# Shellfish Review Project– scope, arrangements and progress to date

## 1 Purpose and recommendations

1.1 This paper provides an update on FSS's Shellfish Review Project which is referenced in the Corporate Plan under Strategic Outcome 1 as follows:

***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.*

1.2 The review as a whole will be considered through the prism of the FSS Regulatory Strategy and aligns with the principles for effective and sustainable official controls that were agreed in August 2016.[1.]

1.3 The purpose of this paper is to demonstrate to the Board how this significant element of the Corporate Plan will be delivered in a way that fits with FSS's established strategic objectives and also with developing approaches to regulatory Strategy and sustainable official control delivery that the Board has agreed to date.

1.4 The Board is asked to:

- **Note** the scope of this Shellfish Review Project, the progress to date and that this is the first project being developed under the Official Control principles agreed by the Board in June, as well as the August paper on ensuring we have sustainable and effective control systems in place;
- **Agree** that the approaches set out in this paper provide sufficient assurance that the Executive has taken proper account of the Board's strategic aims in relation to this review; and
- **Note** that there will be updates to the Board as this work progresses.

## 2. Strategic Aims

2.1. The work of the review supports FSS's strategic outcomes 1, 2, 4 and 6 as follows:

**Outcome 1: Food is Safe**
The project will review current and potential policy approaches to the delivery of official controls which might better deliver improved service and public health outcomes.

[1] Agreed by FSS Board on 17th August 2016: http://www.foodstandards.gov.scot/sites/default/files/Effective%20and%20Sustainable%20Official%20Controls%20-%20FSS160808.pdf

**Outcome 2: Food is authentic**
This project will identify priorities for action in relation to traceability and compliance with a focus on the wild catch sector.

**Outcome 4: Responsible food businesses flourish**
In line with the regulatory strategy, the project will explore ways of working with businesses to achieve public health outcomes; as well as targeted interventions for businesses failing to meet their legal obligations.

**Outcome 6: FSS is efficient and effective**
The project will identify and deliver efficiencies and improve the effectiveness of the controls applied.

2.2. The issue of full cost recovery is not considered as part of this review and is out of scope. The Board would wish to note however that while it is an area that will inevitably have to be considered in the future, a sensible and reasonable first step is to identify how the current controls can be improved first. Certainly, the Executive's view is that identifying ways to reduce costs first is fully in line with better regulation principles and will provide assurance to industry that costs are no more than they need to be.

2.3. As a strategic outcome, we will end up with a revised system of controls that is more efficient and cost effective and where good compliance is recognised and poor compliance is identified and tackled effectively.

## 3. Background

3.1. 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[2] and history of illness associated with shellfish an extensive raft of official controls is explicitly set out in EU law.

3.2. This review is the first undertaken by FSS, but shellfish official controls have been under considerable scrutiny by Food Standards Agency prior to April 2015, and FSS and FSA continue to liaise on these matters. This scrutiny has in part been driven by the fact that the shellfish official control monitoring budget in 2016-17 is £2.4m, from an overall FSS programme budget of £8m.
Further background can be found in **Annex 1**.

[2] Scientific Opinion of the Panel on Contaminants in the Food Chain on a request from the European Commission on Marine Biotoxins in Shellfish – Summary on regulated marine biotoxins. The EFSA Journal (2009) 1306, 1–23 http://www.efsa.europa.eu/en/efsajournal/pub/1306

## 4. Workstreams and progress

The key elements of the review are divided into 5 cross-cutting workstreams which are summarised below alongside progress to date.

4.1. **Workstream 1: Specifications for the re-tendering of shellfish monitoring contracts**
These contracts set baseline costs for the shellfish monitoring project over 3 years and it is essential that every effort is made to drive efficiencies and improve delivery where possible. This work needs to be completed by January 2017 as new contracts must be in place by April 2018.

