

Shellfish Review Project– scope, arrangements and progress to date

1 Purpose and recommendations

1.1 This paper provides an update on the Food Standards Scotland's (FSS) 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 purpose of this paper is to provide an update to the Board following the paper presented in October 2016¹ and subsequent consultations undertaken on shellfish official controls which ended in May 2017².

1.3 The Board is asked to:

- **Note** the progress of work to date and the identification of a revised shellfish work plan following consultation (Annex 1);
- **Note** the potential for changing the way that shellfish classification determinations are made in future through increased use of harvesters' own results within the programme; and
- **Note** the establishment of a FSS Shellfish Classification and Monitoring Industry Forum which will assist in delivering any significant changes to shellfish official controls in the future.

2. Strategic Aims

2.1. The work of the review continues to support FSS's strategic outcomes that **Food is Safe** and that **food is authentic**. In line with the FSS Regulatory Strategy which was agreed in May, the shellfish review also aligns with our objective that **Responsible food businesses flourish** through better targeted interventions. The review has also identified potential actions in order to ensure that we remain an **efficient and effective** regulator.

3. Background and progress to date

3.1. As discussions with shellfish delivery partners are at a critical stage, this paper **does not** include specific details on potential costs or savings associated with the review. Delivery efficiencies, in tandem with improvements to public health protection have however been at the forefront of our considerations and are discussed in general

¹ [FSS 16/10/06](#)

² [FSS seeks views on its shellfish official controls review](#)

terms below. The Board will be updated once the baseline cost for shellfish official controls has been established.

3.2. Following the last update to the Board, FSS issued three consultations covering a number of proposals for shellfish classification, monitoring and compliance across the sector as a whole. This involved detailed discussions with industry, science and enforcement interests which included an industry workshop on 20th April in Aberdeen, as well as engagement with local authorities through the Fish and Shellfish Hygiene Working Group - a Scottish Food Enforcement Liaison Committee (SFELC) subgroup. In addition, extensive discussions have taken place with potential suppliers and with Scottish Government Procurement regarding arrangements for the delivery of contracted services for shellfish. As this review has focussed on technically complex areas considered to be relevant primarily to businesses, science and enforcement communities, no specific engagement with consumer groups was undertaken, however a web story flagged the consultations to all stakeholders in February, and consumer engagement forums have taken place in previous years in order to gauge consumer perceptions on shellfish biotoxin risk management. An updated summary of progress against the specific workstreams, identified at the start of the Shellfish review which were outlined in the last progress report to the Board, is included below:

3.3. **Specifications for the re-tendering of shellfish monitoring contracts**

Further to engagement with Scottish Government (SG) procurement partners which included extensive consultation with potential Scottish suppliers, we can confirm that the FSS Commodity Strategy determined a Crown to Crown delivery model for a fully managed service for shellfish analysis and sampling. Lawyers have confirmed that this approach is exempt from the requirement for FSS to undertake a formal tender exercise. High quality shellfish official controls support the shellfish industry in Scotland to meet their aspiration for growth in line with Aquaculture Vision 2030 by ensuring a high level of public health protection. It is the intention of FSS to review this service at year three with a view to a further extension. This is in line with the wider FSS procurement strategy.

3.4. **Delivery of a cross-Government, risk based approach to sanitary surveys and chemical contaminants monitoring**

FSS has been collaborating with SEPA and other partners across Scotland to identify where there is scope for joint approaches for the monitoring of shellfish growing waters. Through the sharing of data on chemical contaminants in shellfish, FSS is now able to make use of an IT tool developed by SEPA which allows monitoring to be targeted more effectively to areas where there is evidence of increased risk. FSS and SEPA are also working together to explore the possibility of developing a new protocol for sanitary surveys and microbiological classification which makes better use of public funding, whilst delivering the regulatory obligations of both organisations. The previous sanitary survey programme in Scotland was resource intensive and an internal review has assessed the possibility of rationalising the programme in a way that could reduce costs without impacting on compliance with official control requirements. The review identified that there was scope to assess where monitoring undertaken by FSS could be better aligned with the procedures employed by SEPA to monitor shellfish water protected areas. Subsequent collaboration with SEPA has informed a new project which is intended to support the development of new,

scientifically robust and cost effective approaches to microbiological monitoring. Pending the completion of this joint project in March 2018, FSS has suspended the full survey programme and has instead maintained a programme of desk top survey assessments which ensure that potential pollution sources arising from major commercial and residential areas are considered prior to initial classifications being made. Resumption of the full survey programme, which includes a physical shoreline survey and more detailed interrogation of available data sources, is likely to incur additional programme costs to FSS, but the extent of those costs will not be known until the output of this work is completed. However, we are satisfied that the alternative arrangements we have put in place are sufficient to enable us to make appropriate decisions with regards to identification of risks to public health. It should also be noted that FSS had already completed existing area surveys when the programme was suspended in April 2015, leaving only new areas requiring a full survey.

