurring phytoplankton (algae) and therefore present a different risk management challenge to faecal-borne pathogenic contaminants such as norovirus, which derive from man-made inputs such as sewage discharges. However, neither of these contaminant risks are inputs over which shellfish harvesters have any control. Given this multi-factorial environment, as well as the potential severity and history of illness associated with shellfish, an extensive raft of official controls is explicitly set out in EU law.
  2. FSS is defined in law as a competent authority in relation to the delivery of a significant number of shellfish official controls (OC) with a particular focus on the monitoring of harvesting waters for the presence of E. coli (as an indicator of microbiological quality) and shellfish toxins. There are no other areas of food law where routine environmental monitoring (as opposed to monitoring within individual businesses) is required to be carried out by the competent authority to such an extent and where the outcome of such monitoring will have such an immediate and direct effect on specific businesses. Official control monitoring is primarily used in order to prohibit fishing in areas when statutory levels are breached. However, the data generated by the programme also provide evidence for biotoxin trends in harvesting areas which should be reviewed on an on-going basis to identify periods of increased risk and inform appropriate risk management decisions by harvesters and processors.
  3. The FSS shellfish OC programme budget in 2016-17 is £2.4m within an overall FSS programme budget of £8m. Given that monitoring, which constitutes the bulk of the OC function, becomes a statutory requirement once FSS provides a classification, it is appropriate that we consider not only our approach to classification and monitoring, but how we might ensure that official control delivery in this sector is as efficient and sustainable as it can be in future. This issue is being considered within the wider context of a FSS Shellfish Review which is currently underway.[[1]](#footnote-2).
  4. Table 1 outlines the FSS Shellfish programme budget for 2016/17:

Table 1: FSS Shellfish Official Control budget 2016/17

|  |  |
| --- | --- |
| **Official control** | **FSS programme Budget at April 16** |
| Biotoxin Monitoring of Classified Shellfish Production Areas | 1,079,389 |
| E. coli Monitoring | 260,000 |
| Inspection of Depuration Plants | 25,000 |
| Phytoplankton monitoring | 297,635 |
| Sanitary Survey of Classified Shellfish Production Areas Prmp[[2]](#footnote-3) | 60,000 |
| Shellfish Chemical Monitoring | 61,000 |
| Sampling Officers | 625,000 |

* 1. This consultation therefore invites views from harvesters, processors, local authorities and all those with an interest in the shellfish safety, on proposed changes in the following areas:
     1. **Shellfish classification**. We want to consider ways in which FSS and industry can work together to deliver a targeted official control programme by looking at the way we classify areas. Proposals on the principles regarding an FSS decision to classify an area in the first place are outlined in **Annex 1**. New legislative criteria for classifications and end product standards applied from 1st January 2017[[3]](#footnote-4). A separate consultation letter has been sent outlining proposed changes to the FSS protocol for determining classifications based on results received.
     2. **Depuration**. FSS currently provides specific support to local authorities and businesses involved in purifying/depurating shellfish. However given that food businesses are required to put in place and validate their own food safety management systems, we consider it appropriate to review approaches in this area. **Annex 2** describes FSS proposals that will affect both food businesses involved in purifying shellfish and local authorities which are responsible for approval.
     3. **Biotoxin monitoring**. Given that biotoxin monitoring accounts for 45% of the shellfish budget within FSS, we are taking the opportunity to review how we deliver this element of the programme in order to ensure best value and effective delivery. See **Annex 3** for detail.
     4. **Sampling, phytoplankton monitoring and general programme issues**. This section invites views on the ways samples could be collected and verified particularly for wild shellfish areas. We are also interested to hear from stakeholders on the ways they use the phytoplankton programme to monitor risk, and to invite wider views on the ways the official control monitoring programme for shellfish could be improved as a whole. **See Annex 4.**
  2. This consultation informs the overall outcome of the Shellfish Review Project which is referenced in the FSS Corporate Plan under Strategic Outcome 1 as follows:

*FSS Corporate Plan under Strategic Outcome 1*

FSS will

*Carry out a comprehensive policy and delivery review of the FSS shellfish official controls, including small scale and local supply chains, working in partnership:*

*Ensure proportionate and targeted interventions to protect public health and maintain consumer confidence thereby promoting sustainable growth.*

*Review and modify as required, such that resources match policy and delivery priorities*.

* 1. The consultation will be considered through the prism of the FSS Regulatory Strategy and aligns with the principles for effective and sustainable official controls agreed by the FSS Board in August 2016[[4]](#footnote-5).

* 1. The closing date for responses is xxx
  2. A **Business and Regulatory Impact Assessment** also accompanies this consultation and is attached at **Annex A**.
  3. A full list of consultation questions is available [**here**.](#ListofConsultationQuestions)

**Annex 1. New and existing classifications – a partnership approach**

* 1. There is no legal obligation on FSS to classify a shellfish area, however shellfish cannot be placed on the market unless they are harvested from areas that the competent authority has classified. The statutory obligation to monitor an area only applies once the decision to classify has been made.
  2. Given that the regulations also allow for classifications to be made with the co-operation of the food business operator[[5]](#footnote-6), it is proposed that each application is processed using a clear decision tree with each step clearly understood by each party. The proposed steps are as follows:

***Step 1: Scrutiny of new shellfish applications***

* 1. Since August 2016, new applications received by FSS (from harvesters via local authorities) have been sent to Scottish Natural Heritage, Marine Scotland, Scottish Water and the Scottish Environment Protection Agency for comment. Each party has 10 days to provide information to FSS which may influence the decision by FSS to classify the area. Our classification protocol will therefore be amended to allow FSS to consider whether there may be conflicts with other legislative requirements including, but not exclusively:
* Whether the area may be subject to a conservation order;
* If the applicant is compliant with Marine Scotland’s licensing requirements (e.g. for razors due to measure to prevent electrofishing)
* If the area is considered unsuitable for shellfish classification due to the likelihood of a pollution event occurring in specified area.

