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| **1.** **Views are sought on the proposal for FSS to undertake sanitary surveys only for aquaculture areas designated as Shellfish Water Protected Areas (SWPAs), and ask prospective aquaculture harvesters out with those areas to undertake their own surveys prior to classification. Do you agree with the approach suggested?** | **Seafish Industry Authority** | **1.** This could act as a barrier to new entrants and to the expansion of existing businesses into new areas. Accessing the expertise required and the costs involved in undertaking these surveys would be a considerable burden to business. Many businesses in the shellfish sector are at the micro or small scale; there are few large operators with substantial financial reserves. On the west coast of Scotland in particular, the data and the level of detail required for the survey is not readily available. This raises the question as to how the survey would be undertaken, who would have the competence to undertake it and the confidence that could / would be placed in the results – and the challenges that could arise from that. A joint approach between FSS, SEPA, Scottish Water and business would be a preferred option. | FSS and other partners in Scotland have commissioned an external review of the sanitary survey/classification programme. It is envisaged that this work will be completed in this financial year (2017/18)  FSS is also working with Food Standards Agency in the rest of the UK to consider the outputs of this review.  The full survey programme therefore remains suspended pending the outcome of this work, with provisional monitoring point surveys continuing meantime. |
| **Blueshell Mussels Ltd** | **2.** Responsibility for creating the sanitary survey sits with the competent authority. Under the proposal an operator choosing a new site would be dependent on SEPA approving a site before FSS would commit to undertake a sanitary survey. There is no evidence that SEPA would permit a new SWPA until shellfish cultivation actually took place, which could not take place without the required sanitary survey. It may be unfair to limit industry by creating a barrier by SEPA before a sanitary survey is undertaken. As the sanitary survey rests entirely with the competent there is no current scope for this to be outsourced to a private enterprise. | FSS is the competent authority for classifications under food law and has an obligation to undertake a survey if classification proceeds. However the need for classification in the first place is determined by the food business operator who has the prime responsibility under Article 17 of EC Reg 178/2002 for ensuring the safety of foods which it proposes to place on the market and to verify the requirements of food law are met.  A sanitary survey and formal classification will therefore not be appropriate in all circumstances, unless a food business proposes to place products on the market having carried out their own assessment of the food safety risks involved.  Scottish Ministers are responsible for designating protected waters, where it is necessary or desirable to do so for the protection or development of economically significant shellfish production; while SEPA has a responsibility for water quality in designated areas.  Industry, SG, and SEPA will be invited to be involved as the output of the survey review is considered (see response 1). |
| **Shetland Mussels Ltd.** | **3.** No. Shetland Mussels Ltd objects to this for various reasons. We should not be adding a new layer of bureaucracy to the process of gaining new shellfish farming capacity. Placing the condition that an area needs to be a SWPA before FSS will instigate a Sanitary Survey is not justifiable. It will lead to a new step in the consenting processes whereas Scotgov is working hard currently to streamline and make applications more efficient.  There is the extra problem here in that the industry would be signing up to do work that FSS are currently suspending pending a review of exactly what a Sanitary Survey needs to entail.  Since the workshop and understanding more about the reasons for Sanitary Surveys to be done (now) we would also point out that the various modelling functions required to access the US market are not being done at present and perhaps they should be.  We are also unclear at the moment how SEPA would react to being asked to add areas to the list of SWPA.  Again we would recommend this area gets put on the new forum agenda and this would allow discussions with SEPA on the point. It needs more thought and we would point out the Scotgov are keen to help industry grow and this we would suggest could be a regressive step. | Noted, please see response above.  The requirement to undertake additional survey and modelling work to access the US market is not a statutory requirement of the EU official controls regime, and is therefore not part of the official control process. Any additional survey work, required for international trading purposes, would require to be considered within the context of FSS obligations generally. In the meantime, we would be happy to participate in area specific discussions regarding compliance with export standards should industry wish to progress this further.  This is not a request for additional SWPA areas, rather the beginning of a process of engagement on how we work with industry and Government partners to deliver a programme that delivers both our statutory obligations as well as industry growth targets where it is possible to do so.  This area will be considered by the proposed Shellfish Classification and Monitoring Forum. |
| **Association of Scottish Shellfish Growers** | **4 & 5**.  Until such time that the FSS sanitary survey review has been undertaken it is not possible to provide an informed view on this question. | Noted. |
| **Scottish Shellfish Marketing Group** |
| **Seafood shetland** | **6.** No. Seafood Shetland holds the view that this should remain a function for the relevant competent authority. Shifting responsibility for conducting this measure in non-SWPAs would only serve to lead to confusion and dubiety over ownership of any survey and its associated material.  It is considered that sanitary surveys in the current format serve little purpose, as well as being extremely costly and largesse in nature, at a time when public sector organisations examine cost-reducing measures.  Desk studies could, perhaps be implemented, if considered to be necessary and a worthwhile pursuit of collating sanitary information. | Noted. The function of classification and the survey process that underpins classification is indeed a CA function. This consultation proposition begins the process of asking whether it is always appropriate for FSS to initiate classification procedures without harvesters having undertaken some of that initial food safety assessment prior to application; and to consider whether there could be survey criteria that if met by 3rd parties, could form an essential component of survey delivery. Industry will be very much involved when considering any change in this area.  Sanitary Surveys provide FSS with sufficient information to classify and monitor a defined area in a way ensures that, in tandem with harvesters’ own risk management processes, serves to protect public health. Whilst our current approach is  considered suitably robust by EU food safety auditors, we are keen to explore what changes could be applied.  Despite the full survey programme being suspended at present pending a formal review, FSS continues to commission desk top preliminary surveys on receipt of valid applications where no survey report exists. |
