SEAFISH

Bivalve Molluscs

Guidance on Procedures to Minimise Risks to Food Safety in Bivalve Mollusc Purification

1st Edition, March 1999

1st Edition, March 1999

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1. PURPOSE AND SCOPE

Persons operating bivalve mollusc Purification Centres are dealing in products intended for human consumption. They are responsible for the safety of their products. Hazard identification and control procedures are recommended as a practical means of addressing that responsibility.

This document provides guidance for Purification Centre operators and their Environmental Health Officers on minimising risks to food safety. It is geared primarily to the typical combined Purification and Dispatch Centre operated in the UK, in which the purification system seawater (natural or artificial) is treated and recirculated, although the principles apply to all types of purification system.

The guidance is based on good practice and simple hazard identification and control procedures rather than formal HACCP procedures. This is considered appropriate to the handling of bivalve molluscs as live animals and to the nature of the generally small businesses concerned.

The essence of hazard identification and control is that business operators should actively investigate the details of operation of their own particular business to see if there are any hazards to food safety. They should then make any improvements to the facilities and practices of the business necessary to control those hazards. They should introduce any checks necessary to ensure that the control measures are effective and all this should be reviewed occasionally or if any changes are made to the business.

Guidance is given in this document on how to carry out these procedures and examples are given of typical hazards, control measures and checks appropriate to the operation of Purification/Dispatch Centres. However, these examples do not substitute for the need for business operators to carry out their own hazard identification and control procedures in the particular circumstances of their own business. The Local Environmental Health Officer can provide further advice and assistance in carrying out these procedures.

This document has been produced by an expert group of scientists, technologists and Environmental Health Officers representing Seafish, CEFAS, Marine Laboratory Aberdeen, LACOTS and SAGB. It should be considered in conjunction with the particular Conditions of Approval issued for the Purification/Dispatch Centre concerned and the recommendations given in the appropriate Seafish 'Purification System Operating Manual'. Further technical guidance is given in the Seafish 'Guidelines for the Facilities and Equipment Required for Handling Bivalve Molluscs from Harvesting through to Distribution to Retail Outlets'.

2. THE NEED FOR CARE

The Hazards

Consumption of contaminated bivalve molluscs can cause food poisoning.

The main hazards are contamination of the inshore waters in which many of the mollusc species are found, particularly sewage contamination, and the occasional growth of toxin producing algae. Bivalve molluscs are filter feeders and accumulate these contaminants and toxins from the water around them. The risk to food safety is exacerbated by the common practices of only lightly cooking these shellfish or eating them raw.

Gastro-enteritis and other serious diseases such as infectious hepatitis can result from sewage contamination. Algal toxins can result in various forms of poisoning including paralytic shellfish poisoning (PSP), diarrhoeic shellfish poisoning (DSP) and amnesic shellfish poisoning (ASP).

Control Measures

Bivalve molluscs must not be taken from heavily contaminated waters or from areas in which there is a toxic algal bloom or residues of toxins that exceed safe levels. Bivalve molluscs may be taken from waters known to have only low levels of faecal contamination, provided that the molluscs are then subjected to a controlled cleansing process in order to purge them of microbiological contamination, or to a controlled heat treatment process sufficient to destroy the pathogens.

The cleansing process, which is suitable only for robust molluscs capable of being handled without dying, consists of immersing them in suitable conditions of clean seawater for a period of time sufficient for the pathogens to be purged by the normal activity of the molluscs. The seawater conditions required, particularly the temperature, vary according to species and must encourage the molluscs to be active. This cleansing can be in man-made purification tanks or by relaying in naturally clean areas. After cleansing, the molluscs must meet a statutory microbiological standard.

Purification (or depuration) is a short-term process used to remove low levels of bacteriological contamination. Purification is not fully effective in removing viral, chemical or algal toxin contamination. To effectively remove any viral contamination, long-term relaying or heat treatment is required.

The Sensitivity of Molluscs

Bivalve molluscs may appear robust but all are perishable and sensitive creatures. In the live state they are prone to temperature stress and physical shocks. If overheated, whether in or out of water, they will die. Overheating in water can induce spawning and then death. If they are physically dropped or otherwise damaged they are likely to deteriorate and die within a day or two. The effects on the molluscs of all these forms of stress are cumulative and repeated incidents of relatively minor mishandling can result in their death.

It is particularly important that bivalve molluscs to be purified are handled carefully and are not held at too high a temperature or for too long, otherwise they may die or may not function and cleanse during purification.

