Official control monitoring programmes for live bivalve molluscs – legislative and regulatory approaches: Scotland

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This chapter should be read in conjunction with chapters 10, 12, 13 and 14. Together these five chapters provide a detailed overview of existing legislation in a number of key countries whilst also highlighting the gaps, anomalies and principal issues that face those charged with the responsibility for monitoring and control programmes for live bivalve shellfish and their waters.
11.1 BACKGROUND AND CENTRAL COMPETENT AUTHORITY ROLE IN SHELLFISH CONTROLS – THE FOOD STANDARDS AGENCY

The Food Standards Agency (FSA; The Agency) in the United Kingdom is an independent food safety watchdog set up by an Act of Parliament in April 2000 to protect the public’s health and consumer interests in relation to food. Although the FSA is a Government agency, it works at “arm’s length” from Government because it does not report to a specific minister and is free to publish any advice it issues. The Agency is accountable to Parliament through Health Ministers and to the devolved administrations in Scotland, Wales and Northern Ireland for its activities within their areas.

The Food Standards Agency Scotland (FSAS) is the central competent authority under European Union (EU) Regulation 854/2004 (European Communities 2004a) and in this capacity is responsible for implementing official controls in relation to live bivalve molluscs. This Regulation is directly applicable in its entirety throughout all European states. Local enforcement powers are delegated in Scotland through the Food Hygiene (Scotland) Regulations 2006.

The Agency undertakes official programmes in relation to microbiological assessment of live bivalve mollusc production areas, administers and classifies all live bivalve mollusc production areas, oversees the approval of depuration facilities and also undertakes the monitoring of each area for biotoxins, phytoplankton and chemical contaminants. The components of the classification system and associated microbiological components will be discussed within this chapter.

11.1.1 Overview of programme

Scotland currently has 186 classified shellfish harvesting production areas covering 246 individual harvesting sites. Six main species of bivalve mollusc are classified. The majority of the production areas are found in the Shetland Isles, Argyll and Bute, and across the Highland areas of Lochaber, Skye and Lochalsh, Ross and Cromarty, Sutherland and Inverness. Further classified production areas are found in Orkney, Western Isles, North Ayrshire, Edinburgh, Moray, Dumfries and Galloway and Fife. The latter areas tend to be home to wild shellfisheries rather than aquaculture sites and hold species such as clam species and common cockles. Within aquaculture areas, common mussel is the main species with Pacific Oyster also being a major species, particularly in the Argyll and Bute area of Scotland. Figure 11.1 shows the location of main shellfish production areas.
11.2 MICROBIOLOGICAL OFFICIAL CONTROL MONITORING PROGRAMMES MANAGED BY THE FOOD STANDARDS AGENCY SCOTLAND

In accordance with Annex II of the EU Hygiene Regulation 854/2004 (European Communities 2004), the FSAS is required to establish the location and fix the boundaries of shellfish harvesting areas. The process involved in area classification is stringent and includes regular sampling of shellfish from representative monitoring points by Enforcement Officers from each Local Authority area, with the assistance of shellfish harvesters. Twelve local food authorities (LFA) are involved in the programme. The regulations stipulate that the competent authority must monitor the levels of *E. coli* within the harvesting area and that according to the sample results, must classify the area as being one of three categories; A, B or C. An A classification allows for the product to be placed directly on the market, whereas B or C classification requires the product to go through a process of depuration (purification), approved heat treatment or relaying before it can be placed on the market (see chapter 9).

Figure 11.1. Scottish areas where shellfish are provided for the analysis of *E. coli* for the harvesting areas to be classified.
Regulation (EC) No 854/2004 (European Communities 2004a) states that if the competent authority decides in principle to classify a production or relaying area, it must:

1. make an inventory of the sources of pollution of human or animal origin likely to be a source of contamination for the production area;
2. examine the quantities of organic pollutants which are released during the different periods of the year, according to the seasonal variations of both human and animal populations in the catchment area, rainfall readings, wastewater treatment and other similar factors;
3. determine the characteristics of the circulation of pollutants by virtue of current patterns, bathymetry and the tidal cycle in the production area; and
4. establish a sampling programme of bivalve molluscs in the production area which is based on the examination of established data, and with a number of samples, a geographical distribution of the sampling points and a sampling frequency which must ensure that the results of the analysis are as representative as possible for the area considered (European Communities 2004a).