| **Cefas** | **7**.  We note that there is a requirement of the current food safety legislation that competent authority classifies production areas from which it authorises the harvesting of shellfish and that if it decides in principle to classify an area, a sanitary survey must be completed.  Sanitary surveys are complex assessments which require rigorous desk and field based exercises to be conducted, the collation and analysis of data from varied sources and access to multi-disciplinary teams. Should separate approaches be implemented for SWPA and non SWPA, there is a risk that areas will be assessed based on surveys conducted according to very different standards.  There is also a potential conflict arising from the fact that the applicants themselves are asked to provide the assessment based on which the area of interest will be classified. Whilst EU guidance documents are in place, there currently are no standard approach/protocol approved by the competent authority.  However, the quality of the sanitary survey is key to determining whether the area can be classified and which preliminary classification status it may be granted. How will FSS ensure that sanitary surveys undertaken by third parties/harvesters meet their requirements and how would the thoroughness and quality of assessments be checked? | Noted. The decision to classify an area in the first place is one underpinned by a wider public interest and invites discussion: Is it always appropriate for the CA to classify an area? Is there a better way of applying resources in this sector? The catalyst for the requirement to classify an area must sit within the general scope of EC Regulation 178/2002 (i.e. there is prima facie a proposal for a food business to place products on the market in the first place).  FSS is clear that any revised survey processes, if agreed, should meet the same minimal criteria in order to ensure compliance with regulatory obligations. This would mean in effect a survey should conform to set criteria and that they would ultimately require to be verified as acceptable to FSS for OC purposes.  However, we are some way from this point and next steps will be determined in part by the outcome of the review outlined in response 1. |
| **Scottish Fishermen’s Federation** | **8**. As the FSS is not legally obliged to classify an area it would seem reasonable for those wishing to open an area up for harvesting to be involved in the supply of samples if this simplifies the process of achieving classification. | Noted, FSS is the CA for making classification decisions based on food hygiene requirements. |
| **Argyll and Bute Council** | **9.** Agree that FSS undertake sanitary surveys in SWPAs. Outside these areas issues develop if the prospective harvesters undertake their own surveys. An individual harvester will be reluctant to allow access to the sanitary survey by other prospective harvesters and indeed the survey will be commercially sensitive. The likelihood that a prospective harvester will have the wherewithal to pay for a survey or be competent to carry one out will need to be addressed by assistance being provided by FSS. | Noted. Please see responses above. |
| **Highland Council** | **10**. FSS should be solely responsible for sanitary surveys of SWPAs. Any areas outside of SWPAs and prohibited areas should be subject to sanitary survey funded entirely by the industry but the implementation of the sanitary survey must be overseen and agreed by FSS up front. | FSS will consider approaches following the review outlined in response 1. |
| **Fife Creel Fishermen’s Association** | **11.** This seems reasonable for the harvester to provide samples. The cost of testing the sample should be born by the FSS. | Noted. This specific question related to the survey process of which sampling could comprise a part. For a response to the issue of classification sampling for new areas, please see response to Q.3 |
| **2.** **Views are sought on the ways in which FSS and industry involved in wild harvest areas and those out with SWPAs might better work together to deliver the sanitary survey requirement in future.** | **Seafish Industry Authority** | **1**. A risk-based approach might be the best option as this would be a major undertaking. Away from the coast and in areas away from major human habitation or farm input, a desk review of likely sources and risk effects may suffice. In locations more likely to have some form of input that is likely to be of interest, then samples could be requested from industry, collected under an agreed protocol, and tested at joint FSS / SEPA / Scot Water / industry expense. As the majority of shellfish from these sources are likely to undergo some form of processing before being placed before consumers, consideration could be given to relying upon EPS testing by the FBO of the final product.  Cost sharing between businesses is unlikely and if a single business were to bear the cost of classifying an area, there is no easily accessible protection available, at present, to prevent a commercial rival from taking advantage of the classification at no cost to their business. | Noted. These points will be considered in the course of the survey review outlined in response 1. |
| **Blueshell Mussels Ltd.** | **2.** As a respondent we are unsure why scallop harvesters are able to harvest molluscs from unclassified water, (Annex III CH 1 of 854/2004) which should be a requirement of the CA to instill. However if these waters are required to be classified and henceforth require sanitary surveys, it would be pragmatic to make the Production Area widespread as possible and henceforth to make sanitary survey as broad bush as possible.  For Shetland this would be comparatively easy vessels fishing is tracked by the SSMO, and this could provide fishing areas to assess.  Sanitary Surveys should continue to be provided by the FSS and not by industry as they serve no other purpose for industry. | Whilst Competent Authorities can classify scallop areas, it is not mandatory for offshore areas due to their motile nature and a system of land based checks are considered permissible by law.  The purpose of a survey is to define an area which shares similar microbiological characteristics and from which representative monitoring can take place. There is no requirement in law to carry out surveys in areas which are not classified. The review of the survey process will explore how we can deliver this for classified areas in the most effective and efficient way in future. |
| **Association of Scottish Shellfish Growers** | **3 & 4.**  It is unclear how ownership of sanitary surveys and their findings would be resolved where private individual parties were responsible for commissioning them?  The rationale for designation of SWPAs was not conducted with food safety in mind and there is no formal or practical link between the two systems.  From the discussion outlined in the consultation the ultimate effectiveness of the sanitary survey process seems to be in question by FSS and subject to review? | Sanitary Surveys are required to be undertaken for official control purposes and would be required to be made public.  The survey process is an important part of official control classification and indeed whilst the full survey programme is suspended pending review, preliminary desk top surveys continue to be applied for all new valid applications. |
| **Scottish Shellfish marketing Group** |
| **Seafood Shetland** | **5.** We do not consider that this is an area for comment by aquaculture organisations. As the onus for scallop testing is assumed by operators onshore it appears profligate and unnecessary to squander precious resources implementing sanitary surveys in large swathes of ocean. | Noted. Scallop areas are not currently required to be classified and are not therefore subject to the survey process. |
| **Cefas** | **6** Combined response given in respect of Q1 & 2. | Noted. |
| **Scottish Fishermen’s Federation** | **7.** The development of the Harvesters protocol and clear communications between applicants and the FSS are both essential elements in ensuring all the appropriate testing is done to the correct standard to ensure harvesting is not disadvantaged. | Noted. It is proposed that this protocol will be reviewed. Please see response to Q. 3. |
| **Argyll and Bute Council** | **8.** Financial assistance Practical advice Build on relationships and include the LA in discussion on any planned harvesting areas | Noted. FSS would welcome engagement with local authorities on this issue. |
| **Highland Council** | **9**. FSS should oversee and approve any industry-funded sanitary surveys outwith SWPAs prior to implementation | Noted, agree. |
| **Fife Creel Fishermen’s Association** | **10.**. Good communication is required between harvesters and the FSS | Noted, agree. |
| **3. We intend to ask all new classification applicants to provide classification samples in accordance with an agreed protocol. Is it reasonable to expect businesses to contribute towards official controls in this way? Please explain your answer.** | **Seafish Industry Authority** | **1**. Businesses already bear the cost of providing stock for testing. Every effort should be made to minimise any additional costs to industry of this proposal. If industry is permitted to provide sample in accordance with the protocol proposed, and the presence of an approved Sampling Officer is not required, then it may assist industry. | Noted. All proposals developed will be considered in the wider context of the FSS Regulatory Strategy which seeks amongst other things to minimise any unnecessary additional burdens on business. |