***Step 2. Shellfish Waters Protected Areas and FSS classification***

* 1. Scottish Government has set out an agenda for the sustainable growth of the aquaculture sector in order to double production by 2020, as well as recognising that inshore wild shellfisheries have significant economic potential. In order to help deliver this target, 85 Shellfish Waters Protected Areas (SWPAs) have been designated by Scottish Government. This protection is “intended to prevent the deterioration of water quality in these areas, and where necessary to improve water quality[[6]](#footnote-7)”. Of the 203 production areas currently classified[[7]](#footnote-8), 93% are located within SWPAs[[8]](#footnote-9). The majority of aquaculture sites are therefore included within SWPAs, with the remainder of those not covered being involved in wild harvest (razors, cockles etc). Given that considerable resource is required by FSS to assess and mitigate against the risks associated with the consumption of shellfish by the public through the classification process, and the resource required to maintain good levels of protection as a SWPA, it is appropriate for FSS resources to focus on those areas which are subject to wider Government support with a view to sector growth.
  2. We propose only to conduct sanitary surveys in areas that Scottish Government has officially protected as outlined in the Water Environment (Shellfish Water Protected Areas: Designation) (Scotland) Order 2013[[9]](#footnote-10); or by similar orders or amendments in future. For new areas that are not subject to designation order it is proposed that industry would be required to undertake their own sanitary survey within an agreed timeframe in order to allow classification to proceed.
  3. However it should be noted that the full extent of what this will mean for industry will require to be considered in light of our reassessment of the sanitary survey requirement as a whole. FSS are working closely with SEPA in order to assess our approaches to classification and sanitary surveys more generally and, in order to ensure that appropriate models are developed, we have taken the decision that no new sanitary surveys will be commissioned pending delivery of this work. This means that for at least the next 2 years, FSS will continue to commission desk top assessments for all relevant applications to determine classification area and provisional monitoring points, for all new areas irrespective of species or location.
  4. Therefore the proposal would mean that whilst FSS would continue to classify aquaculture areas that are outwith SWPAs, it would be for industry in those areas to proactively consider the microbiological and viral risks associated with new areas prior to approaching FSS for classification and indeed prior to the planning stages. Costs will require to be assessed and agreed with the applicant prior to classification.

**Question 1**

Views are sought on the proposal for FSS to undertake sanitary surveys only for aquaculture areas designated as Shellfish Water Protected Areas, and ask prospective aquaculture harvesters outwith those areas to undertake their own surveys prior to classification.

**Do you agree with the approach suggested?**

**Question 2**

Views are sought on the ways in which FSS and industry involved in wild harvest areas and those outwith SWPAs might better work together to deliver the sanitary survey requirement in future.

***Step 3: Submission of samples and business agreements***

* 1. The regulations and guidance allows for industry samples to be considered within the official control programme provided certain conditions are met. Given that FSS are obliged to monitor areas once they are classified – we consider that there is an opportunity for industry to indicate a commitment to that process by supplying the samples required to become classified. We are aware that industry already take a considerable number of E.coli samples from A class waters and it would be useful to explore how these samples might be used to help reduce OC programme costs. In 2015 FSS processed 34 new shellfish classifications. The proposal would save approximately £40k annually in analysis costs alone, but greater savings would be achieved in relation to efficiencies associated with reduced sampling costs. We recognise however that this would involve a transfer of costs to industry and we welcome views on both this proposal and the extent to which this new requirement might be offset by current testing practices across Scottish shellfish businesses.
  2. In summary, it is proposed that by June 2017, for all new classification applications received by FSS, the applicant will be required to provide an agreed number of samples in accordance with a signed protocol. This would usually mean the provision of between 6-10 samples but numbers can vary. This protocol will set out the proposed sampling point, frequency and sampling handling requirements and will essentially follow a pre-existing format which allows harvesters to provide samples in order to help inform classification decision making. The current ‘harvesters own results’ protocol is available here: [Harvesters Own results](http://www.foodstandards.gov.scot/use-harvester%E2%80%99s-own-results)

**Question 3**

We intend to ask all new classification applicants to provide classification samples in accordance with an agreed protocol by June 2017.

**Is it reasonable to expect businesses to contribute towards official controls in this way? Please explain your answer.**

**Step 4: Harvesting plans**

* 1. If shellfish are not being harvested, placed on the market and consumed then there is no biotoxin risk to be managed. As our biotoxin monitoring programme is risk based, it is considered inappropriate to continually monitor areas where no harvesting takes place. For wild shellfisheries harvesting is seasonal and maintaining year round classification infrastructures for areas where no harvesting infrastructure exists may not be sustainable. If at present industry harvest for only 80% of the time that an area is monitored, a 20% reduction in biotoxin monitoring alone could result in savings of around £200k to FSS per annum.
  2. We want to move towards a system that targets official control activity to periods when harvesting of marketable stock takes place where possible, and to provide greater flexibility to businesses who assist in delivering the OC programme.
  3. If businesses do not plan to harvest at set times of the year, then FSS could target *E.coli* sampling, as well as toxin monitoring accordingly. This would mean that if harvest takes place for only 4 months of the year (and the area is dormant for 8 months), provided 10 compliant classification samples are received in that 4 month period classification could be maintained at A class (8 samples for B class areas).
  4. For businesses harvesting on a year round basis with much shorter periods of inactivity, FSS are would be content to receive samples a maximum of 6 weeks apart. This measure is intended to provide greater flexibility in sample provision in order to better accommodate harvesting patterns.
  5. Although FSS do not intend to monitor shellfish toxins in areas where no harvesting takes place, in many cases we have insufficient information that allows us to stop sampling. Any improvement in this area could result in a saving to the public purse.
  6. In order to help achieve this we intend to request that harvesting plans for each classified area are sent by food businesses prior to annual classification awards in April of each year or when they are subject to any significant change. An annual submission would apply to both aquaculture and wild shellfisheries and would be a prerequisite requirement prior for awarding or maintaining classifications.

