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**CLASSIFICATION OF LIVE
BIVALVE MOLLUSCS IN
SCOTLAND.**

**PROTOCOL
FOR CLASSIFICATION AND
MANAGEMENT OF *E.COLI*
RESULTS v. 2 March 2012**

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GLOSSARY

FSAS	Food Standards Agency Scotland
FSA	Food Standards Agency
LFA	Local Food Authority
MICRO LAB	Official control Microbiological Laboratory
EU	European Union
NRL	National Reference Laboratory
E.COLI RMP	Representative Monitoring Point for <u><i>E.coli</i></u>
EPT	End Product Test
<i>E.coli</i>	Escherichia coli
MPN	Most Probable Number
EHO	Environmental Health Officer
SIN	Site Identification Number
LAG	Local Action Group
LAP	Local Action Plan
TCN	Temporary Closure Notice
HPS	Health Protection Scotland
LBM	Live Bivalve Mollusc
FBO	Food Business Operator
CEN	European Committee for Standardization
SSC	Sanitary Survey Consultant
SEPA	Scottish Environmental Protection Agency
SW	Scottish Water

CURRENT SUPPLIERS OF SERVICES		Effective at:
Official control Microbiological Laboratory	Neogen The Dairy School, Auchincruive, Ayr, KA6 5HW, Scotland, UK	March 2011
Official control Microbiological Laboratory	SSQC, NAFC Marine Centre, Port Arthur, Scalloway, Shetland, ZE1 0UN	July 2009
National Reference Laboratory	CEFAS, Berrack Road, The Nothe, Weymouth, Dorset DT4 8UB	July 2009
Sanitary Survey Consultant	CEFAS, Berrack Road, The Nothe, Weymouth, Dorset DT4 8UB	July 2009

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1. Executive Summary

Background

The classification protocol is intended to give direction on the classification of shellfish harvesting areas programme run by the Food Standards Agency Scotland (FSAS) under Regulation (EC) 854/2004.

Representative Monitoring Points

The system is based on a chain of Representative Monitoring Points (E.COLI RMP s). These identified points will submit a minimum of 10 samples and a maximum of 12 samples in separate months per year for classification purposes (unless otherwise dictated by a Sanitary Survey). **Samples should be prioritised to be taken in months not sampled the previous year.** For the most up to date list of classified areas in Scotland, please go to www.food.gov.uk/foodindustry/farmingfood/shellfish/shellharvestareas/

Samples and Classification

The protocol reflects the basic requirements of classification. In particular, it emphasises sampling requirements and gives examples as to how results of such sampling will relate to the final classification.

Application Forms for Classification of New Sites

Application forms for “Fast Track” and “Standard” applications are included for use when applying for a new site to be classified. The form should be completed by the Environmental Health Officer (EHO) in conjunction with the shellfish harvester.

Any application for classification should be submitted by the LFA to FSAS. Each application will be provided with a Site Identification Number (SIN). This SIN will be required to accompany all classification samples and should then be used on all future sample submission forms and be referenced in any correspondence. Please note that the MICRO LAB will not accept samples without a sample submission form quoting an accurate SIN and grid reference point (to an accuracy of 10m).

Appeals Procedure and Application Form

The appeals procedure is similar to the one used in previous years. However, following consultation with industry, the members who sit on the appeals panel have now changed (see section 10). Classification appeals can only be lodged after the draft classification document has been issued and must be received by FSAS within the specified timescales. Classifications provided during the year for new sites are provisional and not eligible for appeal. Further details of the appeals process and appeals panel are included in section 10 and Annex 4.

Site Identification Number (SIN)

In order to manage the classified areas effectively, the FSAS have allocated Site Identification Numbers to each production area and site. This number can be found in the classification document and is provided to each harvester and LFA upon receipt of a classification application form. The SIN consists of 2 letters (Local Authority initials), 3 numbers (Production area), 3 numbers (Site) and 2 numbers (species code).

It must be noted that a SIN is allocated to an area rather than an individual, since an individual may harvest in more than one Local Authority area. An area may also change ownership, or be subject to itinerant gathering.

Collection and Transport of Samples

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The quantity of product required to carry out the analysis is set down in the sampling protocol provided. Any samples arriving at the MICRO LAB out with the specified temperature range (1 to 8°C) will not be accepted (with the exception of local samples delivered to the laboratory within 4 hours of collection), so it is vital that the sampling protocol is followed. Samples must also be accompanied by a completed sample submission form with the correct SIN and accurate grid reference point to 10m.

FSAS has developed a Best Practice DVD focussed on shellfish sampling. If you would like to receive a copy please contact the Shellfish Unit at FSAS on Tel : 01224 288360

2. Legislation

Regulation (EC) 853/2004 specifies the health conditions for the production and placing on the market of live bivalve molluscs, tunicates, echinoderms and marine gastropods, such as Mussels, Oysters, Scallops and Razor Fish. Under Regulation (EC) 854/2004, the Food Standards Agency Scotland, as competent authority of the member state, must establish the location and fix the boundaries of shellfish harvesting areas. Thereafter, the boundaries can only be amended as deemed necessary by a sanitary survey. On the basis of the bacteriological criteria, using the faecal coliform indicating bacteria, *Escherichia coli* (*E. coli*), the competent authority must list and classify these harvesting areas according to the degree of contamination in samples of mollusc flesh.

The two Regulations are directly applicable with national enforcement powers being provided by the Food Hygiene (Scotland) 2006 Regulations.