| **Blueshell Mussels Ltd** | **2**. What the FSS are suggesting is a 2 tier system regarding shellfish classification. FSS seems reluctant to rely on harvesters own results for ongoing classifications, yet under this proposal, and entirely as a cost control exercise are seeking to pass on this to industry.  As an industry we would be content to  propose a system where harvesters submit all the samples that are used for OC, or else the sole responsibility and cost should remain with the FSS. If the consultation only ends on 12th May 2017 how realistic is it to fully answer stakeholder comments of this consultation and then to get a proposal in place by June 2017? | FSS do not propose a 2 tier classification process, rather we seek to accommodate industry samples, where they have been taken in accordance with a robust and transparent process and to utilise industry samples prior to classification being made in new areas. This is permissible by law and we are aware that samples are taken by industry on a regular basis.  We are keen to explore how best we can achieve an efficient and effective way of delivering classification (and other) samples and will work with industry to achieve that.  Whilst the consultation proposed applying certain changes in June, these have obviously been delayed pending consideration of the points raised. It remains our intention that for new areas, harvesters should provide samples in order to allow FSS to provide an initial classification. This requirement will however follow a review of the [FSS harvesters’ protocol](http://www.foodstandards.gov.scot/downloads/Shellfish_-_Harvesters_Own_Results_-_Protocol_-_2016.pdf). |
| **Shetland Mussels Ltd.** | **3.** We would point out that FSS has been reluctant to acknowledge harvesters’ own results in the past and we would assert the harvester results protocol is partially set up to prevent them being considered. It seems a little strange to then get asked to provide them as per the proposal here.  We feel strongly a review of the protocol is needed so it is more accessible and if a company wishes to submit a sample they simply follow a set of rules contained therein and if they do (and they could be spot checked) then the sample will be considered, for all purposes to do with classification, appeals or pre-harvest approval.  We note also that this consultation exercise ends 12th May – we question how the consultation results can be properly taken into account by the June implementation timeline.  We think this should be pushed back to allow the forum to be established and have enough meetings to cover any changes before they are put in place. | FSS continues to welcome industry samples, where they have been taken in accordance with a robust and transparent process. Whilst the current FSS protocol for harvesters’ own results has been deemed acceptable by EU auditors, we acknowledge the feedback provided in discussion suggesting that it is considered overly bureaucratic by businesses. We will therefore review this protocol and would invite industry views on the ways in can be improved prior to asking harvesters to submit their own samples for preliminary classification purposes.  Regarding timings, any changes to the current system will follow a review of the harvesters own results protocol and will be discussed within the proposed FSS forum. |
| **Association of Scottish Shellfish harvesters** | **4&5.** If the agreed protocol being suggested to be implemented by June 2017 is the Harvesters Own Results Protocol this is not considered appropriate at this stage.  It is considered that the “Harvesters Own Results Protocol” should be subject to review and technical evaluation as the shellfish cultivation industry has failed to gain any effective use of this protocol in the years it has been available for implementation.  The use of the Harvesters Own Results Protocol is also being suggested to be used in the context of a new management system and it’s appropriateness needs to be considered in relation to this. |
| **Scottish Shellfish Marketing group** |
| **Seafood shetland** | **6.** We hold the views that FSS has been disinclined to acknowledge harvesters’ results as part of Classification considerations. There is also a belief that the current Harvester’s Own Results Protocol is too prescriptive in its current format and an opportunity to review this document is overdue. In addition, this proposal has the potential to lead to a form of 2-tier system.  Finally, this consultation exercise ends on the 12th May and the desire of FSS is to implement this proposal with effect from June, 2017. | Please see response above |
| **Cefas** | **7**. Current food safety legislation allows for the use of operators own checks to decide on the classification of an area. However, the competent authority is required to designate the laboratory that can carry out the analysis and a sampling/analysis protocol must be agreed between the CA and the FBO. FSS would therefore need to consider both designating laboratories and agreeing protocols if this approach was implemented. It is also our opinion that the method for analysis should be specified and be the approved official control method.  An additional point would relate to the amount of sample verification that FSS may wish to implement (via the LAs) to confirm the validity of the results provided.  The matter regarding charging is not one for us to comment on. | Noted, these points will be taken into account in the review of the FSS protocols in this area. |
| **Scottish Fishermen's Federation** | **8.** Given the need for businesses to demonstrate their own controls are adequate for marketing to be allowed, it is logical to have their inclusion start from the beginning of the sampling process. | Noted. |
| **Argyll and Bute Council** | **9.** The food industry spends a great deal of time taking samples and carrying out checks on Official requirements and well as in-house standards. This practice is well embedded and is the industry norm. Official Control samples are taken as part of the verification process deployed by LAs during interventions on a business. A similar situation is possible within the shellfish sector and it is reasonable for a business to provide samples.  There is however an issue with commercial confidentiality in that the results of the samples are the property of the business and may be of interest to competitors. At businesses currently carrying out their own sampling (manufacturers, etc.) sample results are of course divulged to LA officers during interventions but are not made available publically. | Noted.  All information used for official control monitoring purposes would in general terms be considered available to the public on request. However, we do not at this stage envisage that the results of samples taken by harvesters in accordance with the revised protocol would be published as a matter of routine. |
| **Highland Council** | **10**. Yes, a potentially simpler way would be for FSS to take all OC samples (preferably verified by Sampling Officers) and pass a portion of the cost, up front, onto the FBO by invoicing. Works currently in the case where an FBO pays rent to The Crown Estate for a seabed lease. In this way the FBO will remain committed and FSS will maintain full oversight of OC samples. An upfront 'classification charge' would also deter frivolous classification applications. The problem with charging for wild fishery applications is that once an area is classified anyone can harvest that area unless the applicant has a several order. | Noted. The issue of charging for official controls is one that extends across a number of sectors and will be considered within that broader context. |
| **Fife Creel Fishermen’s Association** | **11.** No issues with this | Noted. |
| **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.** | **Seafish industry Authority** | **1.**This is unlikely to be possible and it would be of limited use as only a few businesses might be able or willing to attempt this. Industry has to remain flexible in its harvesting regime. Various factors outwith the control of the business can cause it to alter their harvest plan at very short notice.  There would be no clear advantage to industry of trying to predict the unpredictable, and their best course of action would be to propose year-round harvesting from all areas to ensure they would always have access to harvestable stock. | Noted. Following the views expressed in consultation, FSS will reconsider this point, but in the meantime would ask that information on harvesting activities – when known – is communicated to FSS as soon as possible. |