In essence, the requirements given in paragraphs (a–c) of the Regulation constitute what has been termed a sanitary survey and paragraph (d) shows that the contents of this should influence the content of the sampling plan.

The Regulations also require the competent authority to undertake sanitary surveys for all new areas. It is additionally the intention of the FSAS to undertake such surveys on all of their existing classified production areas over a reasonable period of time. A formal report will be produced for each area, containing the outcome of the various elements together with an overall assessment of the effects on the shellfishery. The survey information will be reviewed on a regular basis and the LFAs will contribute information to this review. The final product will be the sampling plan(s) for the area. The information contained in these plans will include:

- production area;
- site name and identification;
- geographical location;
- depth of sampling (if relevant);
- frequency of sampling;
- responsible authority; and
- authorised sampler(s).
Currently the FSAS carries out its annual review of classifications every December and awards provisional, seasonal or full classifications on the basis of three years historical *E. coli* monitoring data. A minimum of nine samples is required, taken in separate months between January and December, to maintain an area classification. However, if the shellfish harvesting area is a new site and is yet to be classified or has a history of fluctuating results during specific months, then the minimum sampling frequency will be recommended to be more frequent. A separate fast track classification system also exists, which allows for the immediate harvesting of previously unclassified or a declassified area for a single season in that year. FSAS officers award a provisional B classification for this harvesting period after a general desktop survey has taken place.

In addition to monitoring of microbiological criteria within these classified shellfish production area, programmes for the monitoring of toxic species of phytoplankton and biotoxins specified in EU854/2004 (European Communities 2004a) are also undertaken. These programmes are not discussed further under the remit of this chapter.

### 11.2.1 Classification of new shellfish production areas

New shellfish production areas may be classified at any point during the year when the minimum number of samples has been submitted and results received. A properly completed classification form is essential before the FSAS will proceed with the classification. A standard form is supplied and requires data on sampling locations and full historic details of the area. It also requires full details of the harvester, intended site harvesting patterns and LFA details. FSAS undertake a site assessment prior to classifying a new area. This involves liaison with other government agencies, the LFA and the harvester as necessary. This allows the FSA to award classification in full consideration of available information. The classification decision is communicated to the harvester, LFA and relevant laboratories contracted to carry out official control sample analysis. The awarding letter stipulates a unique reference number for the area which must be used on all sample submission forms and labels. In addition, a standard grid reference from which samples must be taken is stated. The area boundaries are set and any limitations to the classification stated. An opportunity is also taken to reinforce to the harvester their legal responsibilities.

A production area may be given a provisional classification status where the site results are variable. This area will then be subject to continuous review to allow alteration of the classification if required. Once an established trend from results is apparent (a minimum of three years consistent data is required), an area may be given a season classification which splits the classification category over
the year dependent on the pattern observed. An area with proven stable results will be given a full and permanent classification status for the year. Harvesters are able to appeal against the classification award and an appeals panel comprising FSAS staff and other experts consider these appeals. The FSAS publish a yearly classification document which includes a full protocol on classification and appeals, it also provides classification and appeal application forms.

11.3 RESPONSIBILITIES AND INTERACTION WITH OTHER AGENCIES

11.3.1 Interaction with the Local Food Authority

The FSA delegates competence for certain official controls to the LFA. Therefore, enforcement of the provisions is carried out by a combination of central and local government, with The Agency retaining overall accountability to the European Commission (EC).

