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Official Controls of shellfish purification systems: Guidance for Local Authority Officers

**Regulatory Policy Branch and Enforcement Delivery
November 2017**

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audio, large print, Braille – please contact us.**

Summary

Intended audience:	For the use of Local Authority (LA) Authorised Officers (AO)
Regional coverage:	Scotland
Purpose:	This guidance is intended to assist AOs when carrying out Official Controls (OC) of approved purification centres of Live Bivalve Molluscs (LBM).
Legal status:	<p>Regulation (EC) 852/2004 sets-out general hygiene rules that apply to all registered and approved food establishments including structural requirements and the implementation of procedures based on HACCP principles.</p> <p>In addition to those requirements set-out in Regulation (EC) 852/2004, businesses producing POAO are also required to apply the rules laid down by Regulation (EC) 853/2004 .The regulations include the requirement for businesses to be approved by the Competent Authority.</p>
Essential actions to comply with regulation(s):	<ul style="list-style-type: none"> • Approvals • Shellfish • Food law, monitoring and controls • Hygiene and food safety

This guidance follows the Government [Code of Practice on Guidance](#). If you believe this guidance breaches the Code for any reason, please contact us using the number on the front sheet. If you have any comments on the guidance, again please contact us on the number on the front sheet.

Regulations referred to in this guidance

Regulation (EC) 852/2004 on the hygiene of foodstuffs
Regulation (EC) No 853/2004 laying down specific hygiene rules for food of animal origin
Regulation (EC) No 854/2004 laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption
Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules
Regulation (EC) 2073/2005 on microbiological criteria for foodstuffs
The Food Hygiene (Scotland) Regulations 2006 (SSI 2006) as amended

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Glossary - Definitions and Abbreviations used in this guidance.

Authorised Officer (AO)	Any person (whether or not an officer of the Authority) who is authorised by the Local Authority in writing
Clean Seawater	Natural, artificial or purified seawater or brackish water that does not contain micro-organisms, harmful substances or toxic marine plankton in quantities capable of directly or indirectly affecting the health quality of food.
Competent Authority (CA)	The central authority of a Member State competent for the organisation of official controls or any other authority to which that competence has been conferred; it shall also include, where appropriate, the corresponding authority of a third country
Dispatch Centre	Any on-shore or off-shore establishment for the reception, conditioning, washing, cleaning, grading, wrapping and packaging of live bivalve molluscs for human consumption
Depuration (Purification)	The reduction of micro-organisms to a level acceptable for direct human consumption by the process of holding live bivalve molluscs for a period of time under approved, controlled conditions in natural or artificial seawater suitable for the process, which may be treated or untreated. Note: For the purposes of this document, the term purification has been used
EC	European Commission
E. coli	Escherichia coli; a species of bacterium that is a member of the faecal coliform group.
FSS	Food Standards Scotland. A non-ministerial department set up in 2014 to protect the public's health and consumer interests in relation to food
LA	Local Authority
Live Bivalve Molluscs (LBM)	Filter-feeding lamellibranch molluscs
Purification centre	An establishment with tanks fed by clean seawater in which LBM are placed for the time necessary to reduce contamination to make them fit for human consumption
Official Control (OC)	Any form of control that the competent authority or the Community performs for the verification of compliance with feed and food law, animal health and animal welfare rules
Seafish	Non-Departmental Public Body set up to improve efficiency and raise standards across the seafood industry
SFELC	Scottish Food Enforcement Liaison Committee
UV	Ultra-violet
Verification	Checking by, by examination and consideration of objective evidence, whether specified requirements have been fulfilled

Introduction

1. This guidance is for the use of local authority (LA) Authorised Officers (AO) in Scotland in relation to official control (OC) undertaken of purification (depuration) systems for live bivalve molluscs (LBMs). It may also be useful for food businesses when validating or verifying the efficacy of their systems.
2. The guidance is intended to assist LA AOs when undertaking OC's at food business establishments approved by them to operate purification systems and should be read in conjunction with the Food Standards Scotland's (FSS) guidance¹ on the approval of establishments and Hazard Analysis Critical Control Point (HACCP). It does not provide authoritative interpretation of legislative requirements and is not a substitute for an understanding of the applicable law.