| **Blueshell Mussels Ltd** | **2.** It is absolutely impossible to plan harvesting activities per site. Neogen tests are currently undertaken by 80% of the Scottish industry for each batch throughout the year, which since introduction have closed areas well before OC results have closed areas down.  Reading Annex II Chii, B5, would suggest that toxin testing is increased at times of high phytoplankton activity, rather than your proposal in 2.13.  Summary: FSS Decision Tree:  **Step 1 :** Not sure if these Agencies should be able to stop sites being sampled? MS, and CEC are statutory, SNH and SEPA have chance to comment at time of application for new site, Scottish Water will generally only block a site where they have uncontrolled discharges and don’t want the cost of regulation. If SW are polluting they should be made to clean up the discharges than simply block shellfish farm getting approved.  **Step 2 :** Historically sanitary surveys have followed historic harvesting activity. For a new start business the onerous cost of getting a sanitary survey done may be prohibitive to development of the industry.  We strongly oppose conditional sanitary surveys.  **Step 3 :**Seems to be creep to get industry to share results with FSS. The regulation says that the CA (Annex II Chapter II, F) may take into account the FB’s own results, step 3 has effectively changed the may take to must take.  **Step 4 :** We have already said that harvesters cannot give detailed harvest plans, only broad intention of time of year stock will be first ready for a new site. | Noted. Following the views expressed in consultation, FSS will reconsider this point, but in the meantime would ask that information on harvesting activities – when known – is communicated to FSS as soon as possible.  We also acknowledge that the regulations require more intense monitoring when toxin /phytoplankton levels increase. This forms the basis of our current monitoring programme, with sampling frequencies determined on a risk assessed basis for each toxin. However, what is of critical importance is the decision taken after monitoring – areas should be closed when levels are high only reopened only when they comply with legal limits. We consider our proposals to be in accordance with the requirements of the regulations in this regard.  Please see responses to responses provided to previous questions in relation to these specific points.  This proposal concerns the provision of samples for areas that are not yet classified, rather than monitoring samples. Please see response to question 3.  Noted. Following the views expressed in consultation, FSS will reconsider this point, but in the meantime would ask that information on harvesting activities – when known – is communicated to FSS as soon as possible. |
| **Shetland Mussels Ltd** | **3.** Whereby we may be able to point out sites that won’t harvest within the next year, and this number would be low, it is impossible to know exactly where we would harvest at what time. This is due to quality variations, weather within the next year events, logistic constraints, husbandry issues not to mention toxins.  This is basically not something we can do. | Noted. Following the views expressed in consultation, FSS will reconsider this point, but in the meantime would ask that information on harvesting activities – when known – is communicated to FSS as soon as possible. |
| **Association of Scottish Shellfish Growers** | **4 & 5**. It is not reasonable to constrain a shellfish cultivation business to a harvesting plan up to 12 months in advance of harvesting taking place. |
| **Scottish Shellfish Marketing Group** | 5. As above |
| **Seafood shetland** | **6.** It is not reasonable to request harvesting plans 12 months in advance. Harvesting is subject to the vagaries of site closures, inclement weather, and day to day challenges such as vessel breakdowns, staffing issues etc. |
| **Cefas** | **7.** This is a question that industry is best placed to answer. As an OC laboratory, our experience is that keeping track of harvesting activity to inform the monitoring programme requires a lot of information gathering by LAs, sampling contractors and co-ordination by the laboratories.  It is very dependent on individual FBOs.  There are therefore two risks associated with such an approach: the quality of the programme will depend on that of the information available to the sampling contractors & laboratory(ies); information gathering and co-ordination will bear a cost.  It is unclear to us whether there would be sufficient flexibility in the plan to allow for changes in planned harvesting patterns.  In addition, legally, unless an area is formally closed, the requirement or monitoring persists. | Noted. Following the views expressed in consultation, FSS will reconsider this point. Nevertheless we consider that we need to balance both the practicalities and cost effectiveness of running a ‘call off’ monitoring regime and will only make changes in consultation with all parties including contractors. |
| **Scottish Fishermen’s Federation** | **8**. It may be possible in some wild capture shell fisheries to indicate some level of seasonal exploitation, although this would not be set in stone. | Noted. Following the views expressed in consultation, FSS will reconsider this point, but in the meantime would ask that information on harvesting activities – when known – is communicated to FSS as soon as possible. |
| **Argyll and Bute Council** | **9.** Planning for a 12 month period would seem reasonable but will be affected by weather and other unforeseen incidents. Generally it is reasonable to expect poor weather in the winter but this is now extending to all times of the year.  A 12 month plan would be advantageous to the business and to the LA however it may be that the industry is best placed to respond to this question. |
| **Highland Council** | **10.** Yes. For static farms growing times for farmed species are well understood. An FBOs should understand their market such that it should not be unreasonable to ask for a harvesting assessment. This would not work so well for wild fisheries as they are currently open to all once classified. |
| **Fife Creel Fishermen’s Association** | **11**. Harvesting is planned ,weather permitting and depending on the classification at the time. Sufficient warning is required from the FSS when an area is going to be closed | Noted, please see response above. FSS however cannot warn harvesters as to when areas will close – formal closure happens only when a pollution or natural toxin event occurs. |
| **5. We would welcome views from businesses on the impact and implications of the proposals for depuration approvals.** | **Seafish industry Authority** | **1.** This proposal can offer advantages to business. However, LAs will either have to invest resources in additional training for their EHOs or source support from other agencies. It is suggested that FSS, LA EHO representatives, Seafish, MSS and perhaps CEFAS meet to develop and agree guidance and a support materials to ensure consistency of approach across all Authorities.  For this reason the implementation of the cessation of support from FSS should be delayed. As outlined, system verification could be problematic and costly.  Consideration would have to be given as to what would be required for verification – would demonstration of consistent compliance with EPS of all stock depurated be sufficient, or would ‘worse case’ challenges still be required. | Noted. Food Standards Agency in Scotland previously published guidance for local authorities on depuration approvals which has now been revised and will be made available on the website. In addition we recognise that *Seafish* provide considerable advice in this area. |
| **Blueshell Mussels Ltd.** | **2**. Whilst relaxation in depuration testing by the FSS puts the responsibility, like other critical controls in food production back to the industry, as long as systems are checked, maintained and operated in accordance with their designed parameters this should  be acceptable.  On the proposal to reduce depuration times, this will be left largely to the subjective interpretation of EHO’s in LA’s which may not apply consistent appraisal and interpretation of FB’s methodology of testing and justification, which may promote diverse industry standards, (e.g. as experienced with king scallop shelf life.) |
