Guidance for inspection of shellfish purification systems for Local Food Authorities

Local Authority Food Law Enforcement Branch
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CONTENTS

1. INTRODUCTION

The Regulation (EC) 853/2004 specifies the health conditions for the production and placing on the market of live bivalve molluscs. Under Regulation (EC) 854/2004. The Food Standards Agency Scotland (FSAS), as competent authority is responsible for setting the technical approval conditions for depuration tank systems

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

This document outlines parameters that are critical for successful depuration and give guidance to Food Authority officers on aspects of system design and operation that require attention during inspection.

Regulation 854/2004 and 2073/2005 lays down the end product standards required for shellfish.

Shellfish require to meet category 'A' quality before being placed on the market. This is determined to be <230 *E.coli*/100g shellfish flesh. Shellfish can move legitimately between harvesters provided that they are accompanied by a registration form. However once they enter an approved premises they must meet the end product standard before the approved premise number can be applied. Where an approved premises therefore wishes to wash, sort, pack and despatch shellfish they must also ensure that the end product standard is met, hence for Class B product (.230 – 4,600 *E.coli*/100g shellfish flesh), relaying, depuration or heat treatment must be applied.

Product of 'C' class standard (>4,600 *E.coli*/100g shellfish flesh) must be subject to relaying to ensure that it meets the category 'A' standard.

The table below summarises the standards required for each class of shellfish.

Classification			Permitted Levels	Outcome
	A	<230	Less than 230 *E. coli*/100g flesh	May go direct for human consumption if end product standard met.
	B	<4600	Less than 4,600 *E. coli*/100g flesh	Must be subject to purification, relaying in Class A area (to meet Category A requirements)or cooked by an approved method.
	C	<46000	Less than 46,000 *E.coli*/100g flesh	Must be subject to relaying for a period of at least 2 months or cooked by an approved method.
	Above 46,000 *E.coli*/100g flesh			Prohibited. Harvesting not permitted

1.1. Principles of the depuration process

The depuration process involves placing shellfish into a purpose made tank which is then filled with clean seawater. In the UK, seawater is treated by ultraviolet (UV) disinfection prior to purification to prevent possible contamination of shellfish during the process. Water is then recycled through the system via the UV unit and a cascade or spray bar to allow sufficient aeration of the water for the shellfish to function normally. Given the correct physiological conditions, shellfish will resume normal filter-feeding activity and excrete contaminants in their faeces. The faecal material produced should be allowed to settle to the bottom of the tank and then be removed at the end of the cycle. There are a number of requirements that are detailed in the Regulations for the construction and general running of purification centres. These cover elements such as the operation of batch systems, non-mixing of species during purification and the requirement that purified shellfish must meet an end product standard of <230 E.coli /100g of shellfish. As far as the purification process itself is concerned three essential features are identified, namely, that shellfish should rapidly resume filter-feeding activity, remove sewage contamination and not become recontaminated.

1.2. Shellfish Intended For Depuration

Live bivalve molluscs that are to undergo depuration effectively must be in good condition. They are sensitive animals that are susceptible to temperature extremes and physical shock. It is therefore vital to ensure that good harvesting and general handling practices are followed so that the animals are not unduly stressed

At all times post-harvesting, the re-immersion of live bivalve molluscs (other than during depuration) should be avoided.

Before they are loaded in the depuration tank, shellfish must be washed and sorted. Any batch of shellfish undergoing purification must be of the same species and from the same class of production area.

Whilst most shellfish can be harvested by mechanical means, cockles (*Cerastoderma edule*) have been shown to exhibit high levels of mortality under depuration conditions due to the damage and general stress caused by such practices, in particular by suction dredges. The effect of such harvesting on razor clams (*Ensis spp*.) is unclear. **Consequently, it is currently a requirement that cockles and razor clams are only hand-gathered if they are to be depurated.**

1.3. Requirements for depuration systems

For depuration to be effective in removing microbiological contamination, the design of the system and the operation of the entire process must:

- allow rapid resumption of filter-feeding
- facilitate removal of contaminants from the shellfish
- avoid recontamination of the shellfish

The parameters that are considered critical to achieve these requirements are set out below.

1.3.1. Rapid resumption of filter-feeding activity

In order that normal filter feeding may take place, it is essential to create the correct physiological conditions for the shellfish being depurated and these are outlined below.

Dissolved oxygen

To facilitate normal shellfish activity, sufficient oxygen must be available in the water. Minimum dissolved oxygen levels of 50% saturation are recommended for purification systems, however a well designed and operated system will maintain levels that are much higher than this. In recirculating systems the dissolved oxygen content of the water can be affected by a number of factors such as water surface area to volume ratios; flow rates; shellfish to water ratios; seawater temperature; the metabolic rate of shellfish under purification (which may be environmentally and/or genetically determined); seawater salinity and the method of aeration used in the system. All these factors must therefore be carefully controlled during the purification process. The method of aeration must not disturb the normal activity of the shellfish, or the settlement of shellfish faecal material. In addition, the presence of small gas bubbles in the water may inhibit respiration of the shellfish by blocking gas exchange in the gill tissue.

Primary aeration is normally by means of a cascade but supplementary aeration may be added by using air diffusers placed in the bottom of the tank or sump provided such aeration does not disturb the molluscs or the settling of faecal material.

Loading

Shellfish must be loaded in the trays at a density that allows them the space to be able to function normally. They should be able to open as they would in the natural marine environment and carry out their normal filter-feeding activity. This loading arrangement will vary according to the species of shellfish being depurated. (Table 1.)

The level of water above the shellfish should also be sufficient to ensure that the shellfish remain immersed throughout the entire period of depuration. Mussels often move upwards in the trays during the process by attachment of their byssal threads to the side of the trays. A greater depth of water above the uppermost tray of mussels is therefore required (8cm is normally specified in the Condition of Approval). Other species are more sessile and consequently do not need to be immersed to such a depth (3cm is normally specified).

The trays of shellfish within a system need to be arranged in such a way as to ensure that water cannot “short circuit” around them. Therefore trays are normally orientated so as to allow highly oxygenated water to flow through them to the shellfish. In this way, water must pass through the trays of shellfish (providing oxygen and dispersing metabolic by-products as it does so) before it can be recirculated back through the system.

Shellfish to water ratio

The loading of shellfish for a given volume of water needs to be controlled, both to maintain dissolved oxygen levels to ensure optimum shellfish activity and also to ensure that the build-up of metabolic by-products does not reach inhibitory levels. The maximum shellfish capacity is therefore specified in the approval conditions of each type of system. This will be dependent upon the type of system and the individual species concerned.

Water flow

It is essential to provide a sufficient and even flow of water throughout the system to maintain adequate levels of oxygen in the water and prevent the build-up of metabolic by-products which may inhibit normal shellfish activity. The flow of water must not, however, be so great as to prevent the settlement of faecal material or cause the disturbance of such material that has already reached the bottom of the tank.

Salinity

It is also necessary to provide seawater of the correct salinity range for the shellfish being depurated as requirements vary according to species. The minimum allowable salinities for each species are given in table 2.

Artificial seawater may be used where access to a ready supply of suitable natural seawater is not available.

Temperature

In general the metabolism of shellfish is directly affected by the temperature of their environment. With decreasing temperature, shellfish become less active and contaminant removal, as a result, is decreased. Therefore water temperatures are required to be kept above a minimum level during depuration and these are shown for each shellfish species in table 2. If during the cycle the temperature fall below these minimum values then the period of time that the system is below that temperature should be added to the purification time.

The dissolved oxygen (D.O) carrying capacity of the body of water varies dependant on the water temperature. The colder the water the higher the D.O and the higher the temperature the lower the D.O.