Classification		Permitted Levels	Outcome	
	A	≤ 230	Less than or equal to 230 <i>E. coli</i> /100g flesh	May go direct for human consumption if end product standard met.
	B	231-4600	More than 230 and less than or equal to 4,600 <i>E. coli</i> /100g flesh (in 90% of samples)	Must be subject to purification, relaying in Class A area (to meet Category A requirements) or cooked by an approved method.
	C	4601-45,599	More than 4,600 and less than or equal to 46,000 <i>E. coli</i> /100g flesh	Must be subject to relaying for a period of at least 2 months or cooked by an approved method.
	46,000 and above <i>E. coli</i> /100g flesh			Prohibited. Harvesting not permitted

These Regulations highlight the necessity of obtaining more comprehensive environmental information regarding each Production Area classified after 1st January 2006. FSAS are applying this requirement retrospectively to all existing Production Areas. This information will usually be obtained by FSAS undertaking a “sanitary survey”.

Sanitary surveys identify sources of pollution/contamination such as sewage plants, industrial waste sources, sewage overflows and discharge from boats, storm drains, street runoff, rural land with domestic animals and forest or marsh areas dominated by wild animals and/or birds. These factors are then reviewed in conjunction with the effects of rainfall, river and tidal flows, farming activities, and geographical proximity from the source to the harvesting areas. Other environmental influences considered when generating a sanitary survey, include effects of season, temperature, sunshine and wind. For fast track applications, FSAS will in the first instance undertake a desk top sanitary survey and, depending on the results, a full sanitary survey may be required. For standard applications, a full sanitary survey will be required. The sanitary survey process is fully outlined in Section 18 and may take up to twelve months for new applications to be completed.

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Therefore, it is recommended that you contact FSAS to discuss any potential applications at the earliest opportunity, in order to expedite any requests for a sanitary survey.

FSAS reviews the classification of all shellfish harvesting areas in Scotland annually and relies on the previous three year data-set to inform classification decisions. Using a large data-set enables environmental factors and trends to be identified and considered. Under circumstances where an exceptional pollution incident occurs, FSAS will exclude those results, where appropriate, so the future area classification is not detrimentally affected by those poor results.

However, if the most recent complete year's results are consistent (i.e. all Class A all year) then these may override the requirement to consider a full 3 year data set.

3. Representative Monitoring Points

FSAS has set representative monitoring points (E.COLI RMPs) for all classified shellfish Production Areas. These points have been set in accordance with statistical analysis of the E.coli data and are a pre cursor to the sanitary survey requirement which all areas will undergo in due course. From 1 July, 2007, only E.COLI RMPs sample data will be used for classification purposes.

The intended acceptable tolerance of drift around an E.COLI RMP is 10m however, this can vary due to local circumstances. In some instances this may be up to 50 Meters for hand picked/raked and 250 Meters for dredged shellfish. Where there is doubt, FSAS should be consulted for advice on what constitutes acceptable drift in specific locations.

The E.COLI RMPs will be reviewed during the sanitary survey process, the outcome of which will provide a risk assessed sampling plan unique to each individual production area.

4. Types of Classification

Shellfish harvesting Production Areas may have a Full, Seasonal or Fast Track classification.

Full classification:

- is given to a Production Area where historical and current results are within a single category and allow for a straight A, B or C classification to be awarded.

Seasonal Classification:

- is awarded when a distinct pattern of results indicates the need for a Production Area to be classified as an A or B for one period of the year and B or C for the other. It should be noted that a production area can only have one consecutive period of each (unless special circumstances apply).

Fast Track Classification:

- is provided, following a fast track application, to an area requiring quick access to product usually wild harvesting. This process provides a provisional B classification in most circumstances. The classification is time limited to a 4 month period, with no harvesting permitted in the following 8 months.

For harvesters who wish to continuously harvest a wild shellfishery, a full classification may afford the best opportunity to do so in a sustainable way. In these circumstances, a harvester can use a fast track application process to get initially started, whilst submitting a standard classification application at the same time. This will allow quick access to the area with the longer term aim for full classification also being worked towards. Please note that FSAS do not carry out sampling for the purposes of investigating the viability of new areas.

5. Getting started

For new areas to be classified, either a “standard” or “fast track” application form must be completed and the required numbers of samples submitted. For fast track applications, harvesters should contact FSAS for advice on how many samples to submit. You should note this may vary from area to area pending the completion of desk-top survey. See further details at sections 6 and 7. Classification of shellfish harvesting areas is only possible when shellfish samples are taken by Officers from each Local Food Authority, where necessary, with the assistance of shellfish harvesters.

There is anecdotal evidence to suggest that immature or juvenile shellfish may give rise to *E.coli* results that are unrepresentative of mature stock harvested for commercial sale and thus human consumption. For this reason, all efforts should be made to ensure that only mature shellfish are sampled.

Samples are analysed by the MICRO LAB and results are sent weekly to FSAS for review. Results are then forwarded to the relevant Local Authority and in turn on to all harvesters within the relevant production area for information. All testing undertaken by the MICRO LAB is in accordance with the agreed method (ISO TS 16649 part 3). Results obtained using other methods are not acceptable for classification purposes. The MICRO LAB is UKAS accredited for this method and take part in the Health Protection Agency’s Food EQA Shellfish Scheme and UK NRL ring trials.

When a change of ownership of a site occurs within a classified production area, the harvester and/or LFA should notify the FSAS in writing with the appropriate details.