They must also be handled carefully after purification to prevent any recontamination and to avoid stress and damage that may cause them to deteriorate and die before reaching the consumer. Their eating quality declines whilst they deteriorate and they rapidly become unwholesome after their death.

The Purification Process

Purification is usually carried out in some form of tank through which there is a flow of clean seawater. The seawater is usually treated and recirculated through the tank during the purification cycle and may be reused for a number of subsequent purification cycles. In some Purification Centres which have access to ample supplies of suitable clean seawater, it is passed only once through the tank and then to waste.

The essential conditions for depuration are of seawater cleanliness, quality, temperature, flow and aeration. Given the correct physiological conditions that suit the particular species being cleansed, the molluscs resume their normal filter feeding activity and excrete the bacteriological contaminants in their faeces. This detritus must be allowed to settle and must not be re-ingested by the molluscs.

In order for all these requirements to be fulfilled, the design of the purification system and the process itself must be carefully controlled.

The Law

All persons involved in the harvesting, handling, storage, transport, purification, distribution and sale of live bivalve molluscs should be aware that they are handling

food and of the particular hazards that are involved. They should be adequately supervised and trained and/or instructed in carrying out their work. They are all subject to Food Safety legislation and must act responsibly. They must supply only safe food. The only defence available in law, should a public health problem occur, is for persons to prove that they took all reasonable precautions and exercised all due diligence in carrying out their business.

Particular Regulations concerning live bivalve molluscs require that they are harvested only from officially designated areas which are categorised according to their level of contamination by faecal bacteria. Molluscs from category 'A' areas can be placed on the market directly without any treatment, although some purchasers demand that they be purified as a precaution. Molluscs from category 'B' areas may be placed on the market after purification. Molluscs from category 'C' areas, which have higher levels of bacterial contamination and which therefore are considered to have a greater risk of viral contamination, must be relayed or heat treated.

The Regulations require that any purification is carried out in an officially approved Purification Centre and that the purified live bivalve molluscs must also pass through an officially approved Dispatch Centre for wrapping and labelling. Commonly these are one and the same establishment. The Regulations establish further requirements for harvesting, relaying, handling, storing, transporting, wrapping and labelling the molluscs and for the operation of Purification and Dispatch Centres.

The Regulations establish a monitoring and control system which includes the official monitoring, designation and categorisation of harvesting areas and the official monitoring and approval of Purification and Dispatch Centres. In addition, the operators of Purification and Dispatch Centres are required to carry out bacteriological tests, to keep records and to maintain a documentation system enabling the tracing of molluscs back to source. End-product standards are stipulated for the molluscs.

Batches of raw material supplied to a Purification Centre must be accompanied by an official movement document detailing the source of the molluscs (unless there is a 'permanent transport authorisation'). Product dispatched must be labelled with a health mark identifying the dispatch centre. Records must be kept of batches received and dispatched.

The Medical Evidence

Medical records show that viral contamination is the predominant cause of recent outbreaks of food poisoning associated with bivalve molluscs. This indicates that there is particular need to ensure that molluscs for purification are sourced from an officially and correctly categorised harvesting area which has a low risk of viral contamination, and that any seawater used for purification has a similarly low risk of viral contamination.

3. HAZARD IDENTIFICATION AND CONTROL PROCEDURES

The Basics

For most small businesses in the mollusc industry, hazard identification and control amounts to the application of common sense principles to the particular circumstances of operation of the business concerned. It is best achieved by following the molluscs through every step in the sequence of operation of the business, from reception to dispatch, identifying any particular hazards that occur at each step. Then by introducing the practical control measures and checks necessary to control those hazards and which are appropriate to the way in which the business operates. As the seawater used and its treatment are vital to mollusc purification, it should be followed similarly through every step in its use from supply to drainage as waste.

By way of example, particular hazards at mollusc reception could include:

a) lack of information on the source of the molluscs, hence on their level of microbiological contamination
b) leaving the molluscs lying around outside the premises, exposed to further contamination and to temperature stress after delivery.

Appropriate control measures for those hazards include:

a) insistence on the requirement for a movement document to identify the source of every batch of molluscs
b) moving the molluscs directly from the transport vehicle into a protected storage or preparation area.