**Question 4**

It would be useful to know how far ahead businesses can reasonably plan harvesting activities.

**Is it reasonable to request harvesting plans 12 months in advance? If not please explain why this may not be possible.**

* 1. **FSS classification decision tree**. In any system where certain conditions are required to have been fulfilled prior to action, a verification step is proposed, prior to the award of a classification. In the proposals outlined above, this verification step would simply be confirmation by FSS that the steps outlined above have been undertaken. On that basis, the changes outlined above have been summarised in diagram 1 for new areas (caveated by wider considerations regarding sanitary survey approaches that may apply in future):

***Diagram 1 Summary: Proposed classification steps***

**STEP 1**

Has Marine Scotland, Scottish Natural Heritage, SEPA, Crown Estate or Scottish Water provided information which means that the application should not be supported by FSS?

If yes – confirm position with relevant public body. If no proceed to Step 2.

**STEP 2**

Is the proposed classification within a designated protected area as outlined in the Water Environment (Shellfish Water Protected Areas: Designation) (Scotland) Order 2013 and The Water Environment (Shellfish Water Protected Areas: Designation) (Scotland) Order 2016 or by similar orders or amendments in future. ? – If yes – proceed to step 3. If no – agreement on delivery of sanitary survey process step should take place prior to proceeding to Step 3

<http://www.gov.scot/Topics/Environment/Water/15561/ShellfishWaters/LocationMaps>

**STEP 3**

Has the harvester agreed to the provision of samples in accordance with a signed protocol that would permit classifications to be made? If no, do not proceed. If yes proceed to step 4.

**STEP 4**

When is the harvester likely to have marketable stock? Harvest plan to be provided prior to classification.

**STEP 5**

Undertake classification sampling. If for a new site this will be undertaken by FBO, verified by FSS sampling officer or local authority. Up to 10 samples required for new areas over a 12 month period, or during harvest period only (as specified by agreed protocol).

**STEP 6** Have samples been provided in accordance with protocol agreed at STEP 3? If yes – classify in accordance with classification criteria set out in regulation 854/2004. If no, do not classify.

**Annex 2. Changes to depuration (purification) requirements**

***Changes to approval process for depuration***

* 1. Currently new purification establishments are approved following inspections undertaken by local authority officers with assistance from Marine Scotland Science (MSS). MSS, funded by FSS, has historically provided the technical expertise to assess the capability of purification systems (tanks) in achieving the required end product standard and have set specific operating conditions, previously known as “conditions of approval”, for individual purifications systems. These criteria have formed the basis of the technical process aspects of the business approval which is issued by the local authority.
  2. However the regulations do not require that this technical assessment be carried out by the competent authority and it is inconsistent with the process for the approval (and re-approval) of establishments producing other products of animal origin (POAO). **It is proposed therefore that MSS assistance in providing technical advice will therefore formally cease from April 2017.** Given that this consultation document runs into May, specific issues arising after April will be considered on a case by case basis. Like other businesses handling POAO, food businesses involved in purification will need to demonstrate to the relevant competent authority that the systems put in place are effective at controlling all relevant risks and they are meeting end product standards through the implementation of effective HACCP-based food safety management systems.
  3. The triggers for approval are unchanged and applications made to local authorities will be required to include verification information previously provided by MSS.
  4. Please note any change to the HACCP-based approach must be notified to the LA but it does not necessarily trigger re-approval. You may wish to refer to your LA or to Seafish for more information on the general approval process.

***The use of reduced purification times***

* 1. The Regulations do not prescribe any minimum purification time. In the UK a minimum recommended period of 42 hours has been in place as it was considered an appropriate means of ensuring that food placed on the market is safe. FSS has reviewed this position, as has Food Standards Agency elsewhere in the UK, and recognise that given a minimum time is not specified in the Hygiene Regulations, it is therefore proposed that food businesses will be allowed to apply alternative purification times.
  2. However businesses wishing to apply a reduced period must develop their own HACCP-based food safety management system which has considered all relevant hazards (microbiological and viral) and provide evidence to satisfy their relevant local authority that the reduced time requested is protective of human health and produces shellfish compliant with end product standards.

Businesses will need to consider a range of issues which might affect the period of time which LBMs are purified, including (but not necessarily limited to):

* The species
* The time of year and the associated risks from contamination
* Recent weather
* Most recent official control monitoring results
* Other information relating to the harvesting area e.g. pollution event etc.
  1. Seafish have provided the following guide which businesses may find useful:

<http://www.seafish.org/media/Publications/GMPG_Bivalves_downloadable.pdf>

* 1. Please note businesses **must** inform their LA and the LA must have verified that the HACCP-based systems will be effective before reduced purification times are commercially used[[10]](#footnote-11). In the absence of this, the standard period for shellfish purification will remain at 42 hours.

