

Guidance for Local Authority Authorised Officers on the Inspection of Purification Systems for Live Bivalve Molluscs in England Wales and Northern Ireland

November 2016

For all queries about this guidance — including if you require the information in an alternative format such as audio, large print or Braille — please use the email address below.

shellfishharvesting@foodstandards.gsi.gov.uk



Summary

Intended audience:	For the use of Local Food Authority (LA) Authorised Officers (AOs).		
Which UK nations does this cover?	England, Wales and Northern Ireland		
Purpose:	This guidance is intended to assist LA /AO officers when carrying out inspections of purification centres of Live Bivalve Molluscs.		
Legal status:	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. 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. It is a regulatory requirement that Local Authority Authorised Officers need to do to comply with domestic or EU legislation.		
Key words	 Approvals Fish and shellfish Food law, monitoring and controls Hygiene and food safety 		
Review date	November 2017		



Revision history

This guidance follows the Government <u>Code of Practice on Guidance</u>. If you believe this guidance breaches the Code for any reason, please let us know by emailing <u>betterregulation@foodstandards.gsi.gov.uk</u>. If you have any comments on the guidance itself, please call us using the contact number on page 2

Revision No.	Revision date	Purpose of revision and paragraph number	Revised by
1	07/11/16	Addition of flow meter chart to annex B page 21	R Watts



Contents

SUMMARY	3
REVISION HISTORY	4
GLOSSARY	6
INTRODUCTION	7
LEGAL STATUS OF GUIDANCE	8
TYPES OF PURIFICATION SYSTEM	9
APPROVALS AND INSPECTIONS OF PURIFICATION SYSTEMS	10
CHANGES TO EXISTING PURIFICATION SYSTEMS	11
MINIMUM PURIFICATION (DEPURATION) TIME	
Table 1. Types of risk factors to be taken into consideration	13
SUSPENSION OR WITHDRAWAL OF AN APPROVAL	15
CONTACTS	16
ANNEXE A: Aide Memoire	17
ANNEXE B: Technical criteria for the inspection of purification systems	18



Glossary

Definitions and Abbreviations used in this guidance.

Authorised Officer (AO) In relation to enforcement authority, any person (whether or not an officer of the Authority) who is authorised by the Local Authority or District Council in writing, either generally or specifically, to act in matter arising under the Food Safety and Hygiene Regulations 2013.

Cefas

The Centre for Environment, Fisheries and Aquaculture Science (Cefas) is an executive agency of the <u>Department for Environment, Food and Rural Affairs (Defra)</u>. A world leader in marine science and technology, collects, manages and interprets data on the aquatic environment, biodiversity and fisheries.

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

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 fir 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.



Establishment (also refer to Definition of a "Premises")

Any unit of a food business.

Note: "establishment" does not simply mean "premises", but it is linked directly to the business occupying the establishment ("establishment" denotes both premises and the manner in which those premises are being used by the food business operator).

Food Standards Agency – FSA

The Food Standards Agency is a non-ministerial government department set up in 2000 to protect the public's health and

consumer interests in relation to food.

Live bivalve Mollusc (LBM) Filter-feeding lamellibranch molluscs.

Purification centre An establishment with tanks fed by clean seawater in which live

bivalve molluscs are placed for the time necessary to reduce

contamination to make them fit for human consumption.

Seafish Is a Non-Departmental Public Body (NDPB) set up by the

Fisheries Act 1981 to improve efficiency and raise standards

across the seafood industry.

UV Ultra-violet

Introduction

1. This guidance is for the use of local authority (LA) authorised officers (AO) in England, Wales and Northern Ireland in relation to official control inspections of purification (depuration) systems for live bivalve molluscs (LBMs).

The guidance is intended to assist LAs with inspecting purification systems 2. and should be read in conjunction with the Food Standards Agency's (FSA) guidance on the approval of establishments¹ and Hazard Analysis Critical Control Point (HACCP)2. It does not provide authoritative interpretation of

http://www.food.gov.uk/sites/default/files/multimedia/pdfs/enforcement/approvalsguidance.pdf

Guidance for Local Authority Authorised Officers on the Inspection of Purification Systems for Live Bivalve Molluscs in England, Wales and Northern Ireland.