Each site within a production area will be allocated a unique Site Identification Number (SIN). Classifications are area based, may cover several sites and are species specific. Shellfish harvesters who have requested classification for more than one species in an area should ensure that samples of **each** species are submitted for analysis from the nominated E.COLI RMP (unless the use of an indicator species has been agreed with FSAS).

6. Standard Application and Sampling Requirements

In order to meet the obligations under 854/2004, FSAS will undertake a full sanitary survey in conjunction with the LFA, and other relevant bodies, to assess pollution input and potential contamination sources. In discussion with the harvester and LFA, an agreed number of samples from the area will be sent for analysis. The minimum number of samples will be 10 per year. In addition, monthly samples will be required for the remainder of the year, up to a maximum of 12 will be accepted (unless otherwise dictated by a sanitary survey). Where a harvester wishes to contribute additional samples for classification, they must use the protocol outlined in Section 17 and enter into a formal Memorandum of Understanding with FSAS. Full details of what this entails and how to proceed with an application for consideration are provided in annex 11. A standard classification application form can be found at annex 2.

FSAS do not wish to receive application forms from harvesters until there is adequate shellfish stock available for samples and a sanitary survey to be undertaken. Harvesters should also note that applications must be received by August if they wish to harvest within the next calendar year.

7. Fast Track Application and Sampling Requirements

This type of application may be required for a shellfish harvesting area for three reasons:

- A harvesting area which has a short harvesting period, for example *Ensis* spp. (razor fish) and wild sites
- An area that has not been classified before and is looking to be harvested quickly
- An area that was declassified due to insufficient samples being provided the previous year and is looking to be harvested quickly

In order to meet the obligations under 854/2004, FSAS will undertake a desktop sanitary survey in conjunction with the LFA and other relevant bodies to assess pollution input and potential contamination sources. In discussion with the harvester and the LFA, an agreed number of samples from specific grid references in the area will be sent for analysis. Provided the sample analysis and desktop survey does not highlight any significant contamination problem, the area will be given a provisional B Classification for a 4-month period. There is a requirement for monthly official control samples to be taken from the area to sustain the provisional classification for the remainder of the 4 month period. Failure to do so will result in the area being immediately declassified. After 4 months the area will be automatically declassified and the area is not permitted to be reclassified under fast-track system for a further 8 months. The harvester can however apply for a full classification which would necessitate a full sanitary survey. A fast track and standard classification can be applied for concurrently.

Potential harvesters should note that fast track applications will, at best, result in a provisional “B” classification being awarded on a precautionary basis. The only exception being where previous historic substantiated and consistent sample results are available that indicate a more favourable classification is warranted.

The FSAS recommend that shellfish harvesters and LFA Officers obtain advice from FSAS for fast track application, so that any limitations can be properly discussed and understood at the outset. A Fast Track Application Form is available at annex 3.

8. Classified Areas Sampling Frequency

For existing Production Areas, the minimum number of samples required to maintain a classification is 10 per E.COLI RMP in separate months over a twelve month period (unless otherwise dictated by a sanitary survey). The maximum number of samples per production area is 12 per ECOLI RMP. (for more information on E.COLI RMPs please see section 3).

Failure to submit the required number of regular samples can cause difficulty when assessing an area and subsequently awarding a classification. In cases where less than 10 samples, in separate months per E.COLI RMP are submitted, declassification will result (unless otherwise dictated by a sanitary survey). Exceptions will be considered in the case of wild shellfisheries on a case by case basis.

For areas that become commercially inactive for an extended period of time (6 months or more) due to low/immature stocks or formal closure, it may be possible to agree a reduced frequency of monitoring. In this instance the harvester or LFA should seek agreement with FSAS for the Production Area to be provided with a “dormant” status. Please be aware that before an area can have its dormant status revoked, two weekly biotoxin samples must be submitted the fortnight immediately prior to harvesting being permitted.

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FSAS and the LFA may request an increased monitoring frequency (e.g. fortnightly) for areas that have shown uncharacteristically high results (i.e. results out with the existing classification category of an area). Such samples are used to assist assessment of whether the underlying level of contamination has changed.

NB Samples taken in addition to the agreed monitoring frequency e.g. as requested by FSAS or the LFA will not be utilised for classification purposes but will be regarded as investigative only.

9. Classification Procedures

Classified shellfish Production Areas are monitored to ensure the annual classification is appropriate. The classification of the production area is dependent on the *E. coli* results of Official Control samples submitted to the MICRO LAB for analysis.

The present procedure used is as follows:

E. coli results are reported by the MICRO LAB to FSAS on a weekly basis and the data is categorised in accordance with Regulation EC 854/2004.

The table provided in Section 2 indicates the levels required for each classification grade.

- Classifications are recommended on the data received applying the requirements set down in EC 854/2004.
- These allow a 90% tolerance to be applied to class B areas. Therefore providing that 90% of received samples are within the B classification that classification will be applied.
- FSAS additionally awards seasonal classifications which allow for stable A or B periods of a year to be provided with that classification with those periods that habitually indicate fluctuating results to be classified B or C.
- The E.COLI RMP grid reference point for the area is recorded and set to a 10m accuracy. **E.COLI RMPs must not be changed unless otherwise dictated by a sanitary survey or scientific evidence. Where no shellfish are found within 10m of the nominated E.COLI RMP , FSAS should be contacted to agree sampling options.**
- The boundaries for new shellfish harvesting areas are plotted using Ordnance Survey map references. These are noted within the area classification document. Boundaries will not be changed unless otherwise dictated by sanitary survey.
- A Site Identification Number (SIN) is created using specific numbers to identify each Local Authority, production area, site and species.
- FSAS and the MICRO LAB independently assess the classification data. The National Reference Laboratory will be asked to arbitrate where FSAS and the MICRO LAB propose different classifications.