Should the temperature of the water vary significantly, from the temperature of the water the animals are harvested from during times that the animals gonads are full, spawning could take place in the tanks. The animals would then lose condition rapidly and either start dying in the tanks or shortly after being sent to the consumers.

Turbidity

Control of turbidity is important for two reasons. Firstly the UV disinfection rate is considerably reduced by relatively low turbidities and so contamination or recontamination may occur if purged microbial contaminants are recirculated throughout the system but not inactivated by the UV unit.

Secondly, if the turbidity is excessive this may have a detrimental effect on the filtration activity of the shellfish.

No disturbance
In addition to all of the above, it should be noted that shellfish are sensitive animals and if disturbed directly by the effects of cascades, aeration or operator handling during the purification cycle, will cease to function effectively. If shellfish are disturbed in this way the period of purification should begin again and a further 42 hours will be required.

1.3.2. Removal of sewage contaminants

During depuration contaminants are excreted as part of the digestive process predominantly in the form of mucoid faecal strands which must be allowed to settle to the bottom of the depuration tank. Once settled, resuspension of this faecal matter must be avoided as this may lead to its re-ingestion by the filter-feeding shellfish.

At the end of the cycle seawater in the system should be slowly drained down below the level of the shellfish before they are removed. This prevents turbulence caused by removal of trays of shellfish immersed in water leading to the possible resuspension and reingestion of faecal material in neighbouring shellfish. At the end of each cycle, the remaining water, which will be heavily contamininated must be discarded and the bottom of each tank thoroughly cleaned at the end of the cycle, as this is where the shellfish faecal material containing the contaminants will be concentrated. A proprietary cleaning agent such as HypoChloride should be circulated throughout the system on an agreed time scale to prevent algal and marine organism growth.

Protein foam which can contain some faeces can develop on the surface of the water in recirculation systems. After draining down this material may be deposited on the shellfish. This should be rinsed off with either potable fresh water or water that has been used in a purification sytem that is free from detritus.

1.3.3. Avoiding recontamination

Tanks should be covered or housed in a building with a roof to prevent aerial contamination from birds. Vermin such as rodents should also be excluded from the area.

In order to avoid recontaminating the shellfish, it is vital that all steps should be taken to avoid the possibility of resuspension and therefore re-ingestion of shellfish faecal material. One of the most important practices in this regard is the operation of a batch system i.e. once the tank has been appropriately loaded and the cycle has commenced, no additional shellfish should be added or removed until the full cycle (currently 42 hours) has been completed and the tank drained down. If this practice is not followed then recontamination, either from added shellfish or by re-ingestion of resuspended shellfish faecal material caused by trays being removed whilst still immersed, may occur.

Seawater quality and reuse.
Clearly, another factor that must be controlled to avoid the possibility of recontamination is the quality of the intake water. EU legislation defines clean seawater as being: *“sea water or brackish water..... which is free from microbiological contamination and toxic and objectionable substances.... in*

such quantities as may adversely affect the health quality of bivalve molluscs or to impair their taste"

The lack of any defined values has caused some practical problems with the interpretation and implementation of the requirement for clean seawater to be used.
If treatment of the seawater is necessary, then the competent authority must verify the treatment method and authorise its use. SEAFISH can assist the local authority in establishing what this is.

If the purification system is recycling water then steps must be taken to ensure that the recycled water is of adequate quality. Features vital in this respect are some form of in-line disinfection system (currently UV light is the usual form of disinfection in the UK) and adequate provision for the settlement of shellfish faecal material for reasons previously discussed.

Finally, if seawater is to be re-used from batch to batch then this too must be of a suitable quality and effectively conform to the definition of clean seawater. The re-use of raw seawater is currently limited normally to 2 weeks (with an allowance for an extra 2 weeks in exceptional weather conditions). This limitation is due to the risk of build up of shellfish metabolic by-products from batch to batch which can inhibit normal activity, and the possible concentration of contaminants that may occur from batch to batch.

Where systems use water from an area subject to a toxic algal bloom additional risk assessment will be required to ensure depurated shellfish is not with contaminated with biotoxins during the depuration cycle. At the end of the depuration process shellfish must meet all requirements relating to biotoxins prescribed in Chapter V of EU 854/2004 and the microbiological criteria specified in EU 2073/2005.

1.4. Purification Systems

Most depuration systems in the UK use recirculation of either artificial or natural seawater. The size and type of system vary considerably but there are 4 basic designs that are currently approved for use and these are as follows:

1.4.1. Shallow tank

The first shellfish purification tanks to be used in the UK were of the shallow tank design in which oysters and clams were stacked up to 3 layers high. The stacking of mussels however was not permitted due to their high level of metabolic activity and the limited degree of oxygenation associated with this type of system due to the relatively low flow rates involved (normally one exchange of all the seawater in the system per hour).

The need to purify large quantities of mussels therefore resulted in large shallow tanks that, due to their size, were often sited outdoors. This meant that they were exposed to the elements making temperature, salinity and the risk of external contamination difficult to control. **No outdoor systems should now be approved.**

A more recent development has been the small scale shallow tank which has been shown to be able to successfully depurate shellfish, including mussels stacked up to 3 layers high with a minimum flow rate of 20 litres/minute or 2 complete changes per hour. This system has a nominal capacity of 90kg mussels or 750 oysters and approximately 500 litres of seawater. Its relatively

compact size means that it can be comfortably housed within premises as small as a garage and it is relatively cheap, making it popular with the small-scale operator.

1.4.2. Multi-layer system

The use of the multi-layer system enables trays of shellfish to be stacked up to 6 layers high (SFIA, 1995b; SFIA, 1995c). This is an advantage with the lower value shellfish such as mussels where a high-density load is more economical. It has the additional advantage of saving a significant amount of floor space compared to the shallow tank system. The multi-layer system has a relatively high shellfish to water ratio and consequently the flow rate needed to maintain an adequate level of dissolved oxygen in the circulated water is relatively high. The required flow rates for these systems are 12.5 m^3 (208 litres/min) and 9.5 m^3 (158 litres/min) per hour respectively which is equivalent to 5 complete exchanges of seawater per hour. For certain species such as cockles which are generally very active under normal purification conditions, the loading needs to be reduced so that the animals are not stressed by low oxygen levels or the build-up of metabolic by-products.

In these systems baffles are necessary, due to the high flow rate involved, to ensure the highly oxygenated surface water at the spray bar or inlet point is pushed down throughout the depth of the system. There are normally 2 baffles per tank, one immediately after the cascade and the other close to the suction bar. A typical baffle consists of a sheet of plastic evenly drilled with holes through which water is allowed to pass.

There are 750 and 1500kg (nominal mussel loading capacity) versions of this type of system.

1.4.3. Stack system

The vertical stack systems used today were developed in the 1960's. Space saving was again the advantage over the traditional shallow tank system with the additional benefit of ready access to individual containers without the need to drain down the entire system as is the case with all other systems commonly in use (SFIA, 1995d). However, this type of system has the disadvantage of being relatively expensive and consequently its use has been limited to high value molluscs such as clams and oysters.

Such systems generally have a nominal capacity of 2000 oysters using 600 litres tank as sump. The required minimum flow rate for this type of system is 15 litres per minute.

2. Criteria to check during an inspection

The following section details the major criteria that should be looked for when carrying out an inspection of a purification system. The list is not exhaustive but outlines the most often occurring problems that are reasonably easy to identify. It should be remembered that FRS or SEAFISH can give technical advice on any of the following issues if any uncertainty exists. Many of the criteria listed should be checked against the specific Conditions of Approval for the system and these should be referred to during any inspection. Conditions of Approval should be displayed or readily available in the depuration centre.