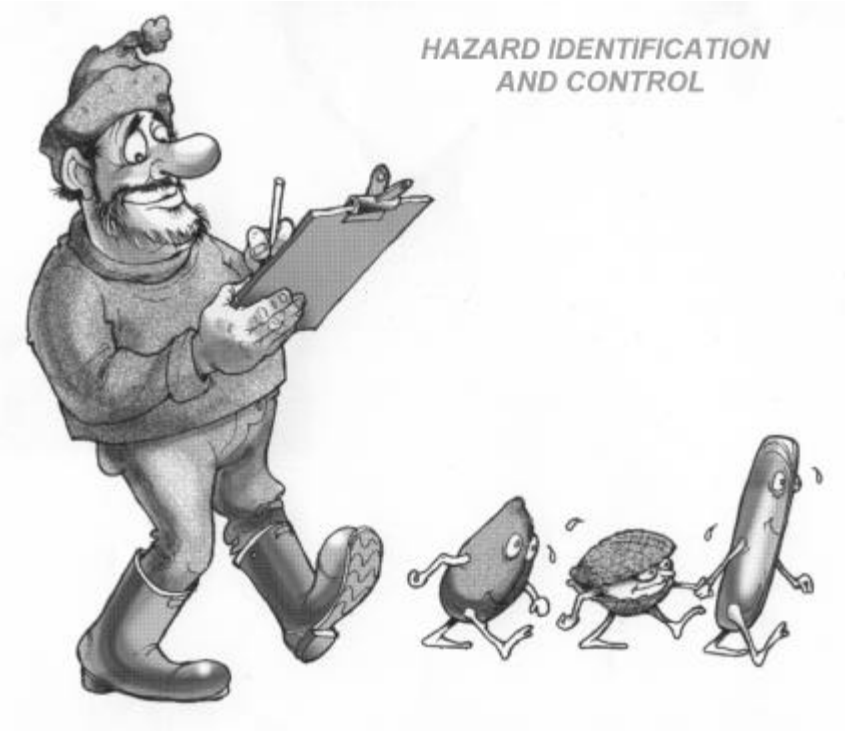
Appropriate checks on those control measures include:

a) the requirement to keep records of all deliveries and to keep all the original movement documents
b) supervision to ensure that the molluscs are not left lying around in unsuitable places.

The Procedures

To carry out the hazard identification and control analysis:

a) start with a blank sheet of paper and work through the business from start to finish, following the flow from raw material reception to product dispatch, and identify and list each process or step
b) for each step, consider the hazards to food safety that are actually present and add the hazards to the list
c) for each hazard, consider the practical measures that, as part of everyday working, will control the hazard and add the controls to the list
d) for each control measure, consider the supervisory checks necessary to ensure that the controls are working and add the checks to the list.



Then implement the necessary improvements to the business. Periodically review the working of the procedures and particularly if any substantial change is made to the fabric or the practices of the business.

Ask the local Environmental Health Officer to assist in and comment on the hazard identification and control analysis.

Example Flowcharts and Checklists

Example process flow charts and hazard identification and control checklists are attached. Because these examples are designed to cover a wide range of possibilities for Purification/Dispatch Centre design and operation, they are more complex than those that will emerge from the analysis of any one particular Centre.

The purpose of these examples is only to provide a model and some guidance. They do not substitute for analysis by operators of their own business which will have its own particular way of working, particular hazards and appropriate control measures and checks.

Flow Chart 1 shows the main process flow and identifies and numbers each process or step. Flow chart 1 links to flow chart 2 at the points A and B shown on the charts.

Flow Chart 2 shows the seawater process flow and identifies and numbers each process or step. Options are shown for supplying either natural or artificial seawater and then for re-using the seawater.

Checklist 1 is a summary of the main hazards together with the general hazards, control measures and checks that apply throughout the operation of the Centre.

Checklist 2 details particular hazards, control measures and checks that apply at each numbered step of the main process flow.

Checklist 3 details particular hazards, control measures and checks that apply at each numbered step of the seawater process flow.

Checklist 4 applies to the use of the purification system for immersed storage after purification.

Note: any re-immersion after purification, including immersed storage, involves the hazard of recontaminating the molluscs. Such immersed storage may be carried out only in controlled conditions in purpose designed facilities (e.g. a suitable purification system) in an approved Purification or Dispatch Centre. Re-immersion is illegal after the molluscs have been wrapped and have left the Dispatch Centre.

4. DOCUMENTATION

Documentation and record keeping are important elements of the system of control measures and checks. They also play an essential part in the ability of the business operator to prove a 'due diligence' defence in the unfortunate event of a public health problem occurring.

Example record sheets are attached in order to help each business develop its own documentation and record keeping system. Again these are only to provide a model but when adapted to the needs of each particular business, they can form the basis of a working system.

Record Sheet 1 records mollusc reception.