| **Shetland Mussels ltd** | **3.** We are concerned about the proposals in that there are doubts about skills available and resources available at local authority level to make consistent decisions on Depuration systems. We have strong views on the Seafish guidelines (which refer to standard systems) as these are only a range of systems picked at one moment in time. Depuration is an important tool and we would like to unlock the option to use this again.  BUT we need to be clearer on the proof required by the operator to demonstrate a system is fit for purpose. We tried to make the point at the workshop (and probably failed) but this is an area that could be deregulated fully IF the output from the system was fully EPT’d.  The middle ground between this approach and a fully rigid system seems fraught with difficulties. EHO’s will be worried about new/unexpected conditions that may impact system performance (and thus could ask for endless testing of every scenario) whereas the shellfish heading to market will still the farmers legal responsibility – so why not leave it to farms judgement to set up a system that they design/build/test/document/EPT? | The regulatory requirement is clear in that food business operators may place molluscs collected from class B production areas on the market only after treatment in a purification centre or after relaying (853/2004 Annex II, Ch II, A.3) Ch IV goes on to describe what food businesses need to do to ensure compliance in purification centres in general terms. As for other businesses, validation will be process and system specific and it may be that different operating parameters can apply depending on inputs at any point in time (subject to FBO validation). The point is that businesses are responsible for assessing those parameters.  We recognise that assessment of these systems by enforcement authorities is a specialism and have produced guidance to support delivery of this function. |
| **Association of Scottish Shellfish Growers** | **4&5.** The impact on businesses will be dependent upon their ability to gain approvals from an EHO. It is unclear at this time whether the EHOs will have access to sufficient guidance to undertake this in a consistent manner and whether reduced times will be judged by the EHOs to be acceptable.  The development of guidance for the EHOs and Food Business Operators is welcomed and awaited by the shellfish cultivation industry and we would welcome being consulted on the detailed provisions during this process. In a Scottish context one of the most important issues is with respect to water temperature during the depuration process and the impact on the filtration rates of shellfish.  The expense of operating a depuration facility is impacted by the potential requirement to heat or cool the recirculated water and as such a range of suitable temperatures and depuration times are required to match ambient seasonal conditions.  It is noted that the technical assistance from Marine Scotland Science provided to local authority EHOs in terms of the approval process for depuration systems ceased from April 2017.  The use of reduced depuration times for bivalve shellfish within approved depuration facilities is broadly welcomed.  However, the technical detail of how the effectiveness of such systems could be proven, approved and monitored based on the range of determinants which can influence depuration rates is open to question.  There is a concern that the conformity required throughout all local authority areas within Scotland will be difficult to achieve without the EHOs responsible having access to detailed guidance.  The commitment given at the 20th April workshop by FSS that such guidance will be prepared in conjunction with a lead local authority body and that EHOs would have access to such an information source provides a degree of comfort to the shellfish cultivation industry. | Previous guidance to local authorities on depuration has been revised and will be published shortly. Food Business Operators may also find this as well as existing *Seafish* guidance a useful resource. |
| **Scottish Shellfish Marketing group** |
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| **Seafood Shetland** | **6.** Seafood Shetland considers that depuration could be considered as the tool of last resort for shellfish growers, bearing in mind that currently all depuration facilities in Shetland are not approved for use. Proposals are not fully clear and the possibility for regional variations in determinations and authorisations exists; the worthiness of Seafish’s guidelines should also be reviewed.  It is questionable whether or not local authorities would welcome this approach, particularly at a time when public sector budgets are under scrutiny and are subject to reduction. | New guidance to local authorities has now been published  There is no intention to increase the resource burden on local authorities. As a public body FSS is also subject to budgetary constraint and we consider that the service provided by MSS, funded by FSS, was a subsidy to industry rather than local authorities. The intention is to normalise approaches to approval in this sector such that business takes full responsibility for system validation as for other business sectors. |
| **Cefas** | **7.** We note that the possible implications of a reduction in depuration time on viral depuration should be considered. | Noted. |
| **Highland Council** | **8.** FBOs will still need to demonstrate that their depuration system is capable of producing 'A' grade LBMs. To achieve this some form of technical assessment including a biological challenge will still need to be undertaken. Perhaps a full challenge test of a given depuration system could incorporate an investigation into reducing depuration cycle times by taking multiple timed samples. This would demonstrate that a system is a) capable of producing safe food and (possibly) b) producing safe food in less than the current minimum time of 42 hours. | We agree that FBOs are required to validate their food safety management systems, and that this must be to the satisfaction of the local authority. |
| **6. What do you think about the proposal that FSS will no longer sample in closed areas on a weekly basis pending verifiable confirmation from food businesses that toxin levels have suitably reduced? Information on the volume of testing currently undertaken by businesses and access to testing facilities or equipment would also be useful.** | **Seafish industry Authority** | **1**. On the face of it, this is a reasonable proposal. However, not every business, particularly those at the micro or small-scale, will have the resources and expertise to carry out and pay for these tests, even though costs have reduced markedly. Better resourced operators already undertake their own testing and would probably welcome this proposal. | FSS intend to take forward this proposal but recognise that clear parameters and guidance will need to be developed taking into account the points made in consultation. Draft guidance will be presented to the new Shellfish Forum for discussion and agreement in due course. |
| **Blueshell Mussels Ltd.** | **2.** Historically before a shellfish harvester can harvest from an “open” area the sampling officer has required 2 clear samples to keep sites open. During summer harvesting, because we need so many site options open, this results in frequent sampling.  If however sites remain open until officially closed by the OC test then this could reduce cost to the FSS budget.  It is probable that the FBO would detect toxins by using EPT.  In the last 2 years the OC have stopped testing sites which are closed for extra toxin presence and this makes the FBO’s less able to risk assess other toxin activity movements. The proposal by the CA to carry out a single OC test to re-open a site is pragmatic on the basis that current industry sample kits are accepted as reputable. We need to understand what “robust data” means. Phytoplankton monitoring should be maintained during periods of closure. |
| **Shetland Mussels Ltd** | **3.** We could find no reason why it would be two kits to demonstrate the downward trend in results. One clear result vs the result which closed a site we would argue shows the trend.  We think this rule/condition should be changed.  We also think that the frequency of closed areas should be reduced to monthly but not stopped. Why?   * to avoid areas becoming blanket closed which would prohibit the public from accessing shellfish in the area * It could create a perception to the market that there is suddenly new problem with our water * safety if areas end up remaining ‘closed’ just because testing not done. * Neighbouring farms (not ones who control testing) could end up being restricted from harvesting because the tester farm has not been motivated to sample/harvest. |