FSAS will produce a draft shellfish harvesting area classification document in January of each year, covering the period from April to the following March. This document will be provided to Local Authorities by FSAS, and distributed to harvesters in each council area by the Local Authority. A six week period will then be allowed for the appeals process. After the appeals process is complete, the final annual shellfish harvesting area classification document will then be distributed electronically to fisheries organisations and associations, LFA Officers, Scottish Fisheries Protection Officers, individual shellfish harvesters, divers, processors and trade organisations by FSAS. This information is also published on the FSA website (www.food.gov.uk/foodindustry/farmingfood/shellfish/shellharvestareas). This list will be updated where necessary. A flow diagram of the classification process can be found at Annex 3.

10. Making an appeal

EC Regulation 882/2004 provides shellfish harvesters the right to appeal the classification awarded by FSAS. FSAS has provided an appeals procedure for this purpose. Details are included at Annex 5. FSAS will only process appeal applications submitted within 6 weeks of the draft classification document being issued. The process allows appeals to be heard independently of those making the original classification. The appeals panel consists of 1 scientist, 1 member of the Scottish Food Advisory Committee and 1 member of Health Protection Scotland. Full details of this are provided in the Annex 5. Only results from UKAS accredited laboratories using the approved method of analysis (a five-tube, three-dilution MPN method and/or use of ISO TS 16649-3 as the reference method as per EU Regulations) can be considered for the basis of appeal. Please be aware that as at 1 January, 2007 the FSAS will not change the boundaries of any production area unless there are scientific reasons for doing so arising out of a completed sanitary survey.

A classification appeals application form can be found at Annex 5.

11. Declassification

This will occur under the following circumstances:

- Where a sanitary survey has dictated a sampling plan that hasn't been met.
- Where no sanitary survey has been completed and less than 10 samples, in separate months over twelve months have been submitted for a specific E.COLI RMP.
- *E.coli* levels are 46,000/100g and above flesh in a specific harvesting area for an extended period of time.
- Shellfish harvesting is no longer occurring at a specific site and declassification is requested;
- Areas have been identified where no harvesting has taken place for two years or more;
- The required number of samples for fast-track areas has not been received within the specified timescales.

A declassified Production Area seeking re-classification will have to make a new standard or fast track application and submit the required number of samples before re-classification can be considered.

12. Continual review of classification

In addition to the annual review, results will be monitored throughout the year and changes to classification issued when necessary to ensure that:

- Business owners can plan for depuration if required.
- Production can be suspended from Production Areas when results indicate a potential risk to public health.

However, it is the responsibility of the shellfish harvesters, within the classified Production Area, to obtain their results from their local Environmental Health Officer.

13. Guidance on Action When Results are Out With Classification

In Scotland, the Local Authority is advised by FSAS when a result has been received that is out with classification.

In these instances the LFA may consult with other parties including:

- The harvester
- FSAS
- Testing Laboratory at the MICRO LAB
- Local Industry
- SEPA
- Scottish Water
- Scottish Fisheries Protection Agency

The LFA should have action plans to cover results out with classification. These should be initiated when it becomes apparent to the LFA that these results are not readily explicable by natural conditions, such as heavy rainfall (following a dry period where run off may be higher). This is further outlined in part 14, Local Action Groups (LAG) and Local Action Plans (LAP).

For any unexplained C result labelled '>18,000', a further Official Control sample should be taken as soon as possible for further dilution testing, to determine whether the levels of E.coli present are over the statutory maximum (46,000 *E.coli*/100g). The LFA and the harvester may wish to agree a voluntary closure pending the results of further analysis, in the interests of public health. If further analysis indicates the result is over the statutory maximum, the area must be closed by a TCN (Temporary Closure Notice). The TCN can only be revoked once 2 Official Control samples, taken at least 7 days apart, yield results under the statutory maximum level.

A model TCN can be found at Annex 6 and a model revocation at Annex 7.

14. Local Action Group and Local Action Plan

Introduction

In Scotland, we currently have procedures in place to deal with high *E.coli* results from classified Production Areas.

This involves introducing two levels of alert states, **investigative** and **incident**. These alert states facilitate a more risk-managed approach when high contamination results occur, which will allow a more open and transparent system of investigation. The two alert states also provide a rapid response facility when levels exceed pre-defined trigger levels.

Our intention for implementation of such a control system includes setting up Local Action Groups (LAGs) and Local Action Plans (LAPs) for those authorities that have shellfish harvesting areas.

Role of Local Action Groups (LAGs)

This system will operate by means of Local Action Groups set up to deal with results out with classification above pre-determined levels. The work will range from providing advice, to more extensive incident investigations. This may result in a temporary downgrade/closure of the affected harvesting area, following the identification of a potential risk to public health. Each LAG is responsible for developing a LAP and laying down investigation procedures.

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The Local Action Group will consist of Officers from the LFA, FSAS, MICRO LAB, local SEPA Officers and the harvester. FSAS will provide the LFA with results out with classification, as is currently the case. Where necessary, the group will be involved in activities such as gathering data pertinent to local factors and/or conditions that may affect test results. The LFA will hold the contact details for their LAG.