*Progress*

4.2. Regulations require toxin monitoring to be risk based, and a robust statistical model has been applied to develop toxin sampling plans in Scotland for the past 10 years. This model, which uses historical data to identify toxin trends in harvesting areas, is updated every 2-3 years to ensure sampling is undertaken at a frequency which is commensurate with risk. The most recent toxin risk assessment was published at the end of September 2016[3] following peer review, and the findings will be used by FSS to design the new sampling programme from 2017. This work is significant in establishing a baseline for contract purposes as toxin monitoring currently forms 45% of the overall shellfish official control budget. Other work in relation to setting the baseline requirement for sanitary surveys, *E. coli* and chemical contaminant monitoring is also underway.

4.3. **Workstream 2: Delivery of a cross Government, risk based approach to sanitary surveys and chemical contaminants monitoring**
This workstream is closely linked with workstreams 1 and 3. Sanitary survey provision is a pre-requisite to shellfish area classification and it will also inform contract tender requirements.

4.4. **Workstream 3. Review of OC classification and implementation**
Work on classification is on-going following EU Commission audit recommendations in 2012; recent statutory changes to the classification criteria which will apply in 2017 and discussions arising more broadly in relation to ways in which we can ensure sustainable and robust official controls in future. There are a number of strands involved and it is proposed that certain key elements of this work and that of work stream 2 are completed by April 2017.

*Progress (workstreams 2 and 3)*

4.5. Given that monitoring only becomes a statutory requirement once we classify an area it is appropriate that we considered the criteria that might apply when we enter into classification agreements with industry.

4.6. If FSS could refine its monitoring regime, for example, based on closer collaboration with harvesters, it may be possible to avoid monitoring during periods

[3] Bioss, *Risk assessment of the Scottish monitoring programme for the marine biotoxins in shellfish harvested from classified production areas: review of the current sampling scheme to develop an improved programme based on evidence of risk* (September 2016) http://www.foodstandards.gov.scot/risk-assessment-scottish-monitoring-programme-marine-biotoxins-shellfish-harvested-classified

where no harvesting is taking place. One way of approaching this would be to have access to harvesting plans prior to classification.

4.7. We also want to consider whether it is appropriate for harvesters wishing to exploit new areas to contribute samples before classification. The proposed consultation will also explore the feasibility and industry impacts of using industry-provided samples on an on-going as basis for classification. We have begun discussions with the aquaculture sector, and will mirror in the wild catch sector, on how collaboration in this area could be delivered.

4.8. Up until August 2016, FSS continued to classify 5 scallop areas in Scotland. Given the flexibility that exists within EU law to move towards more land based checks for this sector, we have declassified these areas with a resultant £62k annual saving.

4.9. The robustness of our classification system had previously been questioned and concerns raised that our protocols did not clearly articulate the process steps involved in making the classification determination. In response, a redrafted protocol (developed by FSS working in partnership with FSA) was published in March 2016[4] and is already being applied. In addition, discussions with industry have begun regarding new legislative criteria for classifications which apply in 2017. This change has provided an opportunity to make more explicit the classification decision making process and this will be subject to consultation by the end of November 2016.

4.10. FSS is exploring options for more efficient delivery of certain monitoring functions in those areas where there is clear multi-agency interest. FSS is already engaging with the Scottish Environmental Protection Agency (SEPA) and Marine Scotland both at working level and through groups such as Cameras[5] and the Clean and Safe Seas Evidence Group (CSSEG), to identify scope for more collaborative and cost effective monitoring approaches in these areas. FSS has also put in place an active consultation step with other regulators prior to accepting new shellfish applications, which took effect from August 2016.

4.11. **Workstream 4: Review official control costs and further opportunities for project efficiencies**

This work area intersects the review as a whole and will be informed by work being undertaken in parallel through the FSS Regulatory Strategy.

*Progress*

4.12. The outcome of our workstream 3 consultation on issues arising in relation to classification and monitoring will be particularly important when considering potential savings for FSS. The consultation will also consider for example, how areas which are closed due to high toxin levels are re-opened and will consider the use of industry samples where it is appropriate to do so.