**Question 5**

**We would welcome views from businesses on the impact and implications of the measures outlined above.**

**Annex 3 Biotoxin Monitoring – proposed changes to how we close and reopen areas**

* 1. Biotoxin monitoring programme is risk based and subject to regular review. The latest version of the risk assessment which will form the basis of monitoring frequencies across Scotland was published in September 2016[[11]](#footnote-12). This system will inform the structure of the FSS biotoxin monitoring programme for the next 3 – 4 years.
  2. In addition to setting out the general monitoring requirement[[12]](#footnote-13), the regulations also set down criteria on which the competent authority must close or open an area in accordance with the health standards laid down in Annex III, Section VII, Ch V of EC Regulation 853/2004.
  3. Specifically , “where the results of sampling show that the health standards for molluscs are exceeded, or that there may be otherwise a risk to human health, the competent authority must close the area concerned, preventing the harvesting of live bivalve molluscs” (Annex II, Ch II, C, 854,2004).
  4. EC regulation 2074/2005 (as amended) lays down the analytical methods that shall be used by the competent authorities to check compliance with the limits. The regulation also allows the use of alternative’ methods, as long as they are ‘internationally recognised’. In the UK the following methods are applied (Table 1):

**Table 1. Methods currently used for official control biotoxin monitoring in Scotland (and across UK)**

|  |  |
| --- | --- |
| **Toxin group** | **Testing method** |
| PSP | HPLC |
| ASP | HPLC |
| LTs[[13]](#footnote-14):  DSP (OA-toxin group)  PTX,  AZAs  YTX | LC-MS/MS |

* 1. There are a number of commercial kits available on the market, and these provide very useful tools for assisting businesses manage toxin risks associated with their product (see table 2 )[[14]](#footnote-15)

**Table 2. Marine toxin test kit suppliers (at March 2015) and types of tests available**

|  |  |  |  |
| --- | --- | --- | --- |
| **Company** | **DSP** | **ASP** | **PSP** |
| Abraxis | PPIAa  ELISAb | ELISAb | ELISAb |
| Beacon | ELISA | ELISA | ELISA |
| Bio Scientific | ELISA | ELISA | ELISA |
| Biosense Laboratories | ELISAb | ELISAb | ELISAb |
| EuroProxima | ELISA | ELISAd | ELISAd |
| Neogen Europe Ltd | LFA | LFA | LFA |
| R-biopharm | - | - | ELISA |
| Scotia Rapid Testinge | LFA | LFA | LFA |
| Zeulab | PPIAa | ELISAd | ELISAd |

* 1. Of these, only the Biosense ELISA for ASP and the Zeulab PPIA for DSP have been subject to an inter-laboratory validation and are recognised as suitable for use by competent authorities. The AOAC 2006.02 Biosense ELISA method can be used for screening purposes to detect ASP toxins and the Zeulab PPIA Okatest kit has been approved as a supplementary method for the detection and quantification of OA-toxin group (DSP), although other tests would still be required to detect other regulated LTs such as PTX, AZAs and YTXs.
  2. Okatest does not detect PTXs, AZAs or YTXs . However prevalence of PTXs and YTXs in Scottish waters is low (0.16% and 3%, respectively) and no toxicity in humans has been reported to date (although both toxin groups are still regulated). AZAs are known to result in human illness, however their prevalence in Scottish waters has also been historically low (the overall prevalence of AZA in Scottish waters has been 5% since 2011, with no results found over the maximum permitted level since April 2013).

Given that these tests are recognised as fit for purpose, and they can be processed more quickly than chemical methods, consideration will be given to introducing these tests to the programme in future.

* 1. Irrespective of the methods applied within the monitoring programme, we are also looking at our approaches in areas that are closed on an ongoing basis due to high levels of toxins, which is a common feature in Scotland during the summer months. At present, we continue to sample closed areas on a weekly basis, for the regulated toxin on which the closure was based.
  2. A partnership approach based on better harvesting information, as outlined in Annex 1, should allow FSS to avoid weekly sampling where there is no impact on commercial harvesting as there is no public health benefit or efficiency in sampling areas that are not harvesting – and obviously closed areas cannot harvest. Likewise in order to ensure that areas are closed for the shortest possible time, FSS believes there is scope to utilise industry samples to support OC sampling. Currently FSS require two official control samples to be taken to re-open an area, one week apart. The regulations allow for areas to be re-opened on a single sample provided robust data is available to support that action.
  3. FSS propose to cease routine sampling for biotoxins in areas that are subject to any closure order and will only sample in closed areas where the FBO is actively seeking to harvest and where he or she can provide evidence that biotoxin levels have sufficiently reduced.
  4. We consider that two suitable rapid test results provided by harvesters indicating “decreasing trends of toxicity”, taken at least 48hrs apart could be considered sufficient evidence to open the area based on a single OC sample tested for all regulated toxins.
  5. Had such a system applied in 2015 it is estimated that FSS may not have been required to analyse on approximately 140 occasions, saving FSS approximately £28k[[15]](#footnote-16). In addition by applying an early opening system based on taking only one OC sample, where industry are able to provide evidence of reduced toxicity for the toxin which closed the area originally, businesses across Scotland may have benefited from having an additional 13 weeks available for harvesting[[16]](#footnote-17). However, such a system would place an additional testing burden on food business operators which has not been quantified.

**Question 6**

FSS will no longer sample in closed areas on a weekly basis pending verifiable confirmation from food businesses that toxin levels have suitably reduced – for the toxin which closed the area originally. However FSS will re-open an area based on 1 satisfactory official control sample if supported by evidence of reducing toxicity from FBOs (2 rapid kit test results from harvesters). FSS intend to review the sampling outcome of this proposal in order to inform future monitoring regimes.