Legal requirements and general obligations

3. Regulation (EC) 852/2004 sets out general hygiene rules that apply to all registered and approved food establishments including structural requirements and the implementation of procedures based on HACCP principles. Article 6 (2) of Regulation (EC) 852/2004 places the legal onus on food business operators (FBOs) to ensure they are approved by the Competent Authority **before they commence trading**.
4. In addition to those requirements set-out in Regulation (EC) 852/2004, businesses producing products of animal origin (POAO) are also required to apply the rules laid down by Regulation (EC) 853/2004. The regulations include the requirement for businesses to be approved by the Competent Authority. In accordance with this regulation, shellfish purification establishments must be approved and satisfy the specific structural and hygiene requirements contained within Annex III.
5. Under Regulation (EC) 854/2004 LAs are the Competent Authority as delegated by the Minister for food businesses handling LBM. This Regulation is directly applicable with national enforcement powers being provided by The Food Hygiene (Scotland) Regulations 2006 (as amended). Under the Regulations, the approval for shellfish purification plants to operate is given by the LA subject to the conditions set out in the Regulations.
6. OCs should be undertaken in the following circumstances (the list is non-exhaustive) :
 - Initial approval of a new purification establishment,
 - Routine audit/inspection (in accordance with the inspection frequency prescribed by the risk rating applied to the establishment).

¹ [FSS Approved Establishments Scottish National Protocol](#)

- As an intervention e.g. following repeated end product failures or outbreaks of illness linked to the establishment.
 - To assess and verify compliance with relevant food hygiene requirements following a request for the approval of a new purification establishment or significant change to an existing purification system (including relocation and re-installation) at an approved establishment.
 - To review evidence when a FBO wishes to apply a reduced period of purification to be satisfied that their HACCP based food safety management system (FSMS) has considered all relevant hazards and associated risks and that the systems in place are protective of human health and compliant with end product standards.
7. Regulations (EC) 853/2004 and (EC) 2073/2005 lay down the end product standards required for shellfish. These standards must be met at all times, and for those FBOs purifying shellfish, the regulations place an onus on the FBO to validate their system in order to ensure that the microbiological criteria set out in 2073/2005 are met.
 8. FSS is responsible for monitoring waters, and it is the responsibility of the FBO to ensure their products are safe.
 9. Classifications are awarded according to the FSS Protocol for Classification of shellfish areas². LBM harvesting areas are classified by monitoring the levels of *E.coli* in shellfish flesh.
 10. Treatment processes are specified according to the classification status of the area.
 11. Shellfish is required 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 document. However once they enter an approved premises they must meet the end product standard before the approval number can be applied.
 12. Where an approved premises wishes to wash, sort, pack and dispatch shellfish they must also ensure that the end product standard is met, hence for class B product (231 – 4,600 *E. coli*/100g shellfish flesh), relaying, purification or heat treatment must be applied.
 13. Product of 'C' class standard ($>4,601$ *E. coli*/100g shellfish flesh) must be subject to relaying or cooked by an approved method to ensure that it meets the category 'A' standard.
 14. There are no classified relaying areas in Scotland at present. Any relaying areas must be subject to classification and must meet class 'A' standard.
 15. The following table summarises the standards required for each class of shellfish.

² [FSS Shellfish E Coli Protocol](#)

Category	Classification Area	Action
A	80% of the samples collected during the review period \leq 230 E.coli/100g of flesh and intravalvular liquid. The remaining 20% of samples \leq 700 E coli / 100g of flesh and intravalvular liquid.	May go direct for human consumption if end product standard met
B	90% of samples collected during review period \leq 4600 E.coli/100g of the flesh and intravalvular liquid. The remaining 10% of samples \leq 46 000 E. Coli/100g of flesh and intravalvular liquid.	Must be subject to purification, relaying in Class A area (to meet Category A requirements) or cooked by an approved method
C	Samples \leq 46,000 E.coli/100g of the flesh and intravalvular liquid.	Must be subject to relaying for a period of at least 2 months or cooked by an approved method
Any value exceeding 46,000 E coli / 100g of flesh and intravalvular liquid		Prohibited. Harvesting not permitted

Principles of the purification process

16. The purification 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.
17. 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.
18. 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.
19. 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 \leq 230 *E. coli* /100g of shellfish.