[4] Food Standards Scotland, E.coli protocol (March 2016) thttp://www.foodstandards.gov.scot/e-coli-protocol

[5] Coordinated Agenda for Marine, Environment and Rural Affairs Science (http://www.gov.scot/Topics/Research/About/EBAR/CAMERASsite)

4.13. In addition, there are options to consider alternative methods of toxin analysis which might result both in quicker turnaround times and reduced unit costs to FSS. We are currently gathering data on the potential for cost savings and we will consider whether there is scope for such methods to be included within the tender specification next year.

4.14. **Workstream 4. To put in place measures to assess and improve compliance** The aquaculture sector has changed significantly in recent years in relation to proactive compliance approaches. FSAS and latterly FSS have worked closely with industry to provide assistance and tools in achieve to achieve that goal and FSS intends to mirror that approach with the wild shellfish sector. It is proposed that a strategic approach is taken to this issue that this work will be completed by December 2017.

*Progress*

4.15. One critical piece of work is to provide guidance to both businesses and local authorities on what compliance in the scallop sector looks like, particularly for those involved in the sale of whole scallops. Draft guidance has been prepared and we intend to consult on this by the end of November (which will be separate from the workstream 3 consultation). This follows a previous consultation on the direct sale of small quantities of shellfish to the local market (which ended in May 2016[6]) and a workshop with local authorities in April.

4.16. The intention is to achieve collective agreement to the approach proposed and then undertake a series of local authority audits across the sector to ensure that controls are being applied consistently. With its significant intra-community trade, it is vital that the regulatory regime for scallops is accepted at an international level.

4.17. Ensuring provenance and traceability of product is at the heart of food safety controls across the food industry as whole. Shellfish traceability is dependent on the use of registration documents but for a number of years concerns have been raised about their application and effectiveness particularly in the wild bivalve sector. Ways in which this system can be improved are under active consideration.

## 5. Risks

5.1. The current cost of shellfish controls is a major financial pressure on FSS resources. Under the current model for delivery of controls, FSS has no control over the scale of funding it will require to meet the needs of the industry. Additional financial pressure arising from expected growth in the aquaculture sector will depend on its nature and scale of that expansion. The potential impact is therefore difficult to quantify but could add severe financial pressure and adversely impact on other FSS priorities.

5.2. Export markets are important for this sector and their potential may be compromised if the legislative standards and regulatory controls in place are not recognised as appropriate by countries in those markets.

[6] http://www.foodstandards.gov.scot/local-sales-small-quantities-live-bivalve-molluscs-review-current-controls

## 6. Recommendations

6.1 The Board is asked to:

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- **Agree** that the approaches set out in this paper provide sufficient assurance that the Executive has taken proper account of the Board's strategic aims in relation to this review ; and
- **Note** that there will be updates to the Board as this work progresses.

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## Annex 1: Background

1. FSS is defined in law as a competent authority in relation to the delivery of a significant number of shellfish official controls 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.

2. Risk management of shellfish toxins in Scotland has developed considerably since an outbreak of toxin-related food poisoning in 2013 which occurred in the south of England, and was directly linked to the consumption of mussels from Scotland. Following this incident Food Standards Agency in Scotland (FSAS) worked closely with the Scottish shellfish industry to develop new guidance aimed at supporting businesses in the management of toxin risks. As such, shellfish toxin monitoring by FSS is now used extensively by aquaculture businesses in Scotland to trigger harvesting and testing actions in accordance with FSS 'traffic light' toxin guidance[7], which is essentially 'powered' by FSS official control results. A recent study which looked at the efficacy of this guidance, found that shellfish processors and producers which applied the traffic light principles to their harvesting regime withheld contaminated products from the market on at least 28 occasions in 2014-2015[8]. Indeed, had the traffic light guidance been used prior to July 2013, it is considered likely that the 2013 outbreak of toxin-related food poisoning would have been prevented.