See the Seafish technical advice and industry HACCP technical guides for advice on depuration procedures. www.seafish.org.uk

2.1. Modifications to the existing system

The Conditions of Approval should request that any intended modifications to the system since the approval date should be notified to the Local Food Authority and to FRS. Even slight changes to the plumbing arrangement, UV system etc., can have a significant effect on the depuration process and such changes should be assessed for their suitability before they are made. However, operators have on occasions proceeded with such modifications without notifying the Local Authority or FRS.

During an inspection the system should be checked for any modifications since the last inspection. It can be difficult to identify where changes have occurred but a good source of reference is the Conditions of Approval and any previous photographs that may have been taken of the system. The operators will also often volunteer information on changes if they are asked.

Any modifications identified should be reported to FRS. It may be worth pointing out to operators at this stage that any modifications made without prior agreement may need to be changed again if they are considered inappropriate.

2.2. System

- The system should be of sound construction with no leaks and all associated plumbing should be of a sturdy construction.

- The system must be self-contained with no sources of external contamination. For example water from near by reservoir or sump tanks should not splash into the tank in use. Potential contamination from animal sources should not occur.

- Circulation of water in the system should be even throughout the entire system with no apparent possible dead spots. Shellfish trays should be stacked evenly in the system. If a flow meter is present a reading can be taken and compared with the stated minimum requirement in the Conditions of Approval.

- Cascades must not fall directly on to shellfish or water immediately above shellfish. Cascades are often changed by operators to spray across the surface of the tank to increase dissolved oxygen levels in the warmer summer months. This is not acceptable if the water falls onto the shellfish.

    - If any supplementary aeration is present this should be supplied away from shellfish to prevent reingestion of another animals faeces.

- Trays and baskets used in the system must be of a suitable design. (e.g. open sides to allow even flow through the shellfish). The trays and baskets should be stacked in a stable condition and raised off the base of the tank to prevent re-contamination by sediment. Operators will often change baskets from those that were approved at the time of the initial inspection.

2.3. Operation

- All shellfish must be totally covered with seawater throughout the period of purification. This may sound obvious but on occasions shellfish can be overloaded so that those in the top layer are not totally immersed. In particular mussels will expand in volume when they open during depuration which can lead to some shellfish not being immersed.

- Shellfish should be thoroughly cleaned before being placed in the tanks. No mud or sediment should be present on the shellfish during depuration.

- Shellfish should be placed into approved trays to standard depths. Depths observed should be checked against the Conditions of Approval.

- Baskets and trays should only be loaded to the number of layers specified in the Conditions of Approval.

- The cycle purification should be for a minimum continuous period of 42 hours without disturbance to the shellfish. No shellfish should be added to purification tank during the cycle. The 42 hour period of depuration should be checked against the operators records,

- Following completion of the cycle, seawater should be drained from the tank to below the level of the shellfish in the bottom layer without disturbing the shellfish. Subsequently shellfish should be removed from the tank and thoroughly cleaned with potable or clean seawater. This can obviously only be seen at the time of draining down but it is worth checking with the operator that this is done.

- The tank should be thoroughly cleaned with potable or clean seawater before a new cycle is started. Evidence of a failure to do this can be seen from excessive sediment on the base of the tank.

2.4. Shellfish

- Shellfish should be clean, not damaged, alive and healthy and appear to be actively filtering. Shellfish should be slightly open but not gaping during depuration. Foam collecting on the surface of the water is indicative of actively purifying shellfish and is not a problem.

- Shellfish should be harvested by an appropriate method (e.g. currently razor clams and cockles may only be depurated if hand gathered).

- Different species of shellfish should not be mixed in the system.

  No crabs or lobsters must be present in a system holding bivalves

- Shellfish from different classification classes (i.e. A and B category) should not be purified in the same system.

- All shellfish should be traceable to the source via the registration document, which must detail the species, classification and area from where the product was harvested. Where the harvester and the approved premise are the same this document is not required.

2.5. Seawater Quality

- Depuration systems will be approved for use with artificial or natural seawater or both. The type of seawater used will effect the permissible water reuse and any pre-treatment required. Only seawater for which the system has been approved should be used. This can be checked against the Conditions of Approval. Should a licensed operation only be approved for use of raw sea water, artificial seawater may be used to mitigate for poor salinity events.

- Only “clean” seawater should be used in the depuration system. If the abstraction point for natural seawater used has changed since previous inspections then investigations should be undertaken to establish whether the current source of water is acceptable. Although no definition of clean seawater exists it should be ensured as far as possible that a change of the source of the water should carry no significantly greater risk of contaminating shellfish. FRS will be able to provide advice on this and some microbiological testing of the source water may be required. Water samples will be taken during the initial approval visit by FRS and tested for quality.

- Water should be visibly clear both during the depuration cycle and prior to entering the system. Pre-treatment of seawater (settlement or filtration) should be undertaken where source water is excessively turbid.

- The system should either be filled through an operational UV or recirculated through the system with the UV operational for a minimum of 12 hours before shellfish are added.

- If seawater is re-used for more than one purification cycle there should be an adequate capacity of seawater storage facilities to hold seawater between cycles. This will have been checked at the time of approval but it should be noted whether the storage tank has been changed. The storage facilities must be clearable and allow drainage. Drainage of the water from the depuration tank at the end of the cycle must allow water to be transferred to the storage tank without sediment also being transferred.

• The food business should have contingencies in place for checks or alternative sources of water (e.g. artificial seawater) during natural toxic events.

2.6. Measurements

During the inspection the following parameters using should be measured;

- Seawater temperature.
  Compare with acceptable minimum temperatures in Table 2.

- Seawater salinity.
  Salinity can be measured by a salinity meter, refractometer or hydrometer following the manufacturers instructions.
  Compare with acceptable minimum salinities in Table 2.

Dissolved oxygen and water flow should also be measured.

2.7. Record keeping

Minimum legal requirements for keeping records at depuration centres are as follows;

- Results of microbiological tests on purification system water entering the purification tanks

- Results of microbiological tests on unpurified live bivalve molluscs

- Results of microbiological tests on purified live bivalve molluscs

- Dates and quantities of live bivalve molluscs delivered to the purification centre and corresponding movement document numbers

  The times of filling and emptying of purification systems (purification times)

  Dispatch details of consignments after purification

  These records should be completed and accurate, legible and recorded and available for inspection.

• Registration documents which should allow shellfish provenance checks.

Operators should also be encouraged to keep the following record for good practice and due diligence purposes.

- Seawater temperature
- Seawater salinity
- Flow rates
- Tank cleaning

- UV usage. The hours of UV usage should be recorded and the maximum permissible hours of use stipulated in the Conditions of Approval should not be exceeded.
- All water use including mixing of batches of water.
- Water reuse in exceptional circumstances.
  Where water is reused more than the normally permissible number of time s due to exceptional circumstances this must be recorded along with the exceptional circumstances causing that extended reuse.

A checklist of the above parameters is given in Appendix 2. This is intended to serve as an aide memoir during an inspection.

3.IMMERSED STORAGE ('RE-WATERING') AS A PROCESS

3.1 What is immersed storage/re-watering

- For the generic term used by industry called re-watering we can confidently use the term immersed storage.
- It is believed that immersed storage after depuration/packing gives the animals a chance to recover from any induced stress and assists in providing a better quality animal to the consumer. It is a widespread practice. Its use can be encouraged when proper guidelines are followed.

3.2 General good practice in relation to immersed storage

- The immersed storage can only take place at an establishment approved for depuration or dispatch.
- The practice should follow good practice. Most importantly only bacteriological clean sea water can be used such as grade 'A' water or water that is a by-product of a depuration process (used, re-circulated raw or artificial seawater)

  'Clean sea water' means sea water or brackish water which is free from microbiological contamination and objectionable substances occurring naturally or after discharge in the environment, including those listed in the Annex to Directive 79/923/EEC (quality required for shellfish waters), in such quantities as may adversely affect the health quality of bivalve molluscs or other shellfish or impair their taste.