Shellfish intended for purification

20. LBMs that are to undergo purification 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
21. At all times post-harvesting, the re-immersion of LBMs (other than during purification) should be avoided.

22. Before they are loaded in the purification tank, shellfish must be thoroughly washed with clean water to remove gross detritus and sorted. Any batch of shellfish undergoing purification must be of the same species and from the same class of production area.
23. Whilst most shellfish can be harvested by mechanical means, cockles (*Cerastoderma edule*) have been shown to exhibit high levels of mortality under purification 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.

Requirements for purification systems

24. For purification 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
25. The parameters that are considered critical to achieve these requirements are set out in detail at **Annex A**.

Types of Purification Systems

26. Some purification systems will be within the range of standard design systems developed by Seafish. These fall into the following categories:
- Medium scale multi-layer stack
 - Large scale multi-layer stack
 - Small scale shallow tank
 - Bulk bin system
 - Vertical stack system
27. Detailed information on these systems can be found on the Seafish website www.seafish.org. It is recommended that the Seafish operating manuals are consulted prior to any OC.
28. The AO should ask for copies of plans of the plant and the proposed system as part of the information required before the approval process. Operating manuals for each of these design systems may also be consulted if required and can be found on the Seafish website.

Non-standard systems

29. There is no legal obligation for FBOs of purification centres to install standard design systems and they may choose to install a system of their own specification. There are a number of non-standard design purification systems approved and in operation in Scotland. FBOs using non-standard design systems will need to provide additional details regarding the design, construction, plumbing and operation of the system.
30. It is the responsibility of the FBO to demonstrate how the system works and to provide validatory evidence to the AO that the system operates

reliably, e.g. proof that it conforms to recognised industry standards. Non-standard designs currently in the UK are built as variations on the shallow tank, multi-layer or vertical stack themes.

Criteria to check during an Official Control (OC) visit

31. It is the responsibility of the FBO to validate their systems and to provide evidence to the AO to demonstrate compliance. AOs should consult and follow the SFELC approved establishments guidance³.
32. For new purification establishments, conditional approval must be granted prior to full approval to allow the FBO to demonstrate that their HACCP-based food safety management system is valid and to verify its effectiveness. The AO will, in turn, need to verify that the system is operating effectively and that **all** hazards and associated risks have been considered in the HACCP plan.
33. If at the end of the conditional approval period the FBO is unable to demonstrate sufficient compliance with Regulations (EC) No. 882/2004 and 853/2004 and other relevant requirements of food law, including the implementation of an effective HACCP-based food safety management system plan, approval should be refused.
34. FSS has developed an Aide Memoire to further assist AOs in the undertaking of a full and thorough OC of a purification system. It has been designed to act as a prompt for AOs to be used prior to and during OC visits. A template is included in **Annex B**.
35. It is important for the AO to record any verification checks undertaken e.g. measurement of technical operating parameters (listed in the Aide Memoire) such as salinity, temperature etc. as well as any other relevant information evidenced during the OC.
36. Further guidance on the minimum information required is included in **Annex B**. Should further assistance be required the AO may contact FSS for enquiries related to enforcement and regulatory compliance. **Note:** For enquiries regarding specific technical operating requirements of purifications systems and the implementation of HACCP-based plans we recommend that FBOs and AOs contact Seafish.
37. AOs will need to familiarise themselves with the equipment needed to carry out verification checks and ensure it is used in accordance with the manufacturer's instructions. It is important that equipment used is appropriately calibrated prior to use and inspected for damage. Any defective equipment should be removed from use. The following equipment will be required during OC:

³ [FSS Approved Establishments Scottish National Protocol](#)

- Charts, Maps and/or GPS devices to verify the location of seawater abstraction
- Tape measure, salinity refractometer, dissolved oxygen meter including digital thermometer, calibrated temperature probe and turbidity meter

Note: It is not expected that full verification checks are carried out at every OC visit. The level of checks should be regular and proportionate to the risk, taking account of checks carried out by the FBO under HACCP-based controls and as part of ad-hoc checks, for example (but not limited to) instances when non-compliance is suspected or following an outbreak.