**What are your views on these proposals? We would welcome an assessment by businesses as to what the impact of such an approach would be. Information on the volume of testing currently undertaken by your business and access to testing facilities or equipment would also be useful.**

**Annex 4. Sampling issues, phytoplankton monitoring and general programme issues**

* 1. Statistics from the annual report on biotoxin monitoring indicate that over 86% of samples were collected by appointed sampling officers[[17]](#footnote-18). In specific circumstances (for example where it might involve the commissioning of vessels etc. and dependent on location or accessibility) it can be impractical for sampling officers to collect these samples themselves. In such circumstance FSS also allow the collection of samples by the industry.
  2. Most of these samples relate to wild catch sites as accessing species such as razors, which are often collected from subtidal areas, can be difficult.~~,~~ 98% of razor samples used in the programme were collected by industry and delivered to sampling officers for onward transit to the laboratory.
  3. Given the recent advances in mobile device technology we would like to consider whether alternative ways of verifying sample collection should be considered. Likewise in terms of longer term regulatory developments, land based verification checks for certain bivalve species, in line with current requirements for scallops, could be considered, provided traceability can be maintained throughout. Industry and local authorities may have their own ideas as to how a robust system could work in future and we would be interested in hearing your views.

**Question 7 How could mobile technology assist in ensuring both sample collection and traceability controls are maintained for shellfisheries? Please describe the ways in which such technology might be deployed.**

* 1. FSS are also considering the roles played by phytoplankton and biotoxin monitoring within the programme, with a view to ensuring the programme continues to deliver our regulatory obligations; is risk based and protective of public health as well as delivering best value for money. Some countries place considerable emphasis on the use of phytoplankton as a primary indicator of toxicity and only test in shellfish flesh should high phytoplankton counts be observed. However given that Scotland experiences frequent and intense biotoxin events with rapid onset, in general terms whilst we would wish to maintain current monitoring levels for both phytoplankton and shellfish toxins where verified samples can be provided, if there are options to consider alternative regimes in future we would wish to do so. One contributing factor to future decision making would be a greater appreciation of the ways in which harvesters use phytoplankton results to manage shellfish toxin risk.
  2. The purpose of the Shellfish Review is to look across the full suite of official controls in this sector and to drive efficiencies and improvements in delivery where possible. We would welcome views from all stakeholders as to how this can be achieved.

**Question 8**

For both wild and aquaculture shellfish businesses we would be interested to hear about how phytoplankton is used at a local level. **Do you apply different triggers to those used in either the monitoring programme or in the ‘toxin traffic lights’ guidance document? Please describe the ways you use them.**

**Question 9**

We are aware that certain aspects of the current and future Shellfish OC programme could not be delivered without considerable assistance from industry. Whilst both FSS and Local Authorities work within certain fiscal and legislative parameters we would welcome your thoughts more generally – this is an opportunity for ‘blue sky’ thinking.

**Which areas within the official control programme should be changed and why?**

**LIST OF CONSULTATION QUESTIONS**

|  |  |
| --- | --- |
| **Food Standards Scotland bivalve mollusc classification and monitoring: consultation on changes to the official control programme** | |
| **Question 1** | Views are sought on the proposal for FSS to undertake sanitary surveys only for aquaculture areas designated as Shellfish Water Protected Areas, and ask prospective aquaculture harvesters outwith those areas to undertake their own surveys prior to classification.  Do you agree with the approach suggested? |
| **Question 2** | Views are sought on the ways in which FSS and industry involved in wild harvest areas and those outwith SWPAs might better work together to deliver the sanitary survey requirement in future. |
| **Question 3** | We intend to ask all new classification applicants to provide classification samples in accordance with an agreed protocol from June 2017.  Is it reasonable to expect businesses to contribute towards official controls in this way? Please explain your answer. |
| **Question 4** | It would be useful to know how far ahead businesses can reasonably plan harvesting activities.  Is it reasonable to request harvesting plans 12 months in advance? If not please explain why this ,may not be possible. |
| **Question 5** | We would welcome views from businesses on the impact and implications of the proposals for depuration approvals. |
| **Question 6** | FSS will no longer sample in closed areas on a weekly basis pending verifiable confirmation from food businesses that toxin levels have suitably reduced – for the toxin which closed the area originally. However FSS will re-open an area based on 1 official control sample if supported by evidence of reducing toxicity from FBOs (2 rapid kit test results).What are your views on these proposals? We would welcome an assessment by businesses as to what the impact of such an approach would be. Information on the volume of testing currently undertaken by your business and access to testing facilities or equipment would also be useful. |
| **Question 7** | How could mobile technology assist in ensuring both sample collection and traceability controls are maintained for shellfisheries? Please describe the ways in which such technology might be deployed. |
| **Question 8** | For both wild and aquaculture shellfish businesses we would be interested to hear about how phytoplankton is used at a local level. Do you apply different triggers to those used in either the monitoring programme or in the ‘toxin traffic lights’ guidance document? Please describe the ways you use them. |
| **Question 9** | Which areas within the official control programme should be changed and why? |