3. Regulatory oversight and monitoring of the aquaculture sector is relatively straightforward as shellfish farms, which comprise largely of rope-grown mussels and trestle-grown oysters, are geographically fixed and ownership within classified areas is known. However, irrespective of whether an area is wild catch or aquaculture however, the same official controls are required to be applied. For the majority of bivalve shellfish species caught in Scotland this means that FSS is required to classify harvesting areas according to microbiological criteria set down in law, and once classified, to then monitor those areas for their microbiological quality on an ongoing basis, as well as for shellfish toxins, toxin producing phytoplankton and chemical contaminants. Whilst there is no requirement in EU law for the competent authority to classify an area, harvesting for food production is only permitted from classified areas (other than for scallops). However, if the competent authority chooses to classify an area, it must monitor that area and it is that on-going monitoring requirement that drives costs into the programme as a whole.

[7] Managing Shellfish Toxin Risks – Guidance for shellfish harvesters and processors, Food Standards Agency (2014). https://www.food.gov.uk/sites/default/files/multimedia/pdfs/guidance/managing-shellfish-toxins-guidance.pdf

[8] Evaluation of the Shellfish Traffic Light Toxin Guidance for Food Standards Scotland, Cath McLeod, Seafood Safety Assessment , (2016) http://www.foodstandards.gov.scot/sites/default/files/Evaluation%20of%20traffic%20light%20guidance%20for%20toxins%20in%20shellfish.pdf

4. The wild catch sector comprises largely the scallop dredge fishery but other bivalves are also commonly fished in Scotland, including razor clams and cockles. The razor clam sector has also grown in recent years, but illegal fishing methods are considered at least in part to have been responsible for that growth[9]. As part of Marine Scotland efforts to combat illegal electrofishing, new powers were introduced in 2013 to allow Fishery Officers to seize objects, including generators, cables and probes potentially being used for electrofishing. From August 2014, the Scottish Government also introduced new licensing arrangements to minimise the risk of electrofishing. An additional licence for fishing for razor clams was introduced and vessels were inspected to seek to ensure they are not equipped for electrofishing. These actions have seen annual recorded landings and values in 2013 of 915 tonnes worth £3.1m (the high point), drop to 350 tonnes worth £1.6m in 2015.

5. FSS officials recently responded to a Scottish Government consultation which examined whether it might be appropriate to propose that the electro-fishing method for razor clams be permitted "within a regulated and sustainable fishery." In our response we advised that ensuring the provenance and safety of shellfish harvested in Scotland should be a priority in any well regulated razor fishery and highlighted that FSS would be well placed to work with partners across Government to ensure that outcome is delivered. It is therefore appropriate to include actions arising in relation to verification and traceability in this sector within the scope of this review.

6. The wild catch sector is also of significant economic value to Scotland - scallop landings alone were worth over £32.5m in 2014[10]. Whilst the aquaculture shellfish sector had a first sale value of £10.1m in 2015[11], Scottish Government and industry have will shortly announce plans for growth in the aquaculture sector as part of a new strategic approach across the food and drink industry.

7. Official controls which are applicable to scallops require mostly land based verification checks by the competent authority, in line with other approved food businesses outwith the shellfish sector. This is because, under EU law, it is not mandatory for competent authorities to classify scallop harvesting areas.

8. Despite the relatively low level of official controls, there are however very explicit requirements in food law which require food businesses harvesting pectinidae to demonstrate compliance with safety standards 'as proved by a system of own checks'. This system requires verification by local authorities (LAs) and we are aware of differences in both compliance levels between businesses and enforcement approaches across Scotland. This disparity has generated significant work in recent years for FSAS and FSS, culminating in the completion of a scallop policy review in early 2015 by FSAS, and an FSS consultation on national measures for the direct supply of small quantities of scallops which issued earlier this year.

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[9] Marine Scotland, *A report on electrical fishing for razor clams (ensis Sp) and its likely effects on the marine environment,* Breen et al, (2011). http://www.gov.scot/Resource/Doc/295194/0113795.pdf

[10] Scottish Government, *Fishery Statistics* (2014) http://www.gov.scot/Topics/Statistics/Browse/Agriculture-Fisheries/PubFisheries/2014LandingsTables

[11] Scottish Government, *Scottish Shellfish Farm Production Survey 2015,* (2016) http://www.gov.scot/Publications/2016/05/2841 2.1.