- Batches of Molluscs from different Production Areas must be kept separate.
- There should be no possibility of cross contamination via the seawater.
- For immersed storage to be effective, the mollusc must be placed in suitable conditions of sea water such that they survive and remain in good condition. They should be free to open and function whilst immersed.
- The cleanliness of the water must be appropriate to the category of microbial cleanliness of the mollusc e.g category 'A' molluscs should only be placed in Category 'A' water. If the category of the water is less than the mollusc then the status of the mollusc will be lost to be lower category.
- Regulation 852/2004 and 853/2004 places obligations upon the centre with regard to microbiological checks and the keeping of records. You should be able to audit the relevant documentation to assess the suitability of the system that they have in place.
- It cannot be assumed that whilst the harvesting area is a category 'A' that U.V is not required. Human and animal contamination can still take place in a grade 'A' site and in the absence of a water testing regime that gives 100% confidence of the quality of the water used it is always recommended that the UV bank of sufficient wattage is used and turned on.
- It is essential that man made installations used for re-immersion are designed and operated such that the risk of contaminating the molluscs is minimised, whilst maintaining suitable seawater conditions. This applies also to purification systems and therefore the same basic principles of design, construction and operation apply to installations for immersed storage.
- There are a wide variety of systems. As stated no official approval requirements and 'conditions of approval' (other than the general approval

of the dispatch centre) and there are no standard designs of system as such.

- It is recommended however that the system be based on known and proven types in a man made installation for purification system design and construction with changes appropriate to the situation.

Table 1. Shellfish Loading densities and arrangements

	Density	Loading Arrangement
Pacific Oysters (*Crassostrea gigas)*	530animals/m^2	Double overlapping layer
Native Oysters (*Ostrea edulis*)	530animals/m^2	Single overlapping layer
Mussels (*Mytilus edulis*)	50kg/m^2	80mm
Cockles (*Cerastoderma edule*)	50kg/m^2	80mm
Hard clam (*Mercenaria mercenaria*)	70kg/m^2	80mm
Native clam (*Tapes decussatus*)	50kg/m^2	80mm
Manila clam (*Tapes philippinarum*)	50kg/m^2	80mm
Razor clams (*Ensis spp.*)	60kg/m^2	Bundles of 10-12 stacked horizontally

Table 2. Minimum salinities and temperatures during depuration.

	Minimum Salinity(‰)	Minimum Temperature(°C)
Pacific Oysters (*Crassostrea gigas)*	20.5	8
Native Oysters (*Ostrea edulis*)	25.0	5
Mussels (*Mytilus edulis*)	19.0	5
Cockles (*Cerastoderma edule*)	20.0	7
Hard clam (*Mercenaria mercenaria*)	20.5	12
Native clam (*Tapes decussatus*)	20.5	12
Manila clam (*Tapes philippinarum*)	20.5	5
Razor clams (*Ensis spp.*)	30	10

3. Associated Literature

1. The Food Hygiene (Scotland) 2006 Regulations.

2. EU Regulation 853/2004 and 854/2004

3. Sea Fish Industry Authority (SFIA) — Guidelines for the Facilities and Equipment Required for Handling Bivalve Molluscs from Harvesting through to Distribution to Retail Outlets-Final draft. February 1997

4. SFIA — Generalised Operating Manual for Purification Systems of Non-Standard Design. March 1995

5. SFIA — Operating Manual for the Small Scale Shallow Tank Purification System. March 1995

6. SFIA — Operating Manual for the Medium Scale Multi-layer Purification System. March 1995

7. SFIA — Operating Manual for the Large Scale multi-layer Tank Purification System. March 1995

8. SFIA — Operating Manual for the Bulk Bin System for Mussels. March 1995

9. SFIA — Operating Manual for the Vertical Stack System. March 1995

10. Shellfish Association of Great Britain — Guidance on the Frequency of Microbiological Sampling of Purified Molluscs by Operators of Purification Centres. February 1995

Appendix 1: Sample Conditions of Approval document.

CONDITIONS OF APPROVAL FOR THE PURIFICATION SYSTEM
OPERATED BY
{Company Name}
The Food Hygiene (Scotland) Regulations 2006
{Operator name}
{Address}
This system is identified as **System No. 1** at these premises

Specifications:

The system is approved for the purification of {species (*latin name*)}
The system shall consist of a tank measuring 1160 x 980 x 600mm internally containing a minimum water volume of X litres.
The maximum capacity of the system shall be X species subject to the loading conditions given below.
The system must be fitted with a 25 watt, or greater, UV steriliser.

Conditions:

1. All shellfish must be alive and healthy before undergoing purification.
2. Pacific oysters may only be loaded in approved trays up to a double layer in such a way as to ensure a minimum water depth of 30mm above each layer. Trays may be stacked up to 3 layers high. All trays in the bottom layer must be raised off the base of the tank by 25mm.
3. Purification, without disturbance to shellfish, must be for a minimum period of 42 hours once the correct conditions of purification have been achieved.
4. The total volume of water in the system must be recirculated through the UV lamps and evenly through the whole system at a rate of at least 20 litres per minute.
5. UV lamps must be changed after every 2,500 hours of use. A record of UV usage must be kept for this purpose.
6. UV lamps must be maintained free of slime and other substances which may impair efficiency of irradiation.
7. After each purification cycle the tank must be drained down, without causing resuspension of sediment, before shellfish are disturbed or removed.

Seawater:

Seawater must meet the following criteria when in use in the purification system:

Pacific oysters: Minimum temperature 8°C. Minimum salinity 20.5‰.
Seawater should only enter the system via the operating UV system.
Seawater should not normally be re-used for more than 2 consecutive weeks. However, extended re-use up to a maximum of one month is permitted where exceptional climatic or other circumstances dictate. A record must be kept when seawater is used for such extended periods.

Only seawater which conforms to the definition of “clean seawater” as described by Central Government may be used for purification.

No modifications may be made to the purification system as described above and as at the time of approval to operate is given, without prior approval from {Food Authority name} Environmental Health Department.

{Officer Name} 15.09.04
Fisheries Research Services, Marine Laboratory Aberdeen
375 Victoria Road
Torry
Aberdeen
AB11 9DB Telephone : (01224 ------)

Appendix 2

Purification system inspection checklist	
Operators name	
Company/System name and address	
Date of inspection	
Name of inspecting officer/s	
System identification/Approval Number	
Date system approved	
Dates of any further specialist visits by FRS	
Type of inspection Routine/revisit/complaint investigation	
Announced Visit /unannounced visit	
Scope of inspection	

Modifications			
Have any of the following changed since previous inspections (record details separately)			
Pumps	UV system	Cascades	Seawater storage
Shellfish trays	Heaters	Cooling system	Pipe work

System	
Type of tank	
Identification number/mark of tank	
It the tank of sound construction and maintenance?	
Are there any sources of external contamination?	
Is there an even flow through the system?	
Do the cascades fall onto shellfish ?	
Can the cascades cause suspension of sediment?	
Does the aeration disturb shellfish?	
Are the trays of suitable design?	
Are the trays raised off the base of the tank?	