**ANNEX A**

**Partial Business and Regulatory Impact Assessment**

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| --- |
| **Title of Proposal**  **Shellfish classification and monitoring: consultation on changes to the Food Standards Scotland official control programme** |
| **Purpose and intended effect**   * **Background**   FSS is defined in law as a competent authority in relation to the delivery of a significant number of shellfish official controls, particularly in relation to monitoring functions, with local authorities described both as the competent authority and enforcement authority in relation to certain land based shellfish functions.  The nature of current shellfish official controls is directly linked to the risk and severity of the pathogens and toxins which can be found in bivalve shellfish. They are filter feeders and can accumulate dangerous toxins and pathogens quickly. Shellfish toxins, which can be fatal, occur naturally and are heat stable which means that they cannot be removed through cooking. Whilst faecal borne pathogenic contaminants such as norovirus derive from man-made inputs such as sewage discharges, both toxin producing phytoplankton on which shellfish feed and viral pathogens are inputs over which shellfish harvesters have no control. Given this multi-factorial environment, as well as the severity and history of illness associated with shellfish an extensive raft of official controls are explicitly set out in EU law. This consultation seeks views on the ways in which these controls should apply in relation to shellfish classification and biotoxin monitoring.     * **Objective**   **To help ensure that official controls in relation to shellfish continue to be sustainable, responsive and robust.**   * **Rationale for FSS intervention**   Principally this work contributes to a key FSS strategic priority, namely to deliver “a comprehensive policy and delivery review of the FSS shellfish official controls, including small scale and local supply chains, working in partnership:   Ensure proportionate and targeted interventions to protect public health and maintain consumer confidence thereby promoting sustainable growth.   Review and modify as required, such that resources match policy and delivery priorities.”  In line with the priorities agreed by FSS in October and in order to deliver on FSS Strategic Outcome 6 (FSS is efficient and effective), it is intended that this consultation will assist in identifying and delivering efficiencies and improve the effectiveness of the controls applied. |
| **Consultation**   * **Within Government**   The draft consultation has been shared with colleagues responsible for both aquaculture and inshore fishery policy.   * **Public Consultation**   A formal consultation on these proposals will take place from 17th February to 12th May.   * **Business**   FSS have held discussions with the Association of Scottish Shellfish Growers (ASSG), Scottish Shellfish Marketing Group and one of the biggest oyster producers in Scotland in July 2016. In addition discussions on approaches to classification more generally took place with Shetland harvesters through Seafood Shetland in April 2016. An outline of the scope of the consultation was shared with industry at the ASSG conference in October 2016. We propose during the course of consultation to invite discussion at workshops throughout the country. |
| **Options**   * Option 1 – Apply all or most of the proposed actions * Option 2 - Do nothing, maintain status quo.   **Outline of available options**  **Option 1 – Apply all of the proposed actions**  In summary, the following actions (1 - 6) would mean that:   1. FSS undertakes sanitary surveys only for aquaculture areas designated as Shellfish Water Protected Areas and ask prospective aquaculture harvesters outwith those areas to undertake their own surveys prior to classification; 2. For new areas, harvester samples taken in accordance with an agreed protocol could be used for classification purposes, with consideration given to extending this requirement more broadly; 3. Harvesters would be required to advise of plans to place marketable stock on the market in advance in order to allow FSS resources to be better targeted. In so doing tailored monitoring in certain areas could be achieved; 4. FSS will no longer fund verification of depuration systems or require a minimum 42 hr depuration cycle. This would bring arrangements into line other sectors; 5. For areas closed due to high toxin levels, FSS would not routinely sample, pending confirmation from food businesses that toxin levels have suitably reduced; 6. Areas could re-open on a single OC result provided industry could supply evidence in the form of two negative results from currently available end-product test kits.   **Option 2 – Do nothing, maintain status quo**  This is not considered tenable on the basis that FSS has committed to undertaking a review as agreed by the FSS Board in October 2016.[[18]](#footnote-19)  **Sectors and groups affected**  The following sectors are likely to be affected by the proposals:   * Shellfish harvesters; laboratories under taking official controls; local authorities; approved shellfish establishments; local authorities   We are aware that the shellfish industry is located in some of the most economically vulnerable areas in Scotland and that any increased financial burden may put that economy at risk. Agriculture forestry and fishery work, for example, accounts for 16% of employment in remote rural Scotland and despite aspirations for growth in the shellfish sector, that growth has flat lined in recent years which is reflected in the Crown Estate maintaining rents at 2010 levels.  <http://www.gov.scot/Publications/2015/03/5411/4>)  Crown estate income from shellfish aquaculture are £0.1million per annum of the £3.4million revenue from aquaculture as a whole[[19]](#footnote-20).  By way of background context, whilst over 70% of Scottish mussel production comes from Shetland, only 55% of Scotland’s classified mussel areas are located there. Almost all Shetland mussels are processed in Motherwell (Scottish Shellfish Marketing Group).  In the Shetland Area profile published in 2014, Shetland had a much higher proportion of the population in employment than the Highlands and Islands and Scotland. Combining full-time and part-time (employment, 83.2 per cent were in employment in Shetland, while in both the Highlands and Islands and Scotland the proportion was 76.7 per cent[[20]](#footnote-21).  All Scotland’s oyster growers are on the west coast (non in Shetland), and only mussels are seen as the growth sector for Scotland in the short to medium term.  In 2015 7,720 tonnes of mussels were produced for the table market in Scotland. This is the second highest level of mussel production recorded in Scotland.  Mussel and Pacific oysters remain the main species produced in terms of value and tonnage although production decreased by 5% and 21% respectively during 2015.  Employment levels showed a decrease of 0.3% from the previous year, with 344 full, part-time and casual staff being employed during 2015. The Scottish shellfish farming industry is estimated to be worth £10.1 million at first sale value.[[21]](#footnote-22)  Further economic and social context for the aquaculture sector can be found in the following report produced for Scottish Government in 2014: The Value of Aquaculture to Scotland <http://www.gov.scot/Resource/0045/00450799.pdf>  The wild shellfish sector is focussed in similar areas (bar Shetland) and is not bound in by crown estate or planning requirements in the same way as the aquaculture sector. Indeed the razor sector has seen significant growth in recent years over the past 15 years, as indicated in table 2 (figures supplied by Scottish Government).  ***Table 2: Razor landings in Scotland***   |  |  |  | | --- | --- | --- | | year | liveweight (tonnes) | value | | 2000 | 92 | £222,403 | | 2001 | 71 | £158,654 | | 2002 | 38 | £93,768 | | 2003 | 44 | £109,533 | | 2004 | 102 | £279,405 | | 2005 | 175 | £441,490 | | 2006 | 108 | £276,389 | | 2007 | 257 | £706,617 | | 2008 | 541 | £1,530,615 | | 2009 | 728 | £1,812,011 | | 2010 | 680 | £1,834,608 | | 2011 | 725 | £1,982,202 | | 2012 | 903 | £2,567,333 | | 2013 | 915 | £3,139,009 | | 2014 | 429 | £1,596,777 | | 2015 | 350 | £1,615,835 | |  |  |  |   Scottish Government are also actively exploring options for allowing currently illegal harvest methods to be permitted in the sector which could also stimulate growth[[22]](#footnote-23).  