Changes to existing systems

38. FBOs are required to notify the relevant LA of any significant changes to their activities **before** implementing the desired change. This includes modifications to significantly change the design and operation of existing purification systems.

39. The AO must use their judgement to assess whether a proposed modification may significantly change the design or operation of the system. If deemed so, it will be necessary to verify the proposed new system works reliably and/or request an amended HACCP-based food safety management plan. Examples of modifications that may require an OC visit are (non-exhaustive):

- Change of ownership or name
- Change in location of premises
- Use of an additional purification system on the premises
- Modifications to existing purification systems, including relocation and reinstallation, additional species, recirculation of clean seawater in a system previously using single-use clean seawater
- Reduction in the standard minimum 42 hour purification time
- Additional approvable activities

Note - Article 6(2) of Regulation (EC) 852/2004 places the legal onus on FBOs to “ensure that the competent authority always has up-to-date information on establishments, including by notifying any significant change in activities and any closure of an existing establishment”. Failure to comply with this requirement is an offence under the Food Hygiene (Scotland) Regulations 2006 (as amended).

Minimum depuration time

40. The standard purification cycle time across the UK is 42 hours. This was established under the previous Shellfish Regulations and has been continued as it was considered to be best practice. This policy position has been reviewed and FSS considers it is for FBOs to demonstrate to the AO, in accordance with their HACCP plans, that all relevant hazards and associated risks (from bacteriological and viral contamination) have been considered and the AO is satisfied the system (and any reduced purification time) is effective, reliable and protects public health.

41. FBOs wanting to take advantage of this flexibility are to contact the relevant LA before applying a reduced purification period. The AO is required to review the evidence provided (as documented in an amended HACCP-based plan) and, carry out OC visits to verify the proposed reduced depuration times(s) are validated by the FBO and are appropriate. AOs are to take into account the following:

- **Amendment of HACCP-based plans to** account for the hazards and risks associated with implementing a reduced purification time and demonstration of continued compliance with end product standards
- **Regular and routine pre-depuration and end product testing (EPT)** to validate and verify the correct functioning of their procedures i.e. demonstrate the reduced purification time is as effective at removing *E.coli* (indicator organism) as the standard 42 hour cycle
- The frequency of EPT will depend on the nature and size of the business, and should be based on HACCP principles and good hygiene practice

42. The AO should have regard to all hazards and risk factors associated with LBMs being subjected to reduced purification times. FBOs should document in their HACCP-based plans the validatory evidence to demonstrate these factors have been accounted and are in place in their establishment. The types of risk factors to be taken into consideration are summarised in the following table:

Hazards/Risk factors	Evidence to demonstrate that the FBO has considered the hazard/risk
Shellfish species	Product to be cooked only (separation of product for export and/or that is to be cooked)
Bacterial	Classification monitoring data from the originating production area (EPT results should be consistent in terms of average contamination levels and number of results above permitted thresholds) Pre and post depuration testing results
Viral	Shellfish from different production areas in the same classification category should not be mixed in the batch for reduced purification Seasonal effects on viral pathogen levels (reduced purification times may not be appropriate in winter months) Information on recent pollution events and/or outbreaks of illness and weather (see below)
Structure of the purification system	Seafish standard design, non-standard design, non-standard design with modifications

Weather patterns/seasonal changes	Water circulation patterns and harvesting practices following periods of heavy rainfall, consideration of changes in seasons i.e. increased rainfall or seasonal illnesses.
Human vs. animal effluents	Understanding of sanitary survey report and pollution sources affecting the production area
FBO sampling results (EPT) and record keeping	FBO explain how level of EPT is arrived at and what would trigger enhanced EPT, Frequency and proportion of non-compliant results. Actions following non-compliance Data loggers and record keeping to demonstrate fully functioning system with calibrated equipment in use e.g. temperature control, UV filters, dissolved oxygen etc.