¹ FSA Guidance for local authority authorised officers on the approval of establishments, 2012

² FSA HACCP information http://www.food.gov.uk/business-industry/food-hygiene/haccp



legislative requirements and is not a substitute for an understanding of the applicable law.

Legal status of guidance

- 3. Regulation (EC) 852/2004³ 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. The requirements of Regulation (EC) 853/2004 for the approval of businesses handling products of animal origin (POAO), also apply to shellfish purification centres.
- 4. 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) 853/2004⁴. 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. 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**. The procedures for handling applications for approval are included in the Food Law Code of Practice⁵. Further guidance on the approval process is set-out in the FSA Guidance on the Approval of Establishments.
- 6. Inspections should be undertaken in the following circumstances:
 - Initial approval of a new purification establishment
 - Routine re-inspection (in accordance with the inspection frequency prescribed by the risk rating applied to the establishment ⁶)

_

³ Regulation (EC) 852/2004 of the European Parliament and of the Council

⁴ Regulation (EC) 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin

⁵ http://www.food.gov.uk/enforcement/enforcework/foodlawcop/copengland/ http://www.food.gov.uk/enforcement/enforcework/foodlawcop/codepracticewales/

^{*} www.seafish.org



- As an intervention e.g. following repeated end product failures or outbreaks of illness linked to the establishment.
- To assess 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 reinstallation) at an approved establishment (see paragraph 17 for details).
- To review evidence when an FBO wishes to apply a reduced period of purification to be satisfied that their HACCP based food safety management system has considered all relevant risks and that the systems in place are protective of human health and compliant with end product standards. (see paragraph 18 for details).

Types of Purification Systems

The majority of purification systems are 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

AOs 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*.

FBOs using non-standard design systems will need to provide additional details regarding the design, construction, plumbing and operation of the system. It is the responsibly of the FBO to demonstrate how the system works and to provide evidence that the system is capable of operating consistently, e.g. proof that it conforms to recognised industry standards.

⁶ Food establishment intervention rating scheme https://www.food.gov.uk/enforcement/codes-of-practice/food-law-code-of-practice-2015/5-6-food-establishment-intervention-rating-schemes



Approvals and Inspections of Purification Systems

- 7. Approvals procedures are set-out in Regulations (EC) No. 882/2004 and 853/2004, and further explained in the FSA's <u>approval guidance</u>. Under current procedures set out in the approval guide, establishments requiring approval will not be able to operate until they have been granted "conditional approval". An inspection of the purification system in a new establishment is required <u>before</u> conditional approval is granted. **Note:** it is the responsibility of the FBO to validate their systems and to provide evidence to the AO to demonstrate compliance.
- 8. For new purification establishments, conditional approval⁷ must be granted prior to full approval to allow the FBO to demonstrate that their HACCP-based food safety management plan is valid and to verify its effectiveness. AOs will need to be satisfied that the system is operating effectively and that all associated risks have been considered in the HACCP.
- 9. 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 plan, full approval will be refused.
- The FSA has developed an Aide Memoire to further assist AOs in the undertaking of a full and thorough inspection of a purification system. It has been designed to act as a prompt for AOs to be used prior to and during approval inspections and re-inspection visits. A template is included in **Annex A**.
- 11. It is important for AOs to record any verification checks undertaken e.g. measurement of technical operating parameters (listed in the Aide Memoire)

⁷ Conditional approval cannot last more than 6 months. If establishment is not fully compliant within this time, approval must be withdrawn.

^{*} www.seafish.org

^{**} http://seafoodacademy.org/BVP%20SSTC.htm



such as salinity, temperature etc. as well as any other relevant information evidenced during the inspection. Further guidance on the minimum information required is included in **Annex B**. Should further assistance be required AOs may contact the Food Standards Agency 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 you or the FBO visit the Seafish* or Seafood academy** websites or for more information contact Seafish directly.

- 12. 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 inspections:
 - 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 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 Purification Systems

- 13. 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.
- 14. AOs 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 inspect the proposed new system and/or request an



amended HACCP-based food safety management plan. Examples of modifications that may require inspection 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 safety and Hygiene (England) Regulations 2013 and the Food Hygiene Regulations 2006 in Wales and Northern Ireland.