| **Association of Scottish Shellfish Growers** | **4&5.** While shellfish cultivation businesses would continue to monitor for End Product Testing purposes, the lack of public information associated with stopping monitoring of biotoxin conditions has the potential to negatively impact public health and environmental monitoring considerations.  The FSS proposal to no longer sample in closed areas on a weekly basis pending verifiable confirmation from FBOs that toxin levels have suitably reduced for the toxin which closed the area should reduce FSS expenditure. However, greater information is required as to the impact of such an approach where no industry sampling may subsequently be undertaken for extended periods? | Local authorities are responsible for placing public health related notices in their areas where areas are closed due to toxin levels. There is no suggestion that this approach will change.  As part of the draft guidance document which will be developed to support of this proposal; information on minimum OC sampling frequencies for both flesh and phytoplankton will be provided/confirmed. |
| **Scottish Shellfish Marketing Group** |
| **Seafood Shetland** | **6.** Seafood Shetland holds the view that monthly sampling should be maintained in order to provide a wider toxin picture; this would help to support public gathering of shellfish and reduce the potential for unintended, damaging consequences.  It is also considered that the requirement for 2 rapid kit test results in order to initiate the site re-opening process is unnecessary, particularly given the volume of testing being undertaken by businesses in Shetland. |
| **Cefas** | **7.** In principle, we support the suspension of weekly testing in areas closed due to ASP or OA/DTX toxin event only, until there is sufficient evidence (from FBO testing) that the relevant toxin levels have reduced. We nevertheless recommend the following:  This approach may result in the competent authority losing information on long term toxin events/trends and this may impact on future risk assessments.  FSS would need to define criteria for recommencing OC monitoring. “Evidence of reducing toxicity” and “suitably reduced” do not necessarily suggest that toxins levels have reduced to a level whereby the pod could re-open.  Evidence must be provided using the EU approved alternative methods used by a laboratory that has undertaken single laboratory validation for these methods (to determine method performance for each relevant shellfish matrix) and is also accredited to ISO17025 standard for these methods.  We would not support such approach for closures due to PSP or where other lipophilic toxins have been detected, given the lack of approved test kits for these toxins.  The Okatest does not detect PTXs, AZAs or YTXs and therefore would not cover the suite of regulated toxins which the programme should be monitoring for compliance with current legislation.  We do not agree with the statement that commercial kits allow samples to be processed more quickly than analytical methods in an official control programme setting.  The reopening of areas based on one OC test result is allowed in EU legislation under the condition that there is” robust data on the dynamic of the toxicity for a given area”.  This infers that new areas (and possibly old areas with limited recent data) may have to be monitored continuously.  This may create a two tier system.  In our opinion, the reopening of an area closed for OA/DTX/PTX based on Okatest results and only one OC result using LCMS would not be compliant with current regulatory requirements for this group of toxins.  AZA, PTX and YTX have all been detected in Scotland and areas have been closed in the past due to these toxins. Whilst they have been less prevalent in recent years, there remain a risk, future prevalence cannot be modelled and they continue to be regulated. It is our opinion that monitoring should continue for these toxins. | We agree that the regime should be restricted to those toxins for which appropriate rapid methods exist.  We are aware of potential evidence gaps that could emerge and will monitor the position over time.  Agree – criteria will require to be developed and a protocol produced..  The regulations state that *“where there are robust data on the dynamic of the toxicity for a given area, and provided that recent data on decreasing trends of toxicity are available, the competent authority may decide to re-open the area with results below the regulatory limit obtained from one single sampling.’*  We consider that it would be sufficient within the wider context of available OC data for an area, for only one official control sample to be required where other criteria can be met.  Provided that the instructions for use of commercial kits have been  adhered to, for the relevant toxins only within a process which could be verified, then we consider there is merit in pursuing this option further. |
| **Scottish Fishermen’s Federation** | **8.** We welcome the opportunity for wild capture fishers to participate in the initial testing regime in order to achieve opportunities for fishing at appropriate levels and times. Such engagement is the corner stone of stakeholder buy-in and is to be encouraged. It is expected that there will be an MoU between FSS and industry regarding the procedures required for most species, but, as there are no Classified Scallop grounds at present, it would remain the case that End Product Testing would form a major part of the evidence trail for Scallops, so there should be no additional burden on the Scallop Fleet. | Noted. This proposal applies to classified areas only, therefore no scallop grounds in Scotland will be effected. |
| **Argyll and Bute Council** | **9.** This raises some questions which we are unsure of the answer at the moment- In some pods there are multiple harvesting areas, would it matter if the site the harvester wishes to reopen is not at the designated RMP?  Indicator species are used at some pods, in order to reopen would the harvester need to test the indicator species instead of the harvest species? Again there is the issue of one harvester paying for testing that could be used by others to benefit their business.   We are unaware of the volume of testing carried out by the industry but believe the ability to access test kits and labs is limited. We suggest that if this plan is implemented there still be Official Control sampling on a reduced frequency basis. | Only an official control sample will re-open an area closed due to high toxin levels. These will normally be taken at the RMP.  However provided that there is evidence of reduced toxicity within the pod (at any of the sites within the pod), and the samples have been taken in accordance with an agreed protocol then these samples may contribute to our assessment of a decreasing trend which would lead to an OC sample being taken.  Minimum levels of OC sampling will be considered and advice provided.. |
| **Highland council** | **10.** The rapid test kits available to FBOs produce PASS/FAIL results i.e. they are qualitative or semi-quantitative at best and are therefore of little use for trend analysis.  The rapid test kits are also not comprehensive for all toxin analyses and so are useless if the toxin in question is not measured by the kit. This approach could mean that areas are closed for longer as there would inevitably be a delay in the Harvester 'final' rapid test kit PASS result and a subsequent OC sample. | Noted. However if an area is closed and rapid kits indicates that toxicity has reduced then that could be considered a trend.  Only tests appropriate for the toxins which have closed the area could be considered under this proposal. |
| **Fife Creel Fishermen’s Association** | **11.** It is felt that testing should continue by FSS until the toxin levels fall to a safe level and then Harvesting could recommence | Noted. Only FSS testing would determine whether an area could be opened as is currently the case. |
| **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.** | **Seafish Industry Authority** | **1.** Mobile technologies offer many opportunities for this, and geo-tagging is commonplace in many devices. However, as with any technology, they can be misused, so what reliance would FSS place on the data when verification has been required previously. | Whilst FSS will endeavour to ensure that only verified official control samples are taken, it is recognised that for some fisheries (particularly wild catch sectors) verified sampling is not possible. Therefore there may be opportunities to consider how mobile technology can be utilised in order to improve traceability in this sector. |
| **Blueshell Mussels Ltd** | **2.** Much of Scotland is still in signal black spots.  The scallop industry seems to work under their current system. | Noted. We are currently exploring the use of e-logs within the scallop sector and intend to assess their viability for food law/registration document purposes. |