Operation	
What if the method for filling tank	
Is the recirculation even (no dead spots) and through the UV system	
Are the shellfish fully immersed	
Are the shellfish loaded to correct depth	

Is the minimum period of 42 hours depuration being properly observed and controlled	
Shellfish	
Are Movement documents available where appropriate	
What is classification of the shellfish	
What is the source of shellfish	
Are the shellfish clean, alive and healthy	
Do shellfish appear to be filtering?	
What is the method of harvest for the shellfish	
Is mixing of species evident/batches	

Seawater Quality	
Type of seawater Artificial/natural	
Where is the seawater abstraction point (grid ref) is it close to any source of contamination i.e sewage outlet	
Is the seawater turbid	
Is the seawater pre-treated by UV	
Is seawater reuse in line with recommendations	
What are the seawater storage facilities? Are batches of seawater recorded	
Is there a contingency in the event that seawater cannot be used (access to artificial seawater)	
Measurements	
What is the salinity measurement In accordance with protocol	
What is the temperature of water in tank In accordance with protocol	

What is the Flow rate in tank In accordance with protocol	
Record Keeping/Controls	
Purification times Recorded and adequate	
Purification quantities Recorded and adequate (In and out quantities match)	
Microbiological results Recorded and adequate Onsite lab/external lab Method of analysis	
UV usage Recorded and adequate	
Water Reuse Recorded and adequate	
Seawater temperature Recorded and adequate	
Seawater Salinity Recorded and adeqaute	
Flow rate Recorded and adequate	
Tank cleaning Recorded and adequate	
HACCP systems in place Recorded/adequate	
Movement documents in proper use Kept for 60 days	
Training of staff Recorded and adequate	
Pest control Internal/external company	
Are samples of depuration water taken for analysis	

If conditioning is practised is this subject to adequate controls i.e - Proper tanks UV Water source and quality Batches separate	
Comments	

Appendix 3

Depuration Aide Memoir (To be Completed on the Basis of Objective Evidence)

Business_____

Scope/Product_____

Date_____

Page _____of_____

Step/Process Flow Diagram Validation	Awareness of Hazard	Control Measure (NB Knowledge & Reference to Critical Limits)	Monitoring (NB Knowledge & Reference to Critical Limits)	Corrective Actions (NB Knowledge & Reference to Critical Limits)

Continuation

Scope/Product_____

Date_____

Page _____of_____

Step/Process Flow Diagram Validation	Awareness of Hazard	Control Measure (NB Knowledge & Reference to Critical Limits)	Monitoring (NB Knowledge & Reference to Critical Limits)	Corrective Actions (NB Knowledge & Reference to Critical Limits)
Receipt of shellfish	What is the classification?			
	What is the source?			
	Are the shellfish clean, alive and healthy?			
	What is the method of harvest?			
	Are movement documents available, if appropriate?			

Scope/Product_____

Date_____

Page _____of_____

Step/Process Flow Diagram Validation	Awareness of Hazard	Control Measure (NB Knowledge & Reference to Critical Limits)	Monitoring (NB Knowledge & Reference to Critical Limits)	Corrective Actions (NB Knowledge & Reference to Critical Limits)
Receipt of shellfish	Is mixing of species/batches evident?			

Scope/Product_____

Date_____

Page _____of_____

Step/Process Flow Diagram Validation	Awareness of Hazard	Control Measure (NB Knowledge & Reference to Critical Limits)	Monitoring (NB Knowledge & Reference to Critical Limits)	Corrective Actions (NB Knowledge & Reference to Critical Limits)
Sorting/				
Grading				

Scope/Product_____

Date_____

Page _____of_____

Step/Process Flow Diagram Validation	Awareness of Hazard	Control Measure (NB Knowledge & Reference to Critical Limits)	Monitoring (NB Knowledge & Reference to Critical Limits)	Corrective Actions (NB Knowledge & Reference to Critical Limits)
Cleaning/				
Washing?				

Scope/Product_____

Date_____

Page _____of_____

Step/Process Flow Diagram Validation	Awareness of Hazard	Control Measure (NB Knowledge & Reference to Critical Limits)	Monitoring (NB Knowledge & Reference to Critical Limits)	Corrective Actions (NB Knowledge & Reference to Critical Limits)
Loading of depuration tank/s	Is the tank of sound construction and maintenance?			
	Are tanks identified?			
	Are the trays of suitable design and rose from the floor of the tank?			
	Have there			

	been any modifications since previous inspection?			

Scope/Product_____

Date_____

Page _____of_____

Step/Process Flow Diagram Validation	Awareness of Hazard	Control Measure (NB Knowledge & Reference to Critical Limits)	Monitoring (NB Knowledge & Reference to Critical Limits)	Corrective Actions (NB Knowledge & Reference to Critical Limits)
Loading of the tank	What is the method of filling the tank?			
	Is the loading density as per FRS MLS protocol?			
	Are the shellfish fully immersed?			
	Is there evidence of mixing of species/bathes?			

Scope/Product_____

Date_____

Page _____of_____

Step/Process Flow Diagram Validation	Awareness of Hazard	Control Measure (NB Knowledge & Reference to Critical Limits)	Monitoring (NB Knowledge & Reference to Critical Limits)	Corrective Actions (NB Knowledge & Reference to Critical Limits)
Water supply	Where is the seawater extraction point?			
	What is the			

	seawater turbidity?			
	Are there any potential sources of contamination evident?			
	Is the seawater pre-treated by UV?			

Scope/Product_____

Date_____

Page _____of_____

Step/Process Flow Diagram Validation	Awareness of Hazard	Control Measure (NB Knowledge & Reference to Critical Limits)	Monitoring (NB Knowledge & Reference to Critical Limits)	Corrective Actions (NB Knowledge & Reference to Critical Limits)
Water Supply	Is seawater reuse inline with recommendations?			
	What are the seawater storage facilities?			
				Is there a contingency in the event that seawater cannot be used?

Scope/Product_____

Date_____

Page _____of_____

Step/Process Flow Diagram	Awareness of Hazard	Control Measure (NB	Monitoring (NB	Corrective Actions (NB

Validation		Knowledge & Reference to Critical Limits)	Knowledge & Reference to Critical Limits)	Knowledge & Reference to Critical Limits)
Water UV treatment	Is the UV bulb usage recorded and monitored?			Is the bulb changed as per manufacturer' s instructions?
	Are the UV sleeves cleaned regularly?			

Scope/Product_____

Date_____

Page _____of_____

Step/Process Flow Diagram Validation	Awareness of Hazard	Control Measure (NB Knowledge & Reference to Critical Limits)	Monitoring (NB Knowledge & Reference to Critical Limits)	Corrective Actions (NB Knowledge & Reference to Critical Limits)
Depuration	Is there an even flow through the system?			
	Do the cascades fall directly onto the shellfish or cause suspension of sediment?			
	Does aeration disturb the shellfish?			

Scope/Product_____

Date_____

Page _____of_____

Step/Process Flow Diagram	Awareness of Hazard	Control Measure (NB	Monitoring (NB	Corrective Actions (NB

Validation		Knowledge & Reference to Critical Limits)	Knowledge & Reference to Critical Limits)	Knowledge & Reference to Critical Limits)
	Is the recirculation even through the UV system?			
	Do the shellfish appear healthy and active?			

Scope/Product_____

Date_____

Page _____of_____

Step/Process Flow Diagram Validation	Awareness of Hazard	Control Measure (NB Knowledge & Reference to Critical Limits)	Monitoring (NB Knowledge & Reference to Critical Limits)	Corrective Actions (NB Knowledge & Reference to Critical Limits)
Depuration	Time			
	Quantities			
	Water temp.			
	Water salinity			
	Water flow rate			
	Dissolved oxygen			
	Tank cleaning			

Please refer to following page to record the above measurement for each tank in operation.

Record on Inspection – Purification Tanks

Tank No.				
Species				
Registration Document No./Batch No.				
Loading Density				
Total in tank				
Height of Water above Shellfish				
UV working				
UV Bulb hours used				
Flow Rate				
Seawater Salinity				
Seawater Temp.				
Dissolved Oxygen				
Purification Time				
Mollusc Activity				
Tank Cleaning				

Please refer to FRS MLS protocol and Seafish Guidance for critical limits for the above measurements.