Minimum purification (depuration) time

15. 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 the FSA considers it is for FBOs to demonstrate, in accordance with their HACCP plans, that all relevant risks (from bacteriological and viral contamination) have been considered and the AO is satisfied the system (and any reduced purification time) is effective and protective of public health.



- 16. FBOs wanting to take advantage of this flexibility are to contact the relevant LA before applying a reduced purification period. AOs are required to review the evidence provided (as documented in an amended HACCP-based plan) and, carry out an inspection to ensure they are satisfied the proposed practices are acceptable and feasibly implementable. AOs are to take into account the following:
 - Amendment of HACCP-based plans to account for the 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
- 17. AOs should have regard to all risk factors associated with LBMs being subjected to reduced purification times. FBOs should document in their HACCP-based plans the evidence to demonstrate these factors have been accounted and are in place in their establishment. A summary of the types of risk factors to be taken into consideration is included in the following table:

Table 1:

Risk factors/hazards	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 EPT 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	Seafish standard design, non- standard design, non-			
system	standard design with modifications			
Weather patterns/seasonal	Water circulation patterns and harvesting practices			
changes	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	FBO explain how level of EPT is arrived at and what			
(EPT) and record keeping	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.			

AOs may want to take verification samples at the inspection visit to check against the FBOs own results.

Further information on HACCP for FBOs can be viewed at: http://www.food.gov.uk/business-industry/food-hygiene/haccp

18. Where it is agreed systems can operate at reduced purification times, the changes to purification time must be verified by AO to ensure they are effective. Verification is required before the FBO can begin operating using the agreed reduced time. Confirmation that sufficient evidence has been provided for the FBO to apply the reduced purification time must be clearly



stated in writing to the FBO and changes included in the appropriate 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

19. LAs are to keep the approval of establishments under review when carrying out official controls (Article 31(2)(e) of Regulation 882/2004). LAs must initiate procedures to withdraw an establishment's approval where serious deficiencies are identified and the FBO is unable to provide guarantees regarding future production. More information on suspension and withdrawals, and a non-exhaustive list of "serious deficiencies" can be found in the FSA Approvals Guidance.



Contacts

2. More information or guidance on the technical aspects of purification systems can be obtained from the relevant FSA offices:

England

Becky Watts
Regulatory Delivery Division
Aviation House
125 Kingsway
London WC2B 6NH

Email: shellfishharvesting@foodstandards.gsi.gov.uk

Tel: 020 7276 8046

<u>Wales</u>

Local Authority Support and Audit Team Email: <u>Lasupportwales@foodstandards.gsi.gov.uk</u>

Tel: 02920 678956

Northern Ireland

Debbie Sharpe

Email: Debbie.Sharpe@foodstandards.gsi.gov.uk

Tel: 02890 417703

Annexe A: AIDE MEMOIRE FOR THE INSPECTION OF PURIFICATION ESTABLISHMENTS (TO BE INSERTED)

Authorised officers may use this template to assist in assessing the compliance of purification establishments against hygiene requirements. Further guidance is available in Annex B in the form of best practice guidance on the specific technical criteria purification systems should achieve.

NOTE: The aide memoire document was subject to consultation and will be published in the near future.

November 2016

Annexe B: TECHNICAL CRITERIA FOR THE INSPECTION OF PURIFICATION SYSTEMS

This Annex contains supporting guidance to assist Authorised Officers (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:

- Temperature probe
- Refractometer
- Dissolved oxygen meter including digital thermometer
- Turbidity meter
- GPS

Seawater

Regulation (EC) 853/2004 requires purification systems to use 'clean' seawater. The following information may be used to assess the seawater being used is of a suitable quality. Refer to Seafish and Cefas Guidance 'Water Quality in Purification (Depuration) Systems' https://www.cefas.co.uk/media/52850/2012-water-quality-in-purification-leaflet.pdf Natural or artificial seawater

- Where natural seawater is used, determine the location of the source and confirm reasons for utilising.
- Check FBO records to ensure microbiological and algal toxin quality of the water is regularly and routinely monitored.