43. AOs are encouraged to take verification OC samples at the inspection visit to check against the FBOs own results.

44. Where it is agreed systems can operate at reduced purification times, the changes to purification time must be verified by the AO to ensure they are effective. Verification is required before the FBO can begin operating using the agreed reduced time. Confirmation that sufficient validatory evidence has been provided to the AO for the FBO to apply the reduced purification time must be clearly stated in writing by the AO to the FBO and changes included in the appropriate approval documentation.

NOTE - The FBO will not be able to commence using a reduced purification time until verification or conditional approval (for a new premises) is granted by the LA.

NOTE - In the absence of verification from the relevant LA, the default 42 hours is to remain as the minimum purification cycle.

Suspension or withdrawal of an approval

45. LAs are to keep the approval of establishments under review when carrying out OC (Article 31(2)(e) of Regulation EC 882/2004). In compliment to the suite of enforcement options available LAs should initiate procedures to suspend or withdraw an establishment's approval where **serious deficiencies are identified** and the FBO is unable to provide guarantees regarding future production.

Annex A:

Requirements for purification systems

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

1. allow rapid resumption of filter-feeding
2. facilitate removal of contaminants from the shellfish
3. avoid recontamination of the shellfish

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

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 (5mg/L) 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, see following the Table:

Table 1: Shellfish loading densities and arrangements		
	Loading	
	Density	Arrangement
Pacific Oysters (<i>Crassostrea gigas</i>)	530 animals/m ²	Double overlapping layer
Native Oysters (<i>Ostrea edulis</i>)	530 animals/m ²	Single overlapping layer
Mussels (<i>Mytilus edulis</i>)	50kg/m ²	80mm
Cockles (<i>Cerastoderma edule</i>)	50kg/m ²	80mm
Hard clam (<i>Mercenaria mercenaria</i>)	70kg/m ²	80mm
Native clam (<i>Tapes decussatus</i>)	50kg/m ²	80mm
Manila clam (<i>Tapes philippinarum</i>)	50kg/m ²	80mm
Razor clams (<i>Ensis spp.</i>)	60kg/m ²	Bundles of 10-12 stacked horizontally

The level of water above the shellfish should also be sufficient to ensure that the shellfish remain immersed throughout the entire period of purification. 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 Advice on Approval). Other species are less mobile 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 re-circulated 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 set out in the Table 2.

Artificial seawater may be used where access to a ready supply of suitable natural seawater is not available. It is important that the correct formulation of artificial seawater is used.

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 purification and these are shown for each shellfish species in Table 2 below. If during the cycle the temperature falls 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 carrying capacity of the body of water varies dependant on the water temperature. The colder the water the higher the dissolved oxygen and the higher the temperature the lower the dissolved oxygen.

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.

Table 2: Minimum salinities and temperatures during purification

The minimum temperatures and salinities as recommended in the following table should be used for the species mentioned. **Note:** It is good practice to consider 20% variation in salinity to that of the area that the LBMs are harvested.

Check FBO records to ensure the recommended parameters are in operation and included in the HACCP plan.

Table 2: Minimum salinities and temperatures during purification		
Species	Min Salinity (%)	Min Temp (°C)
Pacific Oysters (<i>Crassostrea gigas</i>)	20.5	8
Native Oysters (<i>Ostrea edulis</i>)	25.0	5
Mussels (<i>Mytilus edulis</i>)	19.0	5
Cockles (<i>Cerastoderma edule</i>)	20.0	7
Hard clam (<i>Mercenaria mercenaria</i>)	20.5	12
Native clam (<i>Tapes decussatus</i>)	20.5	12
Manila clam (<i>Tapes philippinarum</i>)	20.5	5
Razor clams (<i>Ensis spp.</i>)	30	10
Scallops (<i>Pecten maximus</i>)	35	10

Turbidity

Control of turbidity is important for two reasons. Firstly the UV disinfection rate is considerably reduced by relatively low turbidity and so contamination or recontamination may occur if purged microbial contaminants are re-circulated 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. It is recommended that turbidity should not exceed 15NTU (Nephelometric Turbidity Unit, the measure of suspended solids in a sample).