| **Shetland Mussels Ltd** | **3.** We would imagine there are options here but perhaps not for industry to propose. We could see a future whereby sampling officers are less required to validate samples but GPS/checking in/sealed bags and kits could be used to save cost. It depends on how slick this could be made to work but we would support it if it was fit for purpose. | Thank you for this suggestion – we will consider all options where delivery can maintain public health assurance as well as potential efficiencies within the programme. |
| **Association of Scottish Shellfish Growers** | **4&5**. This question appears to be specific to the wild harvest sector. In the shellfish cultivation context, the samples to be collected are held at a fixed site designated through planning permission provisions.  . | Noted – FSS will give consideration to sector specific delivery models. |
| **Scottish Shellfish Marketing Group** |
| **Seafood shetland** | **6.** We consider that the use of mobile technology is not a realistic prospect, given the remote locations involved in shellfish cultivation and fisheries. Inconsistent availability of telecommunication signals in remote locations in Shetland is likely to hamper implementation of any advancing technological applications. | Noted – any changes in this area would of course require to be compatible the limitations associated with the technology and the location in which it is used. |
| **Cefas** | **7.** Tracking systems can be employed to offer greater confidence of locations visited. Restricted access to real time data is possible with certain systems. However FSS must define what level of confidence they require as without actual visual/physical verification, it is impossible to “guarantee” collection location.  Land based verification checks alone for classified species would not comply with current regulatory requirements. | Noted. Any changes in this area must balance the regulatory requirement with the practical implications of delivery. |
| **Scottish Fishermen’s Federation** | **8**. Mobile technology can provide a cost effective way to include Date/ Time/ Latitude & Longtitude details in the chain of custody. | Noted. This is one of the reasons that we consider that it is worth exploring further. |
| **Argyll and Bute council** | **9**. Use of GPS is in place but as you are aware this can be altered and is subject to the accuracy of the satellite fix. The poor coverage for other devices on the West Coast is an issue but the advent of AIS (Automatic Identification System) used to record and track boat movements does mean there may be the opportunity for satellite tracking of the harvester (provided of course a boat is in use!) in terms of the actual sample and subsequent tracking the use of bar codes and handheld device (downloaded to a computer later) may be of assistance. | Noted. Any changes in this area would of course require to be compatible with both the scope and limiting factors associated with the technology; the location in which it is used and in accordance with conditions for use which the CA requires. This is being considered within the scope of the future IT system which will support the programme as a whole. Fundamentally the question would need to be asked – would any proposed change improve confidence in the system? The answer to that would have to be yes at the outset , and confirmed following use. |
| **Highland Council** | **10.** Whatever mobile technology is used the honesty of the FBO providing the sample remains the critical factor for a sample's veracity. Even if boat skippers were provided with a GPS for example, that would still give no guarantee to the providence of a sample without and independent officer being present. Not all boats have chart plotters but one verification check could be to ask boats to provide electronic logs of boat movements. This information could be assessed against provided sample information. This would be an improvement to the current system but still not an absolute guarantee of sample providence. |
| **Fife Creel Fishermen’s Association** | **11.** Gps could monitor where the samples are taken | Thank you for these suggestions and comments. |
| **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.** | **Seafish industry Authority** | **1**. Some of the larger businesses have the resources and expertise to undertake and process their own phytoplankton samples, but many, particularly those that operate at the smaller scales make use of the ‘toxin traffic light’ document. |
| **Blueshell Mussels Ltd** | **2**. We use Phytoplankton levels to predict toxin closures and toxin trends and the general activity and movement of toxic algae onto sites. |
| **Shetland Mussels Ltd** | **3.** This adds a lot of value for public food safety in being the main tool to see what is going to happen in the future. We use the data in the SAMS report too. We still test all harvests with the kits but where we harvest is steered to a great extent by plankton. |
| **Association of Scottish Shellfish Growers** | **4&5.** The shellfish cultivation industry uses models to predict the occurrence of phytoplankton blooms principally in Shetland. Interpretation of these model predictions is typically ground through the use of rapid test kits at individual harvest sites.  There is interest from the shellfish cultivation industry to further refine these models and also to invest in other systems of monitoring including satellite monitoring. |
| **Scottish Shellfish Marketing Group** |
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| **Seafood Shetland** | **6.** We hold the view that phytoplankton greatly assists in harvesting, serving as a very valuable early warning tool, together with initiatives such as the Shetland biotoxin bulletin which incorporates this data. All measures such as these are appreciated, extremely useful and should be retained.  More cost-effective methods of analysing should be investigated and industry could, perhaps, be supportive of providing samples free-of-charge. |
| **9. Which areas within the official control programme should be changed and why?** | **Seafish Industry Authority** | **1**. Industry will be able to give a clearer response to this question. However, notwithstanding the financial constraints on FSS and LAs every effort should be made to minimise the cost burden to industry and to avoid passing cost centres on to industry un-necessarily. |
| **Blueshell Mussels Ltd** | **2.**  A: The industry is cognisant of the budget constraints affecting the FSS. What should be in place is a system that complies with 854/2004 and also most importantly protects consumer safety.  To do this the best way is to understand the process flow of operation and who is best to undertake the work. |
| **Shetland Mussels Ltd** | **3.** We think the forum should be set up asap and used to good effect on an ongoing basis. |
| **Association of Scottish Shellfish Growers** | **4&5.** The shellfish cultivation sector is fully prepared to bring forward revised provisions to allow both the industry to function effectively while maintaining their legal responsibility for food safety and potentially relieving part of the regulatory and fiscal burden from the public sector.  It is considered that the announcement by FSS of the proposal to convene with industry a shellfish forum to consider the detail of classification and monitoring arrangements is an opportunity to achieve such cost-effective solutions for the benefit of all stakeholders. |
| **Scottish Shellfish Marketing Group** |
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| **Seafood Shetland** | **6.** We consider that serious consideration should be given to all official controls being conducted onshore. This would ensure greater protection of public health, with resultant reduction in cost for relevant competent authorities.  As highlighted, the Shetland industry is very keen to explore devising a trial/study of a system which could inform Classification considerations, involving sampling for *E.coli* prior to intended harvest and in line with current Regulations; this could perhaps be a matter for the proposed FSS/Industry shellfish forum to consider. | Noted. FSS will explore all avenues for delivering controls in a way to ensures public health protection and saves money where it is appropriate to do so. If controls currently undertaken at sea can be taken on land, on a risk basis, within legislative parameters, and with a net benefit, then these will be considered. Agree that this is a matter worthy of further discussion in the proposed forum. |