Scope/Product_____

Date_____

Page _____of_____

Step/Process Flow Diagram Validation	Awareness of Hazard	Control Measure (NB Knowledge & Reference to Critical Limits)	Monitoring (NB Knowledge & Reference to Critical Limits)	Corrective Actions (NB Knowledge & Reference to Critical Limits)
Rewatering/ Conditioning	Are batches of shellfish kept separate?			
	Are the tanks used suitable?			
	Is the water used of suitable quality?			

Scope/Product_____

Date_____

Page _____of_____

Step/Process Flow Diagram Validation	Awareness of Hazard	Control Measure (NB Knowledge & Reference to Critical Limits)	Monitoring (NB Knowledge & Reference to Critical Limits)	Corrective Actions (NB Knowledge & Reference to Critical Limits)

Scope/Product_____

Date_____

Page _____of_____

Step/Process Flow Diagram Validation	Awareness of Hazard	Control Measure (NB Knowledge & Reference to Critical Limits)	Monitoring (NB Knowledge & Reference to Critical Limits)	Corrective Actions (NB Knowledge & Reference to Critical Limits)

Scope/Product_____

Date_____

Page _____of_____

Step/Process Flow Diagram Validation	Awareness of Hazard	Control Measure (NB Knowledge & Reference to Critical Limits)	Monitoring (NB Knowledge & Reference to Critical Limits)	Corrective Actions (NB Knowledge & Reference to Critical Limits)

Verification & Process Capability Assessment
External Audit

Verification & Process Capability Assessment
Internal Audit

Verification & Process Capability Assessment
Process Capability Assessment - Triangulation

Verification & Process Capability Assessment
End Product Testing Review
Microbiological results of:-
Purified live bivalve molluscs
Unpurified live bivalve molluscs
Purification system water entering the purification tanks

Verification & Process Capability Assessment
Own Checks Cleaning & disinfect ion

Verification & Process Capability Assessment
Water assay

Verification & Process Capability Assessment
Review – Corrective Actions/Complaints/ HACCP team Meeting Minutes

Verification & Process Capability Assessment

Prerequisite Programmes
Training Status

Prerequisite Programmes
Pest Proofing & Control Measures

Prerequisite Programmes- Cleaning & Disinfection
Agent /Usage/Method/Validity/Verification – Acquire evidence from Supplier if available

Approval Conditions

Food Standards

Appendix 4

Appendix 1. Details of request to inspect a purification system for purposes of approval or for routine inspection

APPLICATION FORM FOR REQUEST FOR APPROVAL/INSPECTION VISIT FOR DEPURATION FACILITY

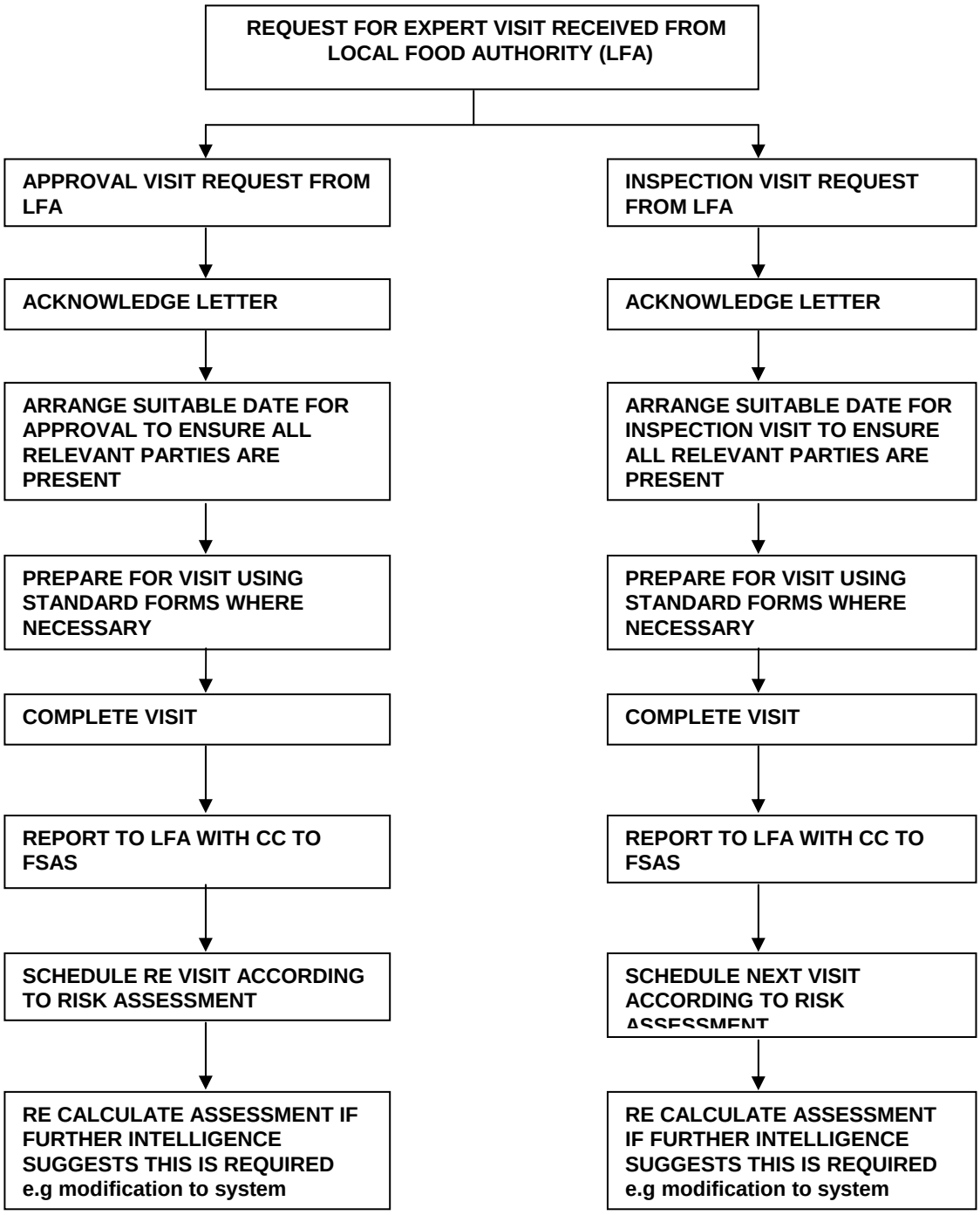
Type of visit required		
Name and contact number of LFA Officer: Food Authority Name and Address		
Date of request		
Operator's Name and contact number Operator Company name and Address:		
Type of Depuration system Specification of depuration system		
Shellfish Species		
Harvesting area name and ID Classification of harvesting area		
Location of seawater to be used		
Suitable dates for inspection		
Comments:		
Signature of Operator Name of Operator Date of request		
Signature of LFA Officer Name of LFA Officer Date of request		

Please note that in emergency situations i.e outbreak or suspect outbreak of food borne illness associated with the facility FRS Officers can be contacted directly and immediately by the LFA and verbally requested to assist in investigation at the facility. Any such contact made by the operator should be referred to the LFA in the first instance. FSAS should be informed when these types of visit request are made.
In this event the relevant contact names and numbers are;