Within Scotland there are 32 LFAs, around half of these have direct and indirect involvement in the controls required in relation to live bivalve molluscs. This may be through the local management of production areas, approval and inspection of depuration facilities, inspection at first landings and auction markets or at the processor. These arrangements necessitate close working between the central and local authorities and between the LFAs themselves. This has been facilitated by formal liaison arrangements made under a joint enforcement working group the Scottish Fish Hygiene Working Group. This group contains representatives of the FSAS and all LFAs with a shellfish interest. In addition, The Agency provides guidance and direction to LFAs via formal statutory Enforcement Codes of Practice and Guidance. This is seen as a mandatory activity by the Food and Veterinary Office of the EU.

The FSA directly engage with the LFA Officers throughout the classification process and in relation to the monitoring programmes as a whole. The Scottish Fish Hygiene Working Group, meets four times a year. Additional focussed meetings may be called on a more regular basis where necessary. The group are consulted on FSA guidance in the relation to shellfish and assist in identifying officer training needs in the area. These needs are supported by the FSA under a low cost training initiative. This initiative financially assists LFAs in staff training.

The LFAs are audited by the FSAS to ensure that they are implementing the legislation properly. The FSAS as central competent authority is subject to audit by the Food and Veterinary Officers of the EC to ensure that it is properly and adequately implementing the relevant European Directives and associated decisions.
11.3.2 Interaction with consumers

The FSAS has the principle of consumer protection as one of its core values. Interaction with consumers is therefore an important aspect of the FSA’s work. All production area classifications are communicated to all interested parties and additionally published on the FSA website.

This allows consumers direct access to classification details. In addition, the United Kingdom legislation ensures the clear labelling of all shellfish. This ensures that the consumer has knowledge as to source and classification of shellfish purchased in a retail establishment in a wrapped condition.

Any public shellfish gathering area is subject to public notices and press publicity if any harvesting restrictions apply. This ensures that casual gatherers are alerted to the potential danger of gathering shellfish from the contaminated area.

Furthermore, any allegations of foodborne illness as a result of shellfish consumption is subject to formal investigation through a network of public health specialists including the LFAs and Community Public Health Medicine Specialists.

11.3.3 Interaction with industry

The microbiological official control monitoring programme results in the collation of data which allows the classification of the shellfish harvesting areas to be determined. This programme is therefore of direct interest to industry whose business is partly dependent upon the classification granted by the FSA.

Industry is advised on an ongoing basis of all results pertinent to their site. This information is communicated via the LFA who is provided with all site results by the FSA on a weekly basis. Any results found to be outside the current classification status are communicated immediately to allow the harvester and LFA to conduct an on-site investigation and re-sampled where determined necessary. The harvester is essential to the proper running of the monitoring programme. They assist the LFA in collecting and transporting samples to the contract laboratory. As such they have an integral role and interest in the programme. In order to support their role the FSA has produced guidance and protocols in the advised method of sample collection and transportation as well as protocols on the classification system as a whole.

It is imperative within Scotland to have a system which allows classification decisions which have such importance to the individual harvesters to be open to challenge and appeal. As a result the FSA has a formal appeals procedure which allows harvesters to appeal their annual classification. The basis for appeal must
be communicated in writing using a standard application form. During this process the harvester may ask for the results of his own sample analysis to be accounted. It is mandatory that the samples have been taken by approved methods and analysed using the National Reference Laboratory accredited method in a United Kingdom Accreditation Service approved laboratory.

The FSA meets regularly with the main industry body, the Association of Scottish Shellfish Gatherers. This assists in ensuring adequate communication and also allows the FSA to ensure that industry responsibilities are properly understood. EU Regulation places responsibility upon the industry to ensure that shellfish placed on the market are within their given classification and meet end product standards. Compliance with these requirements is audited and enforced by the LFA.

11.3.4 Interaction with other official bodies

The Scottish Environmental Protection Agency (SEPA) has a key role in the monitoring of designated waters and in the control of pollution within these areas. The FSA promotes communication with SEPA where microbiological results are received which indicate that a pollution event may have occurred within a classified shellfish production area. The LFA is responsible for local communication with local Scottish Environmental Protection Agency officers. Local action groups, which comprise officers from SEPA, the LFA, Scottish Water and industry will investigate any unusual events with an objective to ensure that there is no ongoing contamination event which may affect shellfish safety.