| **Highland Council** | **7.**  1.Review the use of the 'High' MU biotoxin results as a matter of urgency. If method MU was typically 5-10% this would not be a problem and would most likely be accepted by industry. However, with MUs typically in the 40% region, the analytical method's fitness for purpose is questionable and as a result industry lacks confidence. The methods should be reviewed using historical data with the view of reducing the MU values. This is especially true given that the MU works both ways i.e. it is entirely possible that a site is closed when the result is approximately 40% below the action level. If MU cannot be reduced by review then develop a risk-based approach using OC and possibly rapid test kit data.  Since the 'actual' result is the only hard data provided by the method and the MU is merely a statistical extrapolation, consideration should be given to acting on the 'actual' result and using the 'high' result (i.e. the upper MU) in an advisory, possibly combined with harvester rapid test kit results.  2. For low risk toxin months/sites consider using rapid test kits for OC samples instead of expensive laboratory methods. For sites with known historic biotoxin issues this may not be appropriate.  **3.** Introduce a fee for classifying a site especially wild sites. In the case of fixed sites/farms where boat access is required perhaps this fee could be refunded to the harvester when the site is classified as compensation for providing assistance with a boat.  **4.** Consider suspending biotoxin sampling completely in low risk sites in low risk months and replace with increased phytoplankton sampling. If phyto. results indicate an increasing trend then biotoxin could be re-commenced immediately. | 1. The policy in adding measurement of uncertainty to OC shellfish results was agreed several years ago. This provides a precautionary approach to the opening and closing of shellfish areas. All OC methods are accredited and recognised internationally. In general, all methods, including rapid methods factor in MU to their design in order to provide confidence in results given.. However as has always been the case, if the RMP is closed, other AHAs can challenge that result in order to allow independent monitoring of their area alone. In other words there is some flexibility in the current system but we will consider ideas as to how additional flexibilities can be factored in.  2. Noted. There is some scope for changing the methods used as outlined in the consultation paper. The extent to which this is viable is in part dependent on how actual efficiencies can be realised at a laboratory level, particularly whereby the same sample preparation methodology is required.  All OC tests, must be undertaken using an accredited method by an accredited laboratory which reduces scope for any changes for the foreseeable future.  3. We do intend to ask harvesters to provide pre classification samples in accordance with an agreed protocol in due course. This will be explored further.  4. Our monitoring programme is subject to routine risk assessment which has significantly reduced toxin testing in recent years. Phytoplankton testing has however remained steady in terms of volumes, but the overall balance between flesh/water samples is of interest and will be considered further within legal parameters. If a phyto result breaches a trigger level in an area where no flesh testing is scheduled, then flesh samples are taken. |
| **Fife Creel Fishermen’s Association** | **8.** At Pittenweem surf clams are collected by a number of small boats. This is usually carried out as a supplement to other fishing activities. Although one boat is full time. If the burden of payment is implemented it would cause hardship to these small boats | Noted. Any change to the obligation or burden borne by either FSS or industry will be considered following discussion with industry. |
| **Additional Comments** | **Blueshell Mussels Ltd** | The CA should seek industry input to fix production areas which could for example be larger than current, or deselect problematic sites.  Processors would take E.coli samples from batches/site as they are harvested, frequency as per risk assessment but no longer than 1 week apart. More frequent at times of higher rainfall etc. These would be used to populate the long term classification using the codex method, random production sample analysed by processors and shared.  Phytoplankton: Should be maintained by FSS but taken by FBO. Not required during no harvesting or inactivity. Possible to reduce by 20%?  Toxin pods and production areas should be better aligned.  No harvesting for 4 weeks means areas should be ‘at risk’ for harvest. Prior to harvest an EPT test then an OC to confirm area can be harvested. EPT samples to be sent to FSS lab for testing  Chemical contaminant samples to be sent by industry to FSS lab.  Instead of sampling at site, could EHO checks at processors be used instead.  Likewise whilst toxins are the no1 CC for the industry, we recognise that the regulation states that E.coli monitoring is required. Whilst year round classification is required, some sites will tend to undergo short intensive periods, followed by 6-9 month periods of growth, from a common sense point of view it makes sense to carry out pre harvest E.coli samples and more frequent e-coli samples during the harvest period, bigger picture info is likely informative and anecdotal rather than determining food safety.  It would be much more pragmatic for harvesters to be pre-sampling for E.coli taking 2 samples prior to harvesting a site, and using things like local rain gauges to carry out E.coli spike risk assessments. It would make greater sense for the processing centres to sample (as per risk assessment) for E.coli from actual harvests coming ashore. If a sample failed a test it would be treated by depuration relaying or heat treatment. | Thank you for the points noted. These are issues for potential discussion at the new Classification and Monitoring Forum. All changes made to the programme need to be cognisant of regulatory obligations; be practical to implement and cannot compromise public health protection. We also intend to ensure that any proposals align wholly with the [FSS Regulatory Strategy](http://www.foodstandards.gov.scot/news-and-alerts/food-standards-scotland-regulatory-strategy) which was agreed earlier in 2017. |
| **Additional Comments** | **Association of Scottish Shellfish Growers** | **Step 1: Scrutiny of new shellfish applications**  This step is considered to only apply to wild harvest fisheries.  For shellfish cultivation sites seeking planning permission under the Town and Country Planning Act 1994 these and other checks will be undertaken within the planning process.  Given the public scrutiny of the planning process and the technical and financial investment required by the shellfish cultivation business this process is lengthy and expensive and would not be entered into without the FBO being assured that suitable water quality conditions existed before this process was instigated.  **Step 4: Harvesting Plans**  Elements of this step relating to biotoxin monitoring are clearly not part of any process for establishing the classification of shellfish harvesting waters.  There is also confusion between the process for designation of classified shellfish harvesting waters and the maintenance of the designation once classified.  There would need to be far greater clarity on the process envisaged to enable a view on the operational ability to consider short term periods of classification and the status of the area / water out with any short-term period?  **Annex 4. Sampling issues, phytoplankton monitoring and general programme issues**  This section clearly recognises the inherent differences between the wild harvest sector and the shellfish cultivation industry. | Agree this is most likely to be the case.  Toxin monitoring is unrelated to classification – just that the former must follow the latter. We are looking at ways to ensure that we classify (and therefore monitor) only during periods of activity.  Agree these are issues which would need to be considered in detail should significant changes be introduced in this area. |
| **Scottish Shellfish marketing Group** |
| **Additional Comments** | **Seafood Shetland** | The offer to consider creation of a Food Standards Scotland/Industry shellfish forum is a good one and one which Seafood Shetland supports. | Noted. |

**List of Respondents**

3 shellfish businesses; 5 fishing and industry organisations; 2 local authorities and 1 official control laboratory responded to this consultation.