The LAG is intended to centralise communication and information sharing, while aiding in the investigation of unusual results. The exchange of information will be on an electronic basis thus the impact on resource is expected to be minimal. The LAG encourages the sharing of expertise on specific local issues.

Classification

The LAG will not be able to overturn classification results or remove them from the classification data set. FSAS will however take note of any such recommendations that the LAG wishes to present. The decision on whether to act on this evidence-based recommendation will remain with FSAS, with advice where necessary obtained from the MICRO LAB and the UK NRL.

Results out with classification

The two alert states of response for results out with classification will be essential to ensure that the monitoring and reporting procedures are rapid. The criteria for action and therefore implementation of the LAG and LAP are as follows:

- Investigative State
- Incident State

Investigative State

This state will apply only to A and B Production Areas and is the first alert action level for results slightly out with classification (but below the "Incident State" trigger levels).

When an area is classified as:	Then a result in the range :	Activates an :
Class A	231 – 1000 E.coli/100g flesh	Investigative State
Class B	4601 – 9.100 E.coli/100g flesh	Investigative State

The LFA would initiate an investigation in consultation with the harvester, SEPA and FSAS, if required. In instances where there is no apparent reason for the high result (e.g. heavy rainfall preceding the sample) some assistance from the Local Action Group would be expected under the Local Action Plan in identifying a cause for the high level. **The LFA will need to decide what control measures are needed but temporary closure/restrictions are not expected unless it is deemed otherwise.**

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“Incident State”

This state applies to Class A, B or C Production Areas, where *E.coli* results are as follows :

When an area is classified as:	Then a results in the range :	Activates an
Class A	1001 <i>E.coli</i> /100g flesh and above	Incident State
Class B	9.101 <i>E.coli</i> /100g flesh and above	Incident State
Class C	18,000 <i>E.coli</i> /100g flesh and above	Incident State and Immediate TCN should be considered.

An “Incident State” is activated by the LFA who notify the relevant Local Action Group. The Local Action Group is required to implement the Local Action Plan to assist the authority to provide appropriate control measures. The LFA should implement the necessary control measures.

For any result above 18000 *E.coli*/100g flesh, the LAG should consider an immediate closure of the area.

If high results continue for 3 months or more, classification status is to be reconsidered by FSAS.

Establishing a Local Action Group (LAG)

All relevant LFAs with classified shellfish areas are required to establish a LAG and LAP as all will be subject to alert states if and/or when results for Class A, B or C Production Areas exceed levels specified above.

The LAG will provide LFAs with assistance in investigations of unusually high *E.coli* results under “Incident State” investigation. The LAG should develop LAPs specific to local areas (with the MICRO LAB/FSAS input) to ensure effective and timely information exchange and contribute data and local knowledge. Electronic exchange of information is expected rather than formal meetings and is not expected to be resource intensive.

Formulating a Local Action Plan (LAP)

In order to facilitate this process, it is recommended that the Local Action Group set up and maintain a LAP. This should clarify the process of data collection and exchange as well as identify what measures are to be put in place or removed when an “Incident State” occurs. A template for a LAP is provided at annex 9.

The effectiveness of the LAP relies on it being tailored to specific local needs to enhance existing measures of public health protection. All members of the Local Action Group should therefore be involved in the development of the LAP, and be aware of its function and scope within the two alert states as described in section 3. LAPs should consider the appropriate action and investigations that may be required when *E.coli* results are out with classification and should take into account likely pollution scenarios in these circumstances. The swift implementation of the LAP is of prime importance and must contain contact details for the LAG members, FSAS and other relevant personnel.

All outputs from the investigation undertaken by the LAG upon implementation of the LAP should be provided to FSAS.

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In general terms the LAP should:

- Be sent to FSAS for review and approval indicating the LFA responsibilities as co-ordinator.
- Be ready for use prior to contamination events occurring. They should cover all E.COLI RMPs over which the LFA has responsibility.
- Detail methods and scope of communication.
- Allow for shared responsibilities with other Authorities while giving a clear indication of who takes the lead as the co-ordinator.
- Indicate who should receive information internally and externally.
- Clarify how and in what format this information will be fed back to FSAS.
- Indicate criteria for lifting control measures, ending investigations and time scales for reporting of the outcome.

Checklist for the setting up LAGs and LAPs

1. Note request from the FSAS to form a LAG.
2. Contact SEPA representative to discuss preferences and identify other authorities.
3. Contact harvesters to discuss preferences for being part of the group.
4. Invite relevant bodies/associations with interests to be member of LAG e.g. Scottish Water representative.
5. Formulate LAP based on template and recommendations in conjunction with members of the LAG.
6. Notify and agree plans with FSAS, who should be informed by the LAG at all relevant points.

15. Official Control Sampling Officers

FSAS is committed to ensuring that Official Control samples are taken without bias or potential conflict of interest in accordance with the requirements of Regulation 882/2004.

It is believed that all Official Control samples should be verified as originating from a specified area and grid reference point (to a 10m accuracy) within that area. The best way of achieving this, is to ensure that sampling officers are directly involved in assisting harvesters with the gathering and verification of these samples.

Up until April 2012, local authorities will continue to provide sampling officer functions through funding from FSAS. From April 2012 onwards, following an open tender process in 2011, these services will be undertaken by the following contractors:

FROM APRIL 2012:

- Highland Council: LFA
- Argyll & Bute Council: LFA
- Shetland, Orkney, Comhairle nan Eilean Siar and Fife council areas: Hallmark Meat Hygiene Ltd
- Dumfries and Galloway; North and South Ayrshire council areas: FSA Operations Group staff

These Officers assist industry in gathering their samples and ensure that best practice is adhered to at all times. Benchmark training is provided to these officers by their LFA and FSAS in conjunction with the UK NRL.