On a regular basis the outcome of full sanitary surveys are shared with these bodies to assist in determining risks and action strategies to limit impact upon local shellfisheries.

11.4 MITIGATION MEASURES

11.4.1 Action where samples results are outside the classification limit

All samples received by the laboratory which are outside the current area limit are reported immediately. This information is directed to the LFA who communicate with the harvester as necessary. Dependant on circumstances (such as no natural explanation for elevated result, failure of repeat result), a site visit for investigation purposes may be undertaken as determined by a local action group. A resample may be taken and the harvester’s end-product test results will be inspected. This investigation may result in the classification
status being altered, depuration being instigated or in emergency situations, a Temporary Closure Notice being administered as allowed under EU 854/2004 (European Communities 2004). On these occasions communication with other bodies as described under section 11.3.4 takes place.

11.4.2 Treatment measures

In recognition of the fact that the process of depuration of shellfish is a specialist and high risk activity, FSAS contract technical experts to assist the LFA in the approval of these premises. The contractor is responsible for setting the working protocols for the system’s safe operation. The LFAs base their decision and scope of approval for the establishment upon this protocol and inspection report. Thereafter the contractor revisits the premises on an agreed risk-based frequency to ensure that parameters have not been altered. The LFAs will also visit the premises according to the risk-based system required under the principal Food Control Legislation, The Food Safety Act 1990 and associated Codes of Enforcement Practice.

The FSAS encourage and facilitate close working between the LFAs, contract technicians, the National Reference Laboratory for this area, The Centre for Environment, Fisheries and Aquaculture Science, and The Seafish Industry Authority whose depuration plant designs are endorsed for use within the United Kingdom.

The FSAS has produced LFAs guidance on the inspection of depuration facilities.

11.4.3 Control of production

EU 854/2004 (European Communities 2004a) allows harvesting of live shellfish to be prohibited where the LFA is satisfied that the consumption of the live shellfish is believed likely to cause a risk to public health. The LFA requires evidence with which it is satisfied to justify administering a Temporary Closure Notice. The Temporary Closure Notice has effect for a period of 28 days unless revoked earlier. In order to review the notice, ongoing evidence of a risk to public health is required.

The LFAs also have powers under The Food Safety Act 1990 to seize and detain any product unsuitable for consumption in so far as it may be injurious to health or not meeting food safety requirements as determined by a food examiner. The LFA also has responsibilities to conduct a sampling programme in addition to the Central Authority programme. In Scotland the local authority applies significant resource to supporting the Central Authority programme.
and hence only a proportionate amount of supplementary LFA samples are taken during routine inspection visits to the site and depuration facility. These samples are mainly for verification purposes but will be used to support local enforcement action where appropriate.

11.4.4 Product traceability and product recall procedures

All products placed on the market are required to be labelled appropriately to ensure complete traceability. Every step in the chain requires full traceability. The gatherer of the shellfish is required to ensure that each consignment is accompanied to a dispatch centre, relay area or processing establishment with a valid registration document. A registration document is provided to the gatherer by the LFA and permits the movement of each consignment from the harvest area to one of the approved establishments as mentioned above. The LFA is charged with responsibility for ensuring that such requests for documents are dealt with and for ensuring that the shellfish is accompanied by the appropriate paperwork. The harvester has responsibility for ensuring that the shellfish is accompanied by the correct documentation to ensure full traceability. Any area subject to a Temporary Closure Notice is automatically prohibited from the issue of such documentation.

After treatment or packaging at a dispatch centre, live shellfish must be provided with a health mark to ensure that the original dispatch centre may be identified at all times during distribution and sale. The health mark must indicate the country of dispatch, species, date of wrapping and approval number of the dispatch centre.