Recirculation and storage

- Where seawater is re-used for more than one purification cycle, ensure there is adequate storage capacity between cycles. The storage facilities should be clean and allow full drainage.
- Tanks and water storage containers must meet the following requirements:
 - o Internal surfaces must be smooth, durable, impermeable and easy to clean
 - They must be constructed so as to allow complete draining of water
 - Any water intake must be situated in a position that avoids contamination of the water supply

- The purification system should be constructed in such a way to restrict the transfer of sediment from the purification tank to the storage facility (pre-treatment).
- It is recommended that natural seawater is re-used for a maximum of 2 weeks and artificial seawater for a maximum of 4 weeks.
- The re-use of seawater is not recommended for the purification of sand gapers, cockles and razor clams, and the purification of mussels in bulk bin systems with low shellfish to water ratios (less than 3:1).
- Re-use of seawater is not permitted if suitable storage facilities are not in place.
 The FBO will need to demonstrate that their re-use of seawater is within the recommended parameters for the type of system and species involved.

UV filters

- Where UV filters are to be used to pre-treat (sterilise) the water, this should be done
 before purification commences. This is done by filling the system through the
 operational UV steriliser. If seawater is used, this must be recirculated through the
 operational UV for a minimum of 12 hours before shellfish are added to the system, or
 in accordance with the manufacturer's operating manual.
- UV lamps should be free of slime and sediment to ensure efficient irradiation.
- UV lamps should be changed in accordance with the manufacturer's specified period.
- Check FBO's records to ensure UV lamps are changed at the required frequency in line with manufactures recommendations and appropriately documented in HACCP plans.

Ozone

- Ozone may be used to sterilise seawater providing it does not come into direct contact
 with the shellfish or create harmful by-products e.g. bromates that may affect the safety
 of the shellfish. Residual ozone must be removed from the seawater before it comes in
 contact with the shellfish (the oxidative redox potential [ORP] of seawater entering the
 tank containing shellfish must be within 10% of the base ORP of the untreated water).
- Checks FBO's records to ensure ozone is applied correctly and water is tested for harmful by-products, in accordance with the agreed HACCP plan.
- Use and maintenance of the ozone must be in line with the manufacturer's operating manual.

Turbidity

• Turbidity may limit the effectiveness of UV disinfection due to the presence of suspended particles. It is therefore recommended that these fine particulates are

removed through the use of settlement tanks (for gross sedimentation) and/or the installation of 'in-line' cartridge or sand filters. These must be used in accordance with the manufacturer's operating conditions.

Cefas and Seafish guidance on Water Quality in Purification Systems for FBOs can be viewed here:

https://www.cefas.co.uk/media/52850/2012-water-quality-in-purification-leaflet.pdf

Minimum temperature and salinity

- The minimum temperatures and salinities as recommended in the following tables 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 1: Recommended minimum salinity and temperature

Species	Min salinity (⁰ / ₀₀)	Min Temperature (°C)	
Pacific oysters (C. gigas)	20.5	8	
Native oysters (O edulis)	25.0	5	
Mussels (Mytilus spp.)	19.0	5	
Cockles (C. edule)	20.0	7	
Hard clam (M. mercenaria)	20.5	12	
Native clam (T. decussatus)	20.5	12	
Manila clam (T. philippinarium)	20.5	12	
Razor clam (Ensis spp.)	30	10	
Scallops (Pecten maximus)	35	10	

Thick trough shell (S. solida)	30	12
Peppery furrow shell (S. plana)	20.5	12
Sand gaper (Mya arenaria)	25	10

Flow rate and Dissolved Oxygen

Flow rate/maximum shellfish loading density

- Flow rate can be measured using a flow meter in the purification tank as long as the shellfish are not disturbed. There are alternative methods that the FBO can demonstrate to calculate the flow.
- The flow rate will vary according to the type of system and shellfish species being purified, and the shellfish to water ratio. FBOs should demonstrate the flow of water in their system is at a rate suitable to allow effective purification of the shellfish it contains.