Shellfish Officers ensure that the Official Control sampling timetables for *E.coli*, biotoxin, phytoplankton and chemical contaminants are fulfilled.

16. Sampling Procedure Best Practice

Shellfish samples that undergo microbiological analysis must be maintained in a temperature stable environment (1-8°C) to avoid misleading test results. In order to ensure sample results provide an accurate representation of the shellfish area, it must be taken from the correct E.COLI RMP or nominated sampling point, be handled under the best possible hygiene conditions, taken and packaged as soon as possible and placed in a temperature controlled environment.

Taking samples

At all times, please ensure you take the necessary steps to ensure your personal safety and ensure that all equipment is fit for use.

1. Shellfish samples should be collected from each micro RMP from the grid reference specified by the FSAS.

2. Ideally samples should be collected between Monday and Wednesday and sent to the MICRO LAB by the means pre-arranged with the MICRO LAB for receipt by Thursday afternoon. The MICRO LAB need to be notified when samples are timetables for collection, preferably the week before, and of any changes to the timetable.

3. Samples to be mature stock of commercial size.

Quantity required per Species

Common mussels	15 – 30	King scallops	10 - 12
Pacific oysters	12 – 18	Queen scallops	15 – 30
Native oysters	12 – 18	Sand gapers	10 - 12
Common cockles	30 – 50	Surf clams	30 – 50
Razor shells	10 - 12	Otter shells	minimum of 12
		Carpet clams	18 – 35

4. Samples to be cleaned on site by scrubbing individually and rinsing in fresh seawater from the location. Gloves and equipment for this purpose to be cleaned beforehand. Excess water to be drained off the sample before bagging up.

5. Samples must be accompanied by a Sample Submission Form quoting an accurate SIN, the grid reference point from which the sample was taken and the date and time of collection.

7. Samples should be placed in a re-sealable bag, which is put inside a second re-sealable bag. The double bagged sample should be put in a third bag along with the thermometer and sample submission form and firmly sealed.

8. The sample should be placed in a cool box with 8 ice packs (4 below and 4 above) and protected from direct contact with the ice packs using foam. The samples should reach the MICRO LAB within the 1° – 8°C range otherwise they will be REJECTED for testing.

9. The box should be sealed and either posted to the MICRO LAB at a post office by special delivery using the pre-printed label provided or delivered by hand. The aim of the MICRO LAB is to receive samples within 24 hours of collection.

17. Use of Harvester's Own Results

EC 854/2004 allows for the results of harvester samples to be taken into account for the purposes of Official Control decision making. These results will only be considered if taken in accordance with an agreed protocol.

It is possible, therefore, for harvesters to supplement the FSAS Official Control *E.coli* monitoring results with their own results, including those taken as part of the harvester's end product testing regime, if:

- Samples are taken in accordance with the protocol provided at annex 11.
- Samples are taken from a nominated E.COLI RMP only as agreed with FSAS
- **Harvesters ensure:**
 - that any agreed timetable is met in full.
 - that the official reference method (ISO TS 16649 part 3) is used in analysis of such samples. Results obtained using other methods are not acceptable for classification purposes.
 - that all results are provided to FSAS.
 - that agreed timelines for submission of sample results are met (failure to do so could delay the classification process).
 - that sample result data is provided to FSAS in an agreed and FSAS compatible format.
 - to facilitate any potential audits of such agreed processes by LFA officers.
 - that a Memorandum of Understanding is agreed upon and signed

18. Sanitary Survey Implementation

Regulation 854/2004 lays down explicit requirements for the classification of shellfish Production Areas. As part of the controls to protect public health, the Regulation requires the competent authority in Member States to carry out a programme of sanitary surveys prior to classification of any new production areas.

Regulation 854/2004 states that if the competent authority decides in principle to classify a production or relaying area, it must:

- (a) make an inventory of the sources of pollution of human or animal origin likely to be a source of contamination for the production area;
- (b) examine the quantities of organic pollutants that 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, waste-water treatment, etc.;
- (c) determine the characteristics of the circulation of pollutants by virtue of current patterns, bathymetry and the tidal cycle in the production area; and
- (d) establish a sampling programme of bivalve molluscs, tunicates, echinoderms and marine gastropods in the production area that 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.

Desk Top Survey

As much relevant information as possible will be obtained from existing sources of information and other government bodies such as SEPA and SW.

This information will detail the following.

- ◆ Continuous sewage discharges, rainfall dependent sewage discharges (combines sewer overflows or storm tank overflows, storm water discharges) and Emergency discharges.
- ◆ The location of the above discharges, their size, treatment, sanitary content and load.
- ◆ Land Use – including seasonal variations in use and application of manure on farmed land
- ◆ Farm Animals – location, type, management of waste
- ◆ Wildlife
- ◆ Ships and Boats – in particular their activity and discharge restrictions or allowances

This stage is intended to be a desk top survey, gathering information already held by FSAS and other parties.

Shoreline Survey

The shoreline survey should be undertaken where necessary and is intended to ensure that all known sources of contamination have been identified. It will entail the physical inspection of the land adjacent to the shellfishery. Any shoreline survey undertaken will result in a report noting all relevant information. The objectives of the shoreline survey will be:

- ◆ To confirm the information on the location and extent of the shellfishery.
- ◆ To confirm the presence of sources of contamination identified within the desk study.
- ◆ To identify additional sources of contamination that may impact on the shellfishery.
- ◆ To sample shellfish and water from the sea.
- ◆ To sample water from the sea, discharges and any other sources.