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 cycle will be required.

2. Removal of sewage contaminants

During purification 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 purification tank. Once settled, re-suspension 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 re-suspension and re-ingestion of faecal material in neighbouring shellfish. At the end of each cycle, the remaining water, which will be heavily contaminated, must be discarded and the bottom of each tank thoroughly cleaned, 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 system that is free from detritus.

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 re-contaminating the shellfish, it is vital that all steps should be taken to avoid the possibility of re-suspension 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 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 re-suspended 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. Regulation (EC) 852/2004 defines clean seawater as being: *“natural, artificial or purified seawater or brackish water that does not contain micro-organism, harmful substances or toxic marine plankton in quantities capable of directly or indirectly affecting the health quality of food.”*

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 LA 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.

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. Reuse of seawater may only be permitted where suitable storage vessels are available.

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 purification cycle.

At the end of the purification process shellfish must meet all requirements relating to biotoxins prescribed in Chapter V of (EC) 853/2004 and the microbiological criteria specified in (EC) 2073/2005.

Annex B:

Aide Memoir for OC visits to purification establishments and purification system OC

AOs may use the following template to assist in assessing the compliance of purification establishments against hygiene requirements.

Further guidance is available on Annex B in the form of best practice guidance on the specific technical criteria purification systems should achieve.

Purification Aide Memoir
(To be completed on the basis of objective evidence)

Business _____

Scope/Product _____

Date _____

Page _____ of _____

Officer _____

Step / Process Flow Diagram Validation	Awareness of Hazards	Control Measure (knowledge & reference to Critical Limits)	Monitoring (knowledge & reference to Critical Limits)	Corrective Actions (knowledge & reference to Critical Limits)
Receipt of Shellfish	What is the classification?			
	What is the source?			
	Are the shellfish alive, healthy & clean?			
	What is the method of harvest?			
	Are movement documents available (if relevant)?			
	Is there evidence of mixing of batches/species?			
Sorting/ Grading	Are damaged shellfish removed before purification?			
Cleaning/ Washing	Is clean water used?			
	Does the cleaning process remove gross soil effectively?			

Business _____

Scope/Product _____

Date _____

Page _____ of _____

Officer _____

Step/ Process Flow Diagram Validation	Awareness of Hazards	Control Measure (knowledge & reference to Critical Limits)	Monitoring (knowledge & reference to Critical Limits)	Corrective Actions (knowledge & reference to Critical Limits)
Loading of purification tanks	Is the tank of sound construction & maintenance?			
	Are tanks identified?			
	Are trays of suitable design and raised from the floor of the tank?			
	Have there been any modifications since the previous inspection?			
	What is the method of filling the tank?			
	Is the loading density as per the protocol?			
	Are the shellfish fully immersed?			

	Is there evidence of mixing of species/batches?			
--	---	--	--	--

Business _____

Scope/Product _____

Date _____

Page _____ of _____

Officer _____

Step/ Process Flow Diagram Validation	Awareness of Hazards	Control Measure (knowledge & reference to Critical Limits)	Monitoring (knowledge & reference to Critical Limits)	Corrective Actions (knowledge & reference to Critical Limits)
Water Supply	Is natural or artificial seawater in use?			
	If natural seawater, where is the extraction point located?			
	What is the seawater turbidity?			
	Are there any potential sources of contamination present?			
	Is the seawater pre-treated by UV?			
	If artificial seawater, is the formulation correct?			
	Is water re-use in line with recommendations?			
	What are the seawater storage facilities?			

	Is there a contingency in the event that seawater cannot be used? (e.g. toxicity/ chemical/ microbiological event)			
--	--	--	--	--

Business _____

Scope/Product _____

Date _____

Page _____ of _____

Officer _____

Step/ Process Flow Diagram Validation	Awareness of Hazards	Control Measure (knowledge & reference to Critical Limits)	Monitoring (knowledge & reference to Critical Limits)	Corrective Actions (knowledge & reference to Critical Limits)
Water UV treatment	Is the UV bulb usage recorded and monitored?			
	Are bulbs changed as per manufacturers' instructions?			
	Are the UV sleeves cleaned regularly?			
Purification	Is there an even flow through the system?			
	Do cascades fall directly onto the shellfish or cause re-suspension of sediment?			
	Does aeration disturb the shellfish?			
	Is the re-circulation even through the UV system?			