The United Kingdom has a system of food alerts which are used to recall product placed on the market which is subsequently found to be non-compliant in some respect. Minor non-compliance issues are in the main covered by alerts of a lower priority rating, providing information other than those where there is a potential danger to public health. Food Alerts are brought to the attention of the Central Authority via the LFA who may discover an issue in the course of their local enforcement activity or by the harvester/processor on discovering an issue during quality control procedures, customer complaints or via the EU Rapid Alert for Food and Feed Stuffs system. The Food Alert is administered by the Central Competent Authority and distributed to the LFA for action. Where affected product may have been purchased by the consumer, Press Notices are arranged to bring the matter to the attention of any potential purchaser. All Food Alerts are additionally published on the FSA website. A formal Food Alert will only be used where necessary to protect public health and where a trade withdrawal on the part of the producer/processor is not appropriate or adequate.
11.5 COMMUNICATION OF OFFICIAL CONTROL RESULTS AND MITIGATION ACTIONS

Communication of official control results is very important. The LFA is responsible for managing shellfish harvesting production areas at local level and therefore sampling results from the programme are essential to assist them in determining whether any mitigation action is necessary. The LFA, along with the site harvester, is responsible for gathering the shellfish samples for the programme and for sending these to the laboratory contracted by the FSA for undertaking the flesh analysis. The FSA funds the analysis of these samples and manages the contract for this analysis. All results are communicated to the FSA weekly. These results are forwarded to the LFA as soon as quality checks are completed on the data. The LFA sends this data to individual site harvesters so that they are aware of the results from their site.

Additionally, any samples which are found to be outside the current site classification limits are notified to the FSA immediately after the results are known. These are directed to the LFA immediately to allow them to conduct any necessary site investigation. In the majority of cases a further sample is taken to assist in determining whether there is an ongoing problem. Where a problem is identified other relevant investigatory agencies will be called to assist. In Scotland SEPA will be asked to investigate any potential sewerage contamination issues and to take appropriate action. Where an ongoing matter of public health significance is identified, the site will be subject to harvesting restriction by use of a Temporary Prohibition Order. This will remain in force until the LFA is satisfied that it is safe to resume harvest. In the event of such an incident the opinion of the National Reference Laboratory experts will be sought during the investigation. The National Reference Laboratory in these circumstances as funded by The Agency provides this service to LFAs. Temporary Closure Notices are lifted once perceived risk has been removed and two consecutive results taken at fortnightly intervals illustrate that results are within those acceptable for the area’s classification status.

11.6 CONCLUSIONS – STRENGTHS AND WEAKNESSES OF THE FOOD STANDARDS AGENCY CURRENT SYSTEM

There are a number of strengths with the current system as operated by the FSAS. Firstly, all official control results are taken by dedicated Official Control sampling officers. The LFA employs these officers with grant-assisted funding
from the FSAS. These officers all receive benchmark training in all aspects of their duties, which is provided by the FSA with assistance from the National Reference Laboratory and the official control laboratories involved in the programme. Their function is to ensure that the areas are adequately controlled, that samples are gathered from correct locations and verified and that the programme is operated according to the requirements stipulated under EU 882/2004 (European Communities 2004b). This requires that official control samples are taken in the absence of bias and conflict of interest. The strength lies in having high quality officers who execute controls and ensure that samples are gathered according to timetable and from a verified location. The verification of samples is a fundamental part of the monitoring programme and allows all further regulatory decisions to be taken with confidence.

Training of all officers involved at local level is also a key strength to ensure that LFAs maintain the necessary expertise in this technical area. The FSA ensures a high skill base by provision of regular training for all officers including in the field of depuration plant inspection, sanitary survey process and management of outbreaks of infectious disease in relation to shellfish. A comprehensive package of Codes of Practice and Guidance documentation is provided to assist with uniform and consistent application of enforcement practices.

The handling of incidences related to shellfish is also subject to a formal system, which is documented and assists in the orderly management of such events. Formal communication channels are also strengths of the programme. These have been set up both locally and nationally to allow for adequate flow of information. These channels would, however benefit from the creation of written local action plans to support local action group activity for each area and this issue will be addressed in the near future.

11.7 REFERENCES