Any growth across either the aquaculture or wild shellfish sectors is likely to come at an additional cost to FSS, and it is in that broader context some specific costs in relation to the suggested proposals above are placed.  On that basis, the effect of these proposals is likely to have the largest proportionate impact on the west coast, Highland and Island economies given the propensity for smaller business models and the location of the wild shellfish industry.  **Summary Costs and Benefits (Option 1 – implement Actions 1-6)**   |  |  |  | | --- | --- | --- | | ***Action*** | ***Benefit to FSS/industry*** | ***Cost to FSS/industry*** | | 1. FSS undertakes sanitary surveys only for aquaculture areas designated as Shellfish Water Protected Areas and etc. | FSS resources would be aligned with Scottish Government and Scottish Environment Protection Agency priorities for the sector as a whole. By aligning FSS classifications with measures intended to ensure shellfish growing waters are protected, a more proactive approach across Government to environmental and food risk management could be achieved. FSS would benefit from reduced costs associated with undertaking surveys in such areas. | Potentially difficult for small operators to access certain data sources currently available to FSS and other parts of Government.  Possible obstacle to industry expansion;  Models for future delivery of this function are not known at this stage, but there is potential for costs associated with surveys in new areas outwith SWPAs to be transferred from FSS to industry. However – no changes proposed for at least 2 years and in the meantime full surveys are suspended from the programme. Any cost implication would be discussed with industry prior to classification. **We would welcome views on this approach.** | | 2. For new areas, harvester samples taken in accordance with an agreed protocol could be used for classification purposes, with consideration given to extending this requirement more broadly. | This would reduce the cost burden to FSS. Had this approach been applied in 2015, a saving of over £40K in analysis costs alone would have been achieved. | This would result in an added industry cost of approximately £1000 for new harvesting areas. This cost could be shared if the area will be fished by multiple harvesters.  This programme would require additional resources within FSS to administrate. | | 3. Harvesters would be required to advise of plans to place marketable stock on the market in advance in order to allow FSS resources to be better targeted. | By focussing on periods of active harvest, FSS will achieve a more streamlined and targeted monitoring programme. It is intended that this will provide additional flexibility for industry both in terms of classification and toxin risk management. If at present industry harvest for only 80% of the time that an area is monitored, a 20% reduction in biotoxin monitoring alone could result in savings of over £200K to FSS per annum.  Greater flexibility for industry in terms of classification sample submission | We are aware that harvesting plans can be influenced by factors outwith the harvesters immediate control and such factors would not be considered a barrier to on-going classification and monitoring as appropriate.  **However in general terms we would be interested in the potential impacts/ administration costs associated with this proposal on industry.** | | 4. FSS will no longer fund verification of depuration systems or require a minimum 42hr depuration cycle. | This would bring arrangements for depuration approvals into line with other sectors and is in line with the Scottish Regulators’ Code of Practice[[23]](#footnote-24).  It provides an opportunity for food businesses to assess the opportunity in a commercial sense and to consider the costs and benefits associated with system improvements.  Over the past 2 years, FSS have spent nearly £50k on depuration approvals. This would be saved if the proposal was agreed. | Some businesses’ may have been reliant on the service provided by FSS via Marine Scotland Science in terms of setting out suggested operating practice;  Businesses will need to invest in system verification and validation themselves which could be costly;    Assessment of depuration systems require specific skill sets - local authorities may require training and given the infrequent nature of depuration approvals maintaining skills could be problematic;  Majority of Scottish systems are non-standard and will each require to be assessed individually;  Low *E.coli* levels in Scottish waters could make verification of system efficacy less easy; industry may need technical assistance. | | 5. For areas closed due to high toxin levels, FSS would not sample on a weekly basis | There would be a direct saving associated with cessation of both sampling and analysis for the period that the area was closed. | The proposal would mean less data would be available to run future risk assessments and less data would be available to inform harvester risk assessments. | | 6. Areas could re-open on a single OC result provided industry could supply evidence in the form of 2 negative results from currently available end-product test kits. | Quicker re-opening of areas closed due to high toxin levels. | Industry would be required to take a rapid kit sample in closed toxin areas prior to the OC sample being taken. Given the significant increase in end product testing under taken by industry in recent years we cannot see where significant additional cost to the industry would arise in relation to this proposal but would welcome views. **We would welcome views and information on industry on the potential costs associated with this action**. |   We would welcome specific information in relation to how any of the proposals would impact on your business. This will help inform the outcome of this consultation. |
| **Scottish Firms Impact Test**  No business specific impact test has been carried out at this stage. FSS would welcome an opportunity to meet with a range of Scottish shellfish businesses in the course of this consultation. Please let us know if you would be willing to discuss these issues with us directly on a one to one basis or through a workshop which we would be happy to arrange at a suitable location.  **Competition Assessment**  N/A  **Test run of business forms**  No forms have been developed in support of these proposals. However changes to classification procedures would mean additional administration for businesses. This will be considered as the consultation progresses. |
| **Legal Aid Impact Test**  The proposal is unlikely to have an impact on the legal aid fund. |
| **Equality impact assessment**  These proposals are not considered to have any disproportionate impact on any specific section of the population however we would welcome information from interested parties on this point. |
| **Enforcement, sanctions and monitoring**  No new regulatory sanctions are introduced by these proposals, however should certain conditions not be met prior to classification, then some classifications may not be made. The effect of such action would be to prohibit the placing on the market of shellfish from an affected area, until the conditions are met. These conditions relate to information which we consider to be reasonable to ask businesses to provide, but they will be considered in the course of this consultation.  No new enforcement burden is placed on authorities as a result of these proposals. FSS intend to remove technical support for depuration approvals, and some authorities may not have the technical capacity to assess new systems without additional training. This will be addressed by the FSS Low Cost Local Authority training programme. |
| **Implementation and delivery plan**  It is proposed that these proposals should begin to be applied or considered by June 2017. These will be co-ordinated by FSS through a Shellfish Review project board. Liaison with industry and local authorities will take place during the course of this consultation and following agreement to final proposals. |
| **Summary and recommendation**  **It is recommended that Option 1 apply and that FSS begin work immediately to assess potential impacts on industry and local authorities.** |