John Turriff – 01224 295---
Shona Kinnear – 01224 295---

Appendix 5

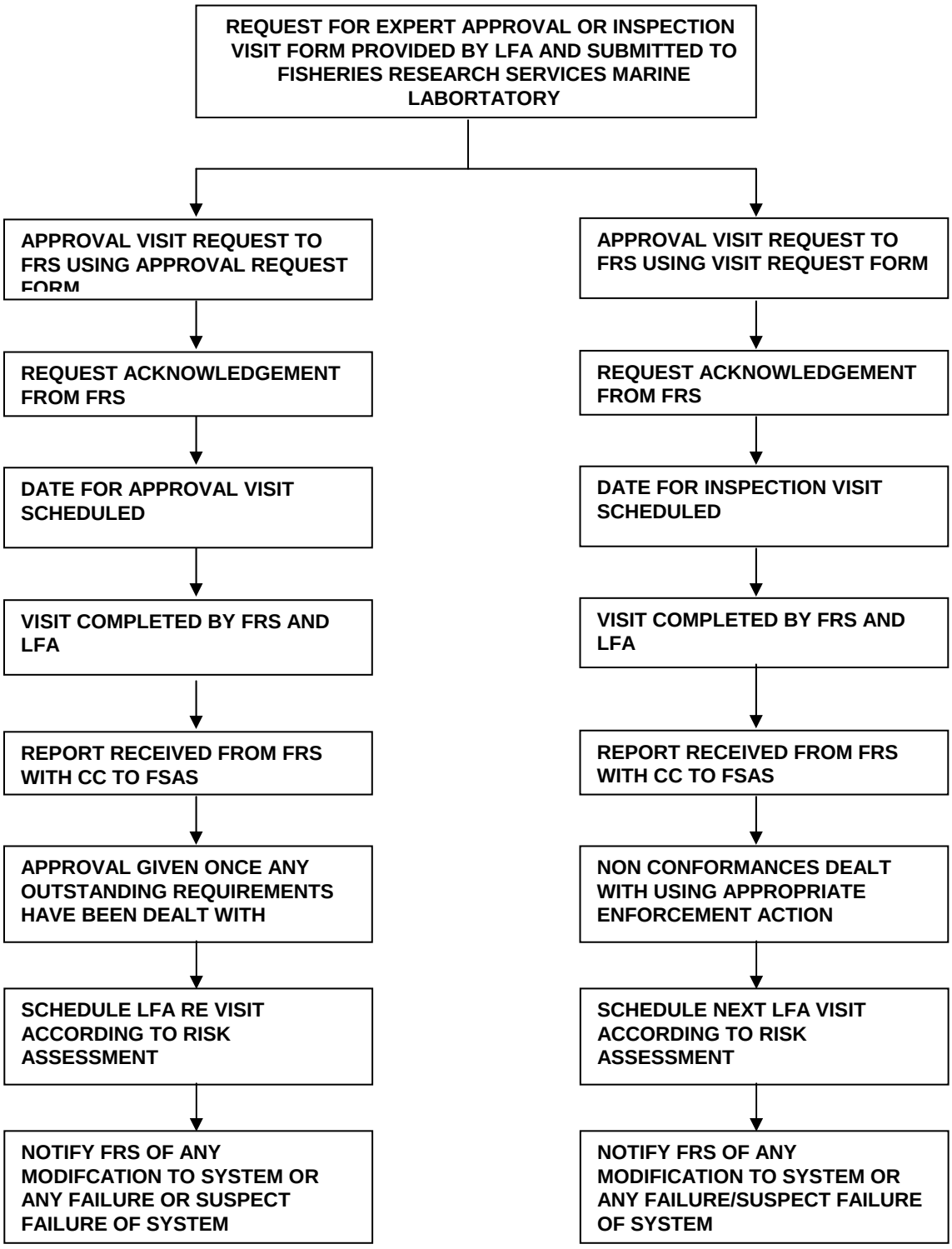
FRS Protocol for Expert Technical Advice in Approval and Inspection of Depuration Tank Facilities



- ANY REQUESTS RECEIEVD BY ANY PARTY OTHER THAN THE LFA WILL BE FORWARDED TO THE RELEVANT LFA FOR FIRST ACTION
- APPROVAL REPORTS SHOULD INCLUDE FACILITY SPECIFICATION WORKING PROTOCOL AND A VISIT REPORT WHICH WILL INCLUDE REQUIREMENTS NECESSARY BEFORE APPROVALSHOULD BE GIVEN AND RECOMMENDATIONS BASED ON GMP
- RISK ASSESSMENT SCORING SHEET TO BE USED FOR RISK ASSESSMENT PURPOSES
- MODIFICATIONS TO SYSTEM, ALLEGATIONS OF FOOD BORNE ILLNESS ETC SHOULD RESULT IN THE SYSTEM AQUIRING A CATEGORY 1 REINSPECTION STATUS

Appendix 6

Local Food Authority Protocol to request Expert Technical Advice in Approval and Inspection of Depuration Tank Facilities