	Do the shellfish appear healthy and active?			
--	---	--	--	--

Business _____

Scope/Product _____

Date _____

Page _____ of _____

Officer _____

Step/ Process Flow Diagram Validation	Awareness of Hazards	Control Measure (knowledge & reference to Critical Limits)	Monitoring (knowledge & reference to Critical Limits)	Corrective Actions (knowledge & reference to Critical Limits)
Purification	Is there an even flow through the system?			
	Do cascades fall directly onto the shellfish or cause re-suspension of sediment?			
	Does aeration disturb the shellfish?			
	Is the re-circulation even through the UV system?			
	Do the shellfish appear healthy and active?			
	Time			
	Quantities			
	Water temperature			
	Water salinity			
	Water flow rate			
	Dissolved Oxygen			

	Tank cleaning			
--	---------------	--	--	--

Business _____

Scope/Product _____

Date _____

Page _____ of _____

Officer _____

Step/ Process Flow Diagram Validation	Awareness of Hazards	Control Measure (knowledge & reference to Critical Limits)	Monitoring (knowledge & reference to Critical Limits)	Corrective Actions (knowledge & reference to Critical Limits)
Draining down	Is water allowed to drain down completely before removing shellfish?			
Post-purification cleaning	Is the water of suitable quality?			
Rewatering/ Conditioning	Are batches of shellfish kept separate?			
	Are the tanks suitable for use?			
	Is the water used of suitable quality?			

Business _____

Scope/Product _____

Date _____

Page _____ of _____

Officer _____

Verification & Process Capability Assessment			
Internal Audit			
External Audit			
Triangulation (3rd Party Verification)			
End Product Testing Review			
Microbiological Results	Purified LBMs	Unpurified LBMs	Purification system water entering the purification tanks
Own Checks Cleaning & disinfection			
Water assay			
Review – Corrective Actions/Complaints/ HACCP team Meeting Minutes			

Business _____

Scope/Product _____

Date _____

Page _____ of _____

Officer _____

Prerequisite Programmes			
Training Status			
Pest Proofing & Control Measures			
Cleaning & Disinfection	Agent	Usage	Method
	Validity	Verification	Acquire evidence from supplier if available

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Business _____

Scope/Product _____

Date _____

Page _____ of _____

Officer _____

Approval Conditions	
Comments	

Record of inspection – purification tanks

Tank No.				
Species				
Registration Document No./Batch No.				
Loading Density				
Total in tank (kg)				
Height of Water above Shellfish (cm)				
UV working				
UV Bulb hours used				
Flow Rate (m³/hour)				
Seawater Salinity (%)				
Seawater Temp (°C)				
Dissolved Oxygen (mg/L/ % saturation)				
Purification Time				
Mollusc Activity				
Tank Cleaning				

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

Purification system official control inspection checklist	
Operator name	
Company/System name and address	
Date of inspection	
Name of inspecting officer/s	
System identification/approval number	
Date system approved	
Type of inspection Routine/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
Shellfish trays	Heaters
Cascades	Cooling system
Seawater storage	Pipe work
System	
Type of tank	
Identification number/mark of tank	
Is 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 is 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 purification 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 adequate?	
Flow rate Recorded and adequate?	

Tank cleaning - Recorded and adequate?	
HACCP systems in place? Recorded and adequate?	
Movement documents in proper use? Records maintained for appropriate time? (min. 1 year recommended)	
Training of staff - Recorded and adequate?	
Pest control - Internal/external company?	
Are samples of purification 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	

**APPLICATION FOR REQUEST FOR APPROVAL OFFICIAL CONTROL VISIT FOR
PURIFICATION FACILITY**

N.B. This form should be completed in conjunction with the Food Business Operator by the AO of the competent authority. Once completed it should be returned to the FSS at the address below.