1. <http://www.foodstandards.gov.scot/board-meeting-19-october-2016> [↑](#footnote-ref-2)
2. Please note that no full sanitary surveys have been commissioned in 16/17. A pRMP survey is initiated for new areas and will establish a provisional representative monitoring point (pRMP) and provision area boundaries. These are desk-top exercises, whereas a full sanitary survey includes a shoreline survey and additional data analysis. [↑](#footnote-ref-3)
3. [EUR-Lex - 32015R2285 - EN - EUR-Lex](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2015.323.01.0002.01.ENG) [↑](#footnote-ref-4)
4. [17th August FSS Board Paper](http://www.foodstandards.gov.scot/board-meeting-17-august-2016) [↑](#footnote-ref-5)
5. Annex III, Section, VII, Chapter II of Regulation (EC) 853/2004 [↑](#footnote-ref-6)
6. <https://blogs.gov.scot/marine-scotland/2013/12/> [↑](#footnote-ref-7)
7. As at 1st October 2016 [↑](#footnote-ref-8)
8. From the Scotland’s aquaculture website (+ Loch Ryan which was added in Sept 2016), 14 areas counted as outwith SWPAs. The number of classified areas was taken from micro RMP list @1st October 2016. [↑](#footnote-ref-9)
9. <http://www.gov.scot/Topics/Environment/Water/15561/ShellfishWaters/LocationMaps> [↑](#footnote-ref-10)
10. Article 5 of Regulation (EC) 852/2004 [↑](#footnote-ref-11)
11. [*http://www.foodstandards.gov.scot/risk-assessment-scottish-monitoring-programme-marine-biotoxins-shellfish-harvested-classified*](http://www.foodstandards.gov.scot/risk-assessment-scottish-monitoring-programme-marine-biotoxins-shellfish-harvested-classified) [↑](#footnote-ref-12)
12. *Annex II, Ch II, B of EC Regulation 854/2004* [↑](#footnote-ref-13)
13. *One test is carried out on a sample providing three results for three toxins groups: DSP or OA-toxin group (reported with PTXs), AZAs and YTXs.* [↑](#footnote-ref-14)
14. [*http://www.foodstandards.gov.scot/sites/default/files/Review%20of%20field%20testing%20methods%20for%20biotoxins%20in%20shellfish%20-%20Final%20Report.pdf*](http://www.foodstandards.gov.scot/sites/default/files/Review%20of%20field%20testing%20methods%20for%20biotoxins%20in%20shellfish%20-%20Final%20Report.pdf) [↑](#footnote-ref-15)
15. Assuming that in the week prior to any ‘first negative’ in OC sampling in 2015 (ie a sample below the maximum permitted level, after a period of results above the permitted level) that harvesters had similarly requested a resumption of harvesting and their own testing results confirmed toxicity has decreased sufficiently. [↑](#footnote-ref-16)
16. 44 closures and therefore weeks (between OC samples as currently applied to the re-opening of areas) divided by 3.5 days which might be available in any week (taking into account OC sampling and analysis turnover times). [↑](#footnote-ref-17)
17. <https://www.cefas.co.uk/media/53034/2015-scotland-biotoxin-phytoplankton-official-control-monitoring-annual-reportdoc.pdf> [↑](#footnote-ref-18)
18. <http://www.foodstandards.gov.scot/board-meeting-19-october-2016> [↑](#footnote-ref-19)
19. A schedule of the rents proposed in the 2010 review, which persist now, is here <http://www.thecrownestate.co.uk/media/5458/shellfish_rent_review_analysis_of_proposed_rent_charges.pdf> with the current charges in the ‘proposed new’ columns. [↑](#footnote-ref-20)
20. From: Shetland economic profile: 2014 <http://www.hie.co.uk/regional-information/area-information/shetland/economic-profile.html> [↑](#footnote-ref-21)
21. From Scottish shellfish aquaculture farm survey 2015: <http://www.gov.scot/Publications/2016/05/2841> [↑](#footnote-ref-22)
22. <https://consult.scotland.gov.uk/marine-scotland/electrofishing-for-razor-clams/user_uploads/444637_p2.pdf> [↑](#footnote-ref-23)
23. <http://www.gov.scot/Resource/0046/00467429.pdf> [↑](#footnote-ref-24)