Table 2: Minimum flow rates stipulated for Approval of standard design systems

System	Small Scale	Medium	Large Scale	Bulk Bin 650	Vertical
Туре	550-600	Scale 2,000-	9,000 litres	litres Bin	Stack 650
	litres	2,500 litres			litres sump
					-
Minimum	20 L/min	208.3 L/min	158.3 L/min	108.3 L/min	15 L/min
Flow Rate	1.2 m ³ /hr	12.5 m ³ /hr	9.5 m ³ /hr	6.5 m ³ /hr	0.9 m ³ /hr

• Shellfish loading arrangements will vary depending on the type of system and species. The loading capacity of a purification system can be determined by calculating the surface area for a tray, multiplying the number of trays in the system and complying with the permissible loading densities. Loading densities should be in accordance with the Seafish manual or, if a novel system, as recommended by the manufacturer. FBOs will need to demonstrate the loading capacities and arrangements in place allow a free and even flow of water and effective purification of the shellfish.

Dissolved oxygen

- The minimum dissolved oxygen (D.O.) at any point in the purification tank must be capable of sustaining normal physiological activity of the shellfish.
- It is recommended that D.O. levels are measured at the spray bar, middle of the system and the suction bar.
- The minimum D.O. currently used in assessing the oxygenation capabilities of purification systems is 5mg/l.

General requirements for purification

Regulation 853/2004 (Annex III, Section VII, Chapter IV, A) requires:

- Before purification commences, live bivalve molluscs must be washed free of mud and accumulated debris using clean water.
- Operation of the purification system must allow live bivalve molluscs to rapidly resume and maintain filter feeding activity, to eliminate sewage contamination, not to become re-contaminated and to be able to remain alive in a suitable condition after purification for wrapping, storage and transport before being placed on the market.
- The quantity of live bivalve molluscs to be purified must not exceed the capacity of the purification tank. The live bivalve molluscs must be continuously purified for a period sufficient to achieve compliance with allow the health standards of Chapter V and microbiological criteria adopted in accordance with Regulation (EC) No 2073/2005*.
- Should a purification tank contain several batches of live bivalve molluscs, they must be of the same species and the length of the treatment must be based on the time required by the batch needing the longest period of purification.
- Containers used to hold live bivalve molluscs in purification systems must have a construction that allows clean seawater to flow through. The depth of layers of live bivalve molluscs must not impede the opening of shells during purification.
- No crustaceans, fish or marine species may be kept in a purification tank in which live bivalve molluscs are undergoing purification.
- Every package containing live bivalve molluscs sent to a dispatch centre must be provided with a label certifying that all molluscs have been purified.

In addition, AOs may wish to be mindful of the following guidelines:

• All shellfish must be alive and healthy before purification commences.

^{*}Regulation 2073/2005 on the microbiological criteria for foodstuffs

- Purification, without disturbance to the shellfish, must be carried out for a minimum of 42 hours unless appropriate permissions have been granted by the relevant LA to allow the minimum purification time to be reduced (in accordance with the approved HACCPbased plan). The duration of the purification should be clearly noted.
- Shellfish should not be weighted down with anything which would prevent them from depurating.
- Shellfish should be distributed evenly in trays in accordance with loading capacities (as stated in HACCP-based plans) to allow a free and even flow of water and effective purification
- Inspections should be carried out on fully loaded systems ideally towards the end of the purification cycle to observe drain down procedures OR at least 12 hours into the cycle.
 The time and date the purification cycle started should be noted.
- Any relevant aspects of the process used (as described by the FBO) should be noted
 e.g. are shellfish thoroughly cleaned (without immersion) before they are loaded for
 purification and after the system has been drained once the purification cycle is
 complete? Are checks in place to ensure that shellfish are completely immersed during
 purification? Are shellfish clean, alive and healthy and appear to be actively filterfeeding?
- Any possible external sources of contamination, along with how they are controlled should be noted e.g. if the purification system is located outside, it must be covered.
- Any supplementary aeration and if so, if it interferes with shellfish activity.
- Trays/baskets should be of suitable design and stacked in a stable condition allowing suitable flow of water through the system, they should also be raised to an acceptable level from the base of the tank to prevent recontamination by sediment and loaded to a suitable capacity/depth.
- After the purification process, seawater should be drained to below the level of shellfish in the bottom layer without disturbing the shellfish. Shellfish should then be removed and thoroughly cleaned (without immersion) with clean seawater or potable water.
- Purification tanks and any trays/baskets used in the process should be properly cleaned in between cycles.