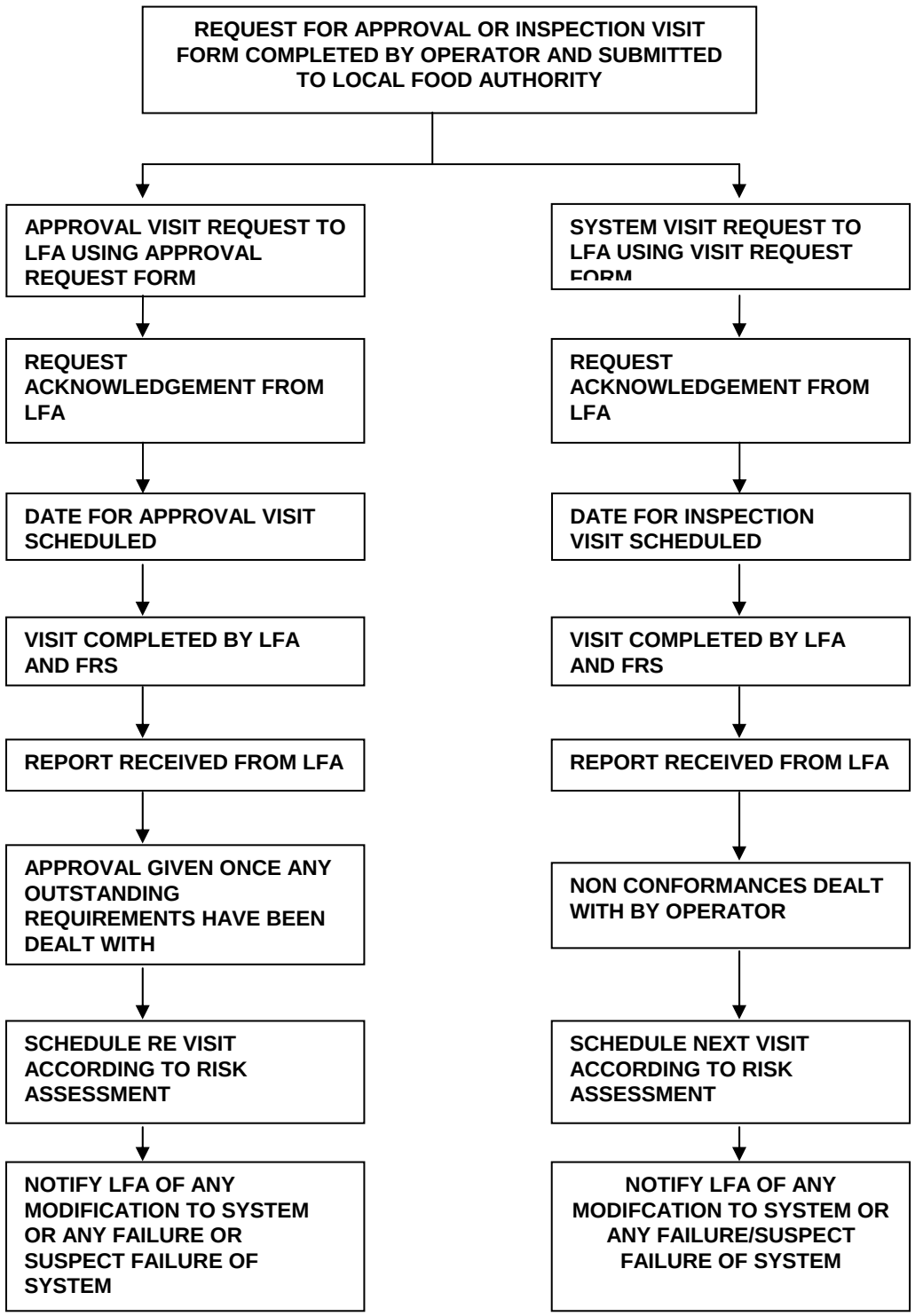


- THE LFA SHOULD MAKE ALL VISIT ARRANGEMENTS WITH THE OPERATOR AND LIASE WITH FRS AS NECESSARY
- FRS WILL ADVISE THE LFA OF APPROVAL VISIT REQUIRMENTS AND OF EXPECTED REVISIT TIMESCALES AND REQUIREMENTS
- THE LFA SHOULD ACKNOWLEDGE RECEIPT OF RELEVANT REQUEST FORMS FROM THE OPERATOR AND SEND THESE REQUESTS TO FRS USING THE RELEVANT FORM
- THE LFA SHOULD ENSURE THAT COPIES OF RELEVANT SYSTEM REPORTS RECEIVED FROM FRS ARE PROVIDED TO THE OPERATOR
- THE LFA SHOULD ADVISE FRS OF ANY MODIFICATION OR SYSTEM FAILURE/SUSPECT FAILURE TO ALLOW RE EVALAUATION OF REVIST TIMESCALE
- WHERE IT IS KNOWN/SUSPECTED THAT A SYSTEM FAILURE HAS LED TO AN INCIDENT OF FOOD BORNE ILLNESS, FRS MAY BE IMMEDIATELY CONTACTED FOR ASSISTANCE IN INSPECTION OF THE SYSTEM

- **OFFICERS AT FRS WILL BE AVAILABLE TO ANSWER GENERAL VERBAL QUERIES IN RELATION TO SYSTEMS ON A DAILY BASIS.**
- **WRITTEN/EMAIL QUERIES WILL BE ANSWERED WITHIN 5 WORKING DAYS**
- **SPECIFIC QUERIES REGARDING DESIGNS/PLANS OF DEPURATION SYSTEMS OR QUERIES IN RELATION TO SEAFISH DESIGNED SYSTEMS MAY BE MADE DIRECTLY TO THE SEAFISH INDUSTRY AUTHORITY**

Appendix 7

Operator Protocol for request of Approval and Inspection of Depuration Tank Facilities



- ♦ OPERATORS SHOULD ENSURE THAT THE FIRST POINT OF CONTACT IN RELATION TO APPROVAL AND INSPECTION OF SYSTEMS IS WITH THEIR RELVANT LFA
- ♦ THE OPERATOR SHOULD ADVISE THE LFA OF ANY MODIFICATION OR SYSTEM FAILURE/SUSPECT FAILURE
- ♦ WHERE IT IS KNOWN/SUSPECTED THAT A SYSTEM FAILURE HAS LED TO AN INCIDENT OF FOOD BORNE ILLNESS THE OPERATOR IS ENCOURAGED TO IMMEDIATELY CONTACT THE LFA
- ♦ THE LFA OFFICER OR OFFICERS AT FRS WILL BE AVAILABLE TO ANSWER GENERAL VERBAL QUERIES IN RELATION TO SYSTEMS
- ♦ WRITTEN/EMAIL QUERIES WILL ALSO BE ANSWERED BY THE LFA/FRS OFFICERS OR FORWARDED ON TO THE SEAFISH INDUSTRY AUTHORITY WHERE APPROPRIATE
- ♦ SPECIFIC QUERIES REGARDING DESIGNS/PLANS OF DEPURATION SYSTEMS OR QUERIES IN RELATION TO SEAFISH DESIGNED SYSTEMS MAY BE MADE DIRECTLY TO THE SEAFISH INDUSTRY AUTHORITY

Appendix 8

RISK ASSESSMENT SCORING SHEET FOR REINSPECTION OF DEPURATION TANK FACILITIES

RISK BASED SCHEME FOR SELECTION OF SHELLFISH PURIFICATION PLANTS FOR RE-INSPECTION

Introduction

The risk posed to the consumer from shellfish produced at each depuration plant will vary considerably. A plant with multiple systems of non-standard design with a history of end-product failures and outbreaks purifying oysters will represent a greater risk than a single system of standard design with no history of non-compliance

The greatest effort in terms of technical inspections should be placed in ensuring that minimum standards are met and maintained at purification centres which represent the greater risk to health.

Proposal

It is proposed that a risk based scheme for selecting purification centres for re-inspection should be introduced. When developing this proposal the following criteria have been used.

- The overall effort (resources) should be maintained (15 re-inspections each year).
- The selection scheme should be simple and transparent.
- Information on which a decision is made must be readily available at FRS.
- Highest frequency of inspection should be 1 year.
- Lowest frequency of inspection should be 3 years.
- The system should as far as possible reflect the principles of The Food Safety Act associated Codes of Practice for risk assessment of food premises.

It is proposed that as each depuration facility is approved or inspected that it be assessed and scored on the criteria given in the following table. This proposal should therefore mean that the centres representing the highest risk will be inspected every year, those representing the least risk every 3 years and those with an intermediate risk every 2 years. Many of the factors that go towards making up the plants assessment will vary with each assessment Information on outbreaks, end product failures and non compliance will lead to the assessed score being added to and hence re-inspection being further prioritised.

Scoring Scheme

CRITERIA	SCORE
Species	
System approved for oysters	10
New species added to CoAs since last inspection	10
Other species	0
Size and number of systems at plant	
Large scale operation	20
Medium scale operation	10
Small scale operation	0
Previous non-compliance (at time of last inspection)	
Major (legal requirement)	20
Minor (recommendation based on GMP)	5
End product Failure* (since last inspection)	10
Associated with outbreak* (since last inspection)	20
Non standard system	10

Time to next inspection

3 years	0 - 20
2 years	21 - 40
1 years	over 41

***Note these criteria may initiate an inspection outside of the re-inspection programme. See note below.**

Notes on scoring criteria.

Size of operation

Small scale operation. –Only one system which has a capacity <4000 oysters, <2000Kg of mussels or cockles.
Medium scale operation –More than one system with total capacity <4000 oyster, <2000Kg of mussels and cockles. One system with a capacity in excess of 40000 oysters or 2000Kg of mussels or cockles.
Large scale operation –More than one system with total capacity >4000 oysters, >2000Kg of mussels and cockle

Size of operation is based on depuration capacity at plant per 42 hours. Actual production will be unknown at the time of selection and therefore cannot be used.

Non-compliance

Interpretation of non compliance should be made on the basis of the relevant statutory Regulations and associated central authority and industry guidance.
Some examples will include;

Major Non Compliance – poor maintenance, inadequate seawater treatment, not keeping legally required records, Major operational problems (draining down, batch operation), significant modifications without informing LFA or FRS.

Minor Non Compliance – slight overloading of shellfish, not keeping due diligence records

End-product failures and association with outbreaks

In most cases FRS will be expected where requested by the LFA to visit systems that were associated with end-product failures or outbreaks as soon as possible after receipt of the information. In cases where it is not felt necessary by FRS (decision taken in conjunction with FSAS) or the LFA to inspect the system immediately the information will be relevant in determining the risk associated with a plant