Hydrography / Hydrodynamics

Hydrography/Hydrodynamics will fulfil the requirement to determine characteristics of the circulation of pollution, appreciating current pattern, bathymetry and tidal cycle. The following methods will be used:

- ◆ Tidal charts/tidal stream software – should be the minimum level employed. It is understood that for some Scottish lochs information from this source may be limited.
- ◆ Simple hydrodynamic modelling – generic packages to enable simple models to be produced are available and could be used for this purposes. Where such packages are to be used or recommended for use, their scope, use and any limitations should be made clear at the outset. It is expected however, that such models will be useful for large Production Areas, especially where the sanitary survey and any bacteriological surveys give conflicting results, where unexpected high *E.coli* results are obtained often in the routine monitoring programme or where the area has been associated with any suspected outbreaks of food borne disease.
- ◆ Complex hydrodynamic models are available however, these are hugely resource intensive. We do not envisage these being used in the programme, however, where these already exist there may be the potential to share these complex models (via SEPA/Scottish Water etc).

Bacteriological Survey (New Areas) where necessary

Such survey is to be undertaken only where the desk top survey and shoreline survey has not established a clear Representative Monitoring Point (E.COLI RMP) to be set or where the area is under a new application. To set an E.COLI RMP for a new production area, samples of flesh and water may be required to assist in determination of the E.COLI RMP.

- ◆ E.COLI RMPs are already set for existing areas. It is recognised that these E.COLI RMPs will require review as part of the sanitary survey process. New Production Areas will require assessment and E.COLI RMPs to be set.
- ◆ SS will coordinate analysis of any samples taken either in their own laboratory or within a laboratory sub-contracted for this purpose.
- ◆ It is expected that samples of shellfish flesh and water may be necessary in conducting a bacteriological survey.
- ◆ Samples should be able to be analysed for *E.coli* and potentially norovirus.
- ◆ In all instances the *E.coli* test will be carried out using the stated reference method ISO TS 16649-3. The MICRO LAB facility used, will be UKAS accredited to this standard. Details of the SOP for this method are available on the NRL website at www.nrlcefas.org
- ◆ Where analysis for norovirus is determined to be necessary the method used is that defined by Jothikmar et al. (Jothikmar,N.,J.A. Lowther, K. Henshilwood, D.N.Lees, V.R Hill, and J. Vinje .2005. Rapid and sensitive detection of noroviruses using TaqMan-based one-step

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RT-PCR assays and application to clinical and naturally contaminated shellfish samples. Appl. Environ. Microbiol. 71:1870-1875) will be used until the draft CEN method is made publicly available.

- ◆ Sample collection and transport will be undertaken in accordance with the NRL protocol and handled at the MICRO LAB according to their published procedures.
- ◆ Where necessary, salinity monitoring may be desirable particularly where areas may have impact from rainfall associated discharges or diffuse input.

Compilation of report

A report will be produced at the conclusion of each sanitary survey. The report will detail:

- ◆ Overview of shellfishery.
- ◆ Bivalve species.
- ◆ Harvesting pattern.
- ◆ Harvesting techniques.
- ◆ Conservation method(s) if applicable.
- ◆ Hydrography/hydrodynamics.
- ◆ Location, size and treatment level of human sources of contamination.
- ◆ Location and estimated volume/load of agriculture sources of contamination.
- ◆ Significant wild animal/bird populations
- ◆ Maps, seasonality effects for these factors.
- ◆ Records of shoreline surveys where these have been carried out.
- ◆ Record of baseline bacteriological monitoring results and or salinity results (where these have been carried out).
- ◆ Expert Assessment of effect on contamination of shellfish.
- ◆ A full practical sampling plan for the area with identified E.COLI RMP (s) where applicable.
- ◆ If it is felt that identified risks cannot be adequately controlled by use of a sampling plan, this must be made clear in the end report.

Sampling plan for area with E.COLI RMP identified

The survey will result in the development of a sampling plan for implementation in the Production Area. It will:

- ◆ Detail co-ordinates for the Production Area boundary.
- ◆ Detail E.COLI RMP /s for the Production Area.
- ◆ Detail number of samples to be taken from each E.COLI RMP.
- ◆ Detail month/s during which E.COLI RMP samples should be taken.
- ◆ Properly reflect the control of the likely risk of pathogen contamination on the shellfish.
- ◆ Be designed to ensure that effective monitoring is carried out with respect to the potential polluting impacts and that public health is prioritised.

Openness and Inclusiveness

Harvesters will be informed in advance when the sanitary survey is scheduled to take place and given the opportunity to be present during any shoreline or bacteriological survey being undertaken. The new sampling plan will be shared with the harvester at the earliest opportunity.

Once the Sanitary Survey sampling plan has been established, the classification process will rely on data derived from those samples taken in accordance with that plan.

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A general report of the sanitary survey outcome, as outlined in the compilation of report section above, will be produced. A copy will be provided directly to the harvester and the LFA for comment. The final report will then be published.

FREQUENTLY ASKED QUESTIONS ON SANITARY SURVEYS (FAQSS)

When should I apply for a Sanitary Survey?

It can take up to 12 months before a Sanitary survey is completed. Therefore, it is recommended that you contact FSAS at the earliest planning stages to discuss any potential application.