3.5. Review of OC classification and implementation

FSS's approach to the classification of shellfish growing waters generated significant discussion during consultation. Of key concern to industry is how sporadic high results can lead to the downgrading of classification. The public health risks associated with spikes in *E. coli* levels can be managed, e.g. through depuration, which acts to reduce contamination to safe levels. However, high results can adversely impact classification status, which has financial consequences for businesses due to both the costs associated with the requirement to depurate shellfish from 'B' class areas and the loss of price premium associated with shellfish harvested from 'A' class sites. As the Board has agreed a low risk appetite with regards to risks to consumers, the Board is asked to note that no changes will apply to the way in which classification determinations are made (a cost neutral exercise as far as the official control programme is concerned), pending a revision of protocols for the use of harvesters' own results within the programme; and confirmation that any new approach will not compromise public health. The use of harvesters' own results, in accordance with agreed protocols for sample collection and analysis is in line with regulatory requirements and provides an opportunity for industry to provide additional data which may support the maintenance of 'A' class status in an area, whilst ensuring public health is protected. Any changes to classification procedures will be considered following the completion of our external review on sanitary surveys and the revision of industry sample provision protocols. This approach was agreed in principle at a consultation workshop held with industry in April. The output of these considerations will be put to the Board for agreement in due course.

3.6. Review official control costs and further opportunities for project efficiencies

A number of specific proposals regarding classification and monitoring approaches were included in the consultation earlier this year. This included requesting harvesting plans prior to classification (in order to target monitoring resource more effectively); submission of samples by industry rather than FSS prior to classification; and utilisation of industry results to inform biotoxin sampling frequency during toxin closures. These measures, if introduced, could provide additional savings and delivery approaches will be considered by a new Shellfish Classification and Monitoring Forum (see paragraph 4.2). In previous discussions the Board has raised

concerns around the cost for official controls for other commodities besides meat. This work is being taken forward under the Regulatory Strategy Programme to ensure there is a coherent approach across all commodities so it is not addressed in any detail here.

3.7. To put in place measures to assess and improve compliance

The aquaculture (farmed) sector has changed significantly in recent years in relation to proactive compliance approaches particularly in relation to toxin risk management. Experience in dealing with incidents and engagement with local authorities and industry have suggested that there is scope for guidance and targeted enforcement approaches to strengthen equivalent controls in the wild shellfish sector. As with any other sector, primary responsibility for ensuring food is safe lies with the producers and that means producers have quality assurance systems in place so the official control over-sight is more focused on assurance, rather than the current system of intensive controls in the shellfish sector which are set out in statute for the majority of shellfish species. FSS consulted earlier this year on draft toxin management guidance for the wild scallop sector, including approaches for the sale of live 'in shell' king scallops to the local market. It is intended that this guidance will be issued by the end of the year, although it should be noted that secondary legislation may be required in order to ensure that specific food safety outcomes can be achieved. FSS is also considering alternative approaches to the delivery of the registration document requirement (for example there may be potential in exploring whether existing fishery management documentation can be used) in order to improve traceability and minimise regulatory burdens for businesses.

4. Next steps

- 4.1. The work plan for the shellfish review originally envisaged an end date of December 2017. It is now anticipated that the review will formally end by the end of 2018, but many of the work areas may return to a business as usual footing well before then. Of the work areas identified for action; all key areas are progressing well. Following consultation a revised workplan is proposed – essentially to reflect progress to date and to accommodate the outputs from the consultation process. This plan coalesces around the need to focus on: **1. Changes to classification and monitoring** and **2. Compliance** – both for industry and FSS. Detailed tasks under these headings are included for reference at **Annex 1**.
- 4.2. In order to ensure that industry have an opportunity to consider fully issues arising in relation to proposed next steps, a Shellfish Monitoring and Classification Industry Forum, chaired by FSS has been proposed and was announced at an industry workshop held in Aberdeen in April 2017. Industry has very much welcomed this initiative which parallels the Scottish Meat industry forum which was set up in October 2016. It is anticipated that the group will convene biannually, with the first meeting taking place later this year.