Type of visit Required (delete as appropriate)	Full technical official control visit			Advisory official control visit		
LA contact officer			LA address			
Contact number						
Date of request						
Operator name			Operator company Name & Address			
Contact number						
Type of purification system	Small scale shallow tank	Medium scale multi layer	Large scale multi layer	Bulk Bin	Vertical Stack	Non-standard design
Specification if non- standard						
Shellfish Species	Common Mussels	Native Oyster	Pacific Oyster	Hard Shell Clam	Native Clam	
	Surf Clams	Common Cockles	Razors	Other (please specify)		
Harvesting Area Name			SIN			Classification
Location & NGR of seawater extraction						
Suitable dates for inspection						
Comments						
Food Business Operator Signature			LA Authorised Officer Signature			
Name			Name			

Please return to: Food Standards Scotland, Pilgrim House, Old Ford Road, Aberdeen, AB11 5RL

Annex C

Technical Criteria for the Inspection of Purification Systems

This Annex contains supporting guidance to assist AOs in assessing the technical function of purification systems. AOs may need to take on-site verification measurements and so should have access to the following calibrated equipment.

Purification 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 nearby 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 Advice on 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 as bubbles in the water can interfere with filtration activity.

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 may not change baskets from those that were approved at the time of the initial inspection.

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 purification 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 purification.

Shellfish should be placed into approved trays to standard depths. Depths observed should be checked against the Advice on Approval.

Baskets and trays should only be loaded to the number of layers specified in the Advice on 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 purification should be checked against the food business 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. It is important at this stage to avoid re-contamination of the shellfish by re-immersing in unsuitable water. 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.

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 purification. Generally, foam collecting on the surface of the water is indicative of actively purifying shellfish and is not a problem. Excessive foaming, however, can be indicative of a problem with the shellfish and should be investigated.

Shellfish should be harvested by an appropriate method (e.g. currently razor clams and cockles may only be deputed 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.

Seawater Quality

Purification systems will be approved for use with artificial or natural seawater or both. The type of seawater used will affect 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 Advice on 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 purification 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. It should be ensured as far as possible

that a change of the source of the water does not significantly increase the risk of contamination.

Water should be visibly clear both during the purification 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 purification tank at the end of the cycle must allow water to be transferred to the storage tank without sediment also being transferred. Storage tanks should not be exposed to light.

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

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.

Record keeping

Purification centres must keep records of the permanent food safety management procedures implemented as required under Regulation (EC) 852/2004. Minimum legal requirements for keeping records at purification centres are not specified by the Regulations. As a guide, the following records should be available;

- 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.

Records should be kept for a minimum of 12 months.

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

- Seawater temperature
- Seawater salinity
- Flow rates
- Dissolved oxygen
- Tank cleaning
- UV usage. The hours of UV usage should be recorded and the maximum permissible hours of use stipulated in the “Advice on 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 times due to exceptional circumstances this must be recorded along with the exceptional circumstances causing that extended reuse.

Immersed Storage (‘Re-watering’) as a process

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 purification/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.

The immersed storage can only take place at an establishment approved for purification 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 purification 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 Water Framework Directive 2013 (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.

Regulations (EC) 852/2004 and (EC) 853/2004 place obligations upon the approved purification 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 the FBO has 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 human 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.

Annex D: Sample Advice on Approval document

ADVICE ON APPROVAL FOR THE PURIFICATION SYSTEM OPERATED
BY

{Company Name}

Made under The Food Hygiene (Scotland) Regulations 2006 (As Amended)

{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 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.

Advice:

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, validated conditions of purification have been achieved. Any reduced period, from 42 hours, must be validated by the FBO in the FSMS and verified by the Authorised Officer from the Competent Authority (LA) BEFORE any reduced purification period is applied.
4. The total volume of water in the system must be re-circulated 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 (or in accordance with instructions for use – evidence to be provided). 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 re-suspension of sediment, before shellfish are disturbed or removed.

Seawater:

Seawater must meet the minimum salinities and temperatures during purification criteria when in use in the purification system.

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 defined by Regulation (EC) 852/2004 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 {Local Authority name} Environmental Health Department.

LA:

Authorised Officer Name