How will the Sanitary Survey affect my classification?

The purpose of the Sanitary Survey is to provide a sampling plan with guidance on the RMP and area boundary. It is not intended to determine classification of an area.

Reference No:

*** Mandatory Fields**

Please Note: If any fields marked with an * have not been fully completed your application form will be sent back.

**STANDARD APPLICATION FORM FOR
 CLASSIFICATION OF SHELLFISH HARVESTING AREA**

APPLICANT DETAILS			LOCAL AUTHORITY DETAILS		
*Name of Applicant:			*Name of Authority:		
Name of Company:			*Enforcement Officer:		
*Address:			*Address:		
*Contact Information:	*Tel No:		*Contact Information:	*Tel No:	
	Mobile Tel No:			Mobile Tel No:	
	Fax No:			Fax No:	
Email:			Email:		

HARVESTING DETAILS	SITE DETAILS						
*Species: (any others?) Pacific Oyster (<i>Crassostrea gigas</i>) Native Oyster (<i>Ostrea edulis</i>) King Scallop (<i>Pecten maximus</i>) Queen Scallop (<i>Aequipecten opercularis</i>) Common Mussel (<i>Mytilus edulis</i>) Sand Gaper (<i>Mya arenaria</i>) Common Razor Fish (<i>Ensis Ensis</i>)	<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%; text-align: center;">1.</td> <td></td> </tr> <tr> <td style="text-align: center;">2.</td> <td></td> </tr> <tr> <td style="text-align: center;">3.</td> <td></td> </tr> </table> Site Name and Area (e.g. site one, area 2 or Mussel Point, Shellfish Bay)	1.		2.		3.	
1.							
2.							
3.							

Reference No:

*** Mandatory Fields**

Please Note: If any fields marked with an * have not been fully completed your application form will be sent back.

<p>Common Cockle (<i>Cerastoderma edule</i>) Surf Clam (<i>Spisula solida</i>) Icelandic Cyprine (<i>Arctica islandica</i>) Carpet Clam (<i>Venerupis senegalensis</i>) <i>Venus Clam</i> (<i>Chamelea gallina</i>) Rayed Artemis (<i>Dosinia exoleta</i>) Horse Mussel (<i>Modiolus modiolus</i>) Brown Crab (<i>Cancer pagurus</i>) Green Crab (<i>Carcinus maenas</i>) Nephrops (<i>Nephrops norvegicus</i>) Periwinkles (<i>Littorina littorea</i>) Whelks (<i>Buccinum spp</i>) ANY OTHER (PLEASE SPECIFY)</p>		
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Reference No:

*** Mandatory Fields**

Please Note: If any fields marked with an * have not been fully completed your application form will be sent back.

Is this site within currently classified production area?

Yes

No

If No, has this site previously been classified?

Yes

No

If yes, please provide year

SAMPLING

A minimum of 10 samples in separate months (with a maximum of 12) are required for a standard application.

*Grid reference of samples taken must be to a 10m accuracy (e.g. NM 9741 3512):
(Please note longitude and latitude are not acceptable). Grid reference(s) should be annotated below:

Grid Ref(s):

Reference No:

*** Mandatory Fields**

Please Note: If any fields marked with an * have not been fully completed your application form will be sent back.

ANY OTHER RELEVANT INFORMATION:

***SANITARY SURVEY INVESTIGATION INFORMATION:**

***Are any of the following located within the area surrounding or area within your site? (YES/NO)**

- Private/municipal sewage plant(s)?
- Industrial waste source(s) (e.g. meat processing plants etc.)?
- Combined sewage overflow(s)?
- Animal feed or poultry house(s)?
- Boating Activity?
- Storm drains or street runoff?
- Rural land with domestic animals?

Signature of applicant:

Date:

Important Information

On submission of a fully completed application form, the FSAS, will propose to process your application within 21 days of receipt. Where application forms have details important to your application missing, then delay in processing your application may occur. In extreme cases, missing details may result in return of the form so as to obtain clarification on relevant points.

The FSAS Classification of Shellfish Harvesting Areas Protocol will give you full details of the classification process and allow you to judge which classification is best suited to the needs of the Production Area.

FSAS staff will be able to assist you in completion of this application form if necessary.

Should you require further information regarding your application or the classification process, please contact the FSAS Shellfish Unit on 01224 285190

Annex 2
ESAS/MICRO LAB USE ONLY

Reference No:

*** Mandatory Fields**

Please Note: If any fields marked with an * have not been fully completed your application form will be sent back.



**FAST TRACK APPLICATION FORM FOR
 CLASSIFICATION OF SHELLFISH HARVESTING AREA**

APPLICANT DETAILS			LOCAL AUTHORITY DETAILS		
*Name of Applicant:			*Name of Authority:		
Name of Company:			*Enforcement Officer:		
*Address:			*Address:		
*Contact Information:	*Tel No:		*Contact Information:	*Tel No:	
	Mobile Tel No:			Mobile Tel No:	
	Fax No:			Fax No:	
Email:			Email:		

HARVESTING DETAILS		SITE DETAILS
*Species: (any others?) Pacific Oyster (<i>Crassostrea gigas</i>) Native Oyster (<i>Ostrea edulis</i>) King Scallop (<i>Pecten maximus</i>) Queen Scallop (<i>Aequipecten opercularis</i>)	1.	Site Name and Area (e.g. site one, area 2 or Mussel Point, Shellfish Bay)
	2.	