5. Risks

- 5.1. The current cost of shellfish official controls remains a major financial commitment in FSS's budget and we will continue to have dialogue with industry and Scottish

Government regarding continued delivery within the current funding framework. This is mitigated in part by the Government to Government procurement arrangements which have been put in place and to a lesser extent by some of the proposed classification and monitoring changes which will be introduced over time. However, it should be noted that as outlined above in para 3.3, the Sanitary Survey element of the programme is currently suspended, and FSS will be required to bring this back on stream in order to ensure full compliance with regulatory requirements. It is envisaged that the full programme will be re-instated following completion of the Survey review, and that FSS will continue to undertake desk top surveys for new applications meantime. Whilst the aim of this review is to develop a more cost effective approach for delivering sanitary surveys to the methods previously employed by FSAS, the outputs will increase the cost of the programme currently delivered by FSS. Wider Government consideration of the resource required to support classification under hygiene regulations may also be required in future. There is no doubt that any expansion of the aquaculture sector also needs to take account of the official control requirements and associated costs as without effective official control over-sight expansion through exports will be severely limited.

- 5.2. A revised framework official control regulation has now been agreed and there is an opportunity to influence discussions at an EU level on the commodity specific requirements currently contained within EC Regulation 854/2004. There are some areas within the current Shellfish official control framework where liaison with other 'like minded' countries may be appropriate. These issues are being explored with FSA at present, particularly in relation to the regulatory regime for scallops. Progress in relation to how these risks are being navigated by FSS will be reported to the Board in due course.

6. Recommendations

6.1 The Board is asked to:

- **Note** the progress of work to date and the proposed revised shellfish work plan following consultation (see **Annex 1**);
- **Note** the potential for changing the way that shellfish classification determinations are made in future through increased use of harvesters' own results within the programme; and
- **Note** the establishment of a FSS Shellfish Classification and Monitoring Industry Forum which will enhance our engagement and assist in agreeing and delivering any significant changes to shellfish official controls in future.

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SHELLFISH REVIEW – PROPOSED WORKPLAN FOLLOWING CONSULTATION May 2017

Key milestones (co-dependencies/links in brackets)

ANNEX 1

	reference	co-dependencies	Milestones – <i>timings tbc following establishment of Shellfish Classification and Monitoring Forum</i>
No.1. Effective and Efficient classification and monitoring procedures	1a		Commission an external review of sanitary survey and classification monitoring programme.
	1b	1a	Following outcome of external review (1a) consider specifications for sanitary surveys which must be followed by contractor and potentially 3 rd parties when survey required by FSS.
	1c		Revise protocol (MoU) for submission of harvesters own results as part of the classification programme
	1d	1c, 1a	Consider feasibility of real time monitoring for classification purposes. This action will follow revision of the harvesters own results protocol, and outcome of external review into survey and classification monitoring programme.
	1e	1c	Request that for new areas, harvesters submit samples in accordance with agreed protocol
	1f		Influence regulatory official control amendments to secure greater flexibility in approach to delivering shellfish assurance
	1g		Reduce official control testing in areas which the competent authority has closed due to high toxin levels in accordance with statute. Reduction achieved by using FBO/OC samples for which clear

			sampling protocol will be required.
No 2> To put in measures to ensure compliance	2a	2b	Develop a standard shellfish registration document in order to provide additional traceability and official control information.
	2b	2a	Investigate the feasibility of an on-line registration document system for use by LA's and FBOs – for the scallop sector
	2c	2d	Develop scallop toxin guidance (including small quantities and enforcement guidance) and implement an agreed roll out programme with FBOs and LAs
	2d	2c	Commission audits of local authorities which approve scallop businesses once guidance and enforcement protocols agreed
	2e		Develop additional guidance for local authorities handling high/outwith classification results.
	2f	2e	Revise depuration guidance for local authorities and shellfish businesses in order to provide necessary technical support and align with principles set out in the regulatory strategy.