Record Sheet 2 one of which is filled in for each purification cycle of each purification tank, records purification system operation.

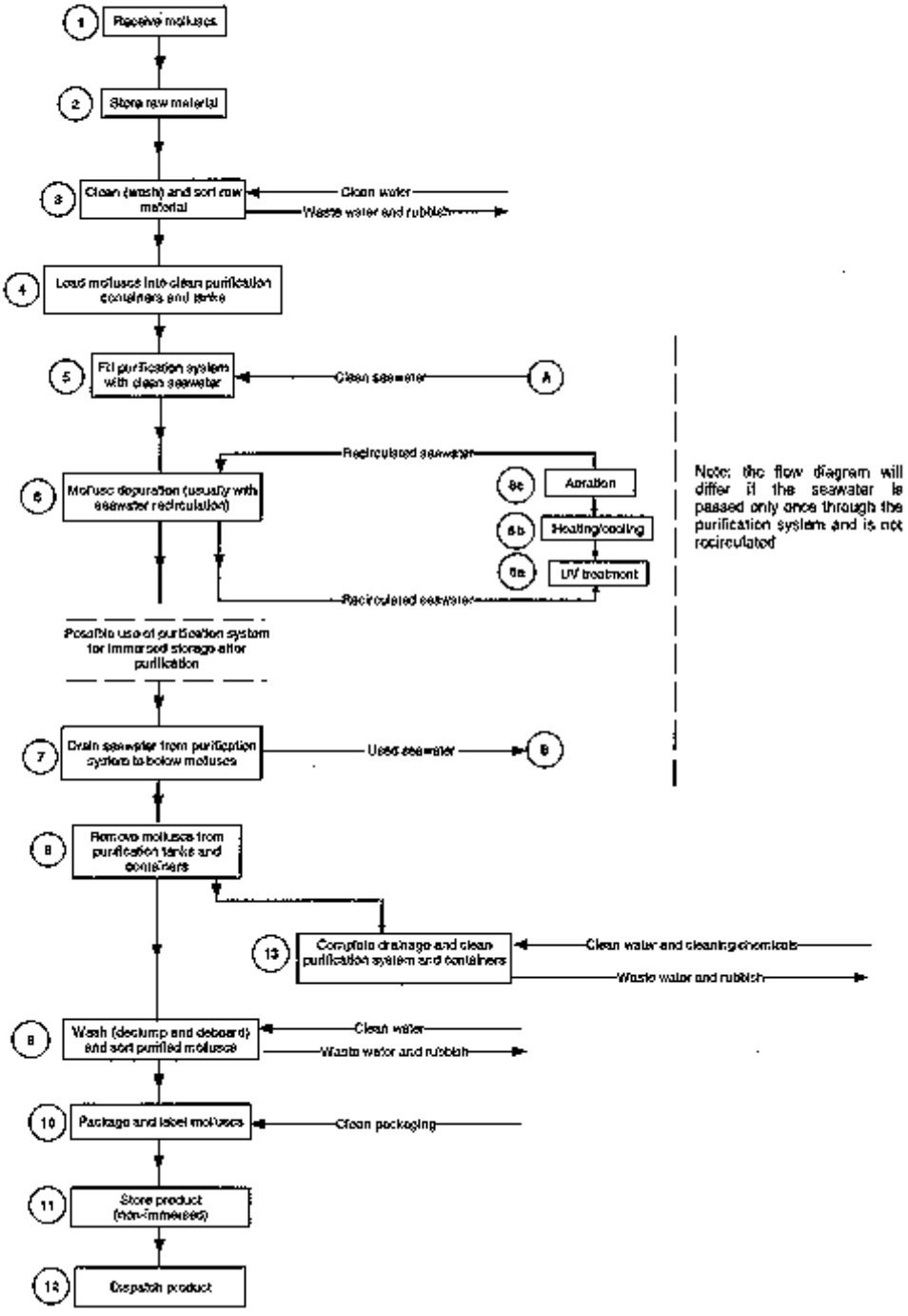
Record Sheet 3 records product dispatch.

Record Sheet 4 records bacteriological testing.

These are the major elements of record keeping. Depending on the nature of the business, other records such as mollusc storeroom temperatures and seawater supplies, etc, should be kept together with a diary of events and of actions taken such as periodic cleaning, maintenance and vermin control. The completed record sheets should be kept in chronological order in a file together with the movement documents and other relevant papers, in order to maintain a permanent record. A record of the hazard identification and control analysis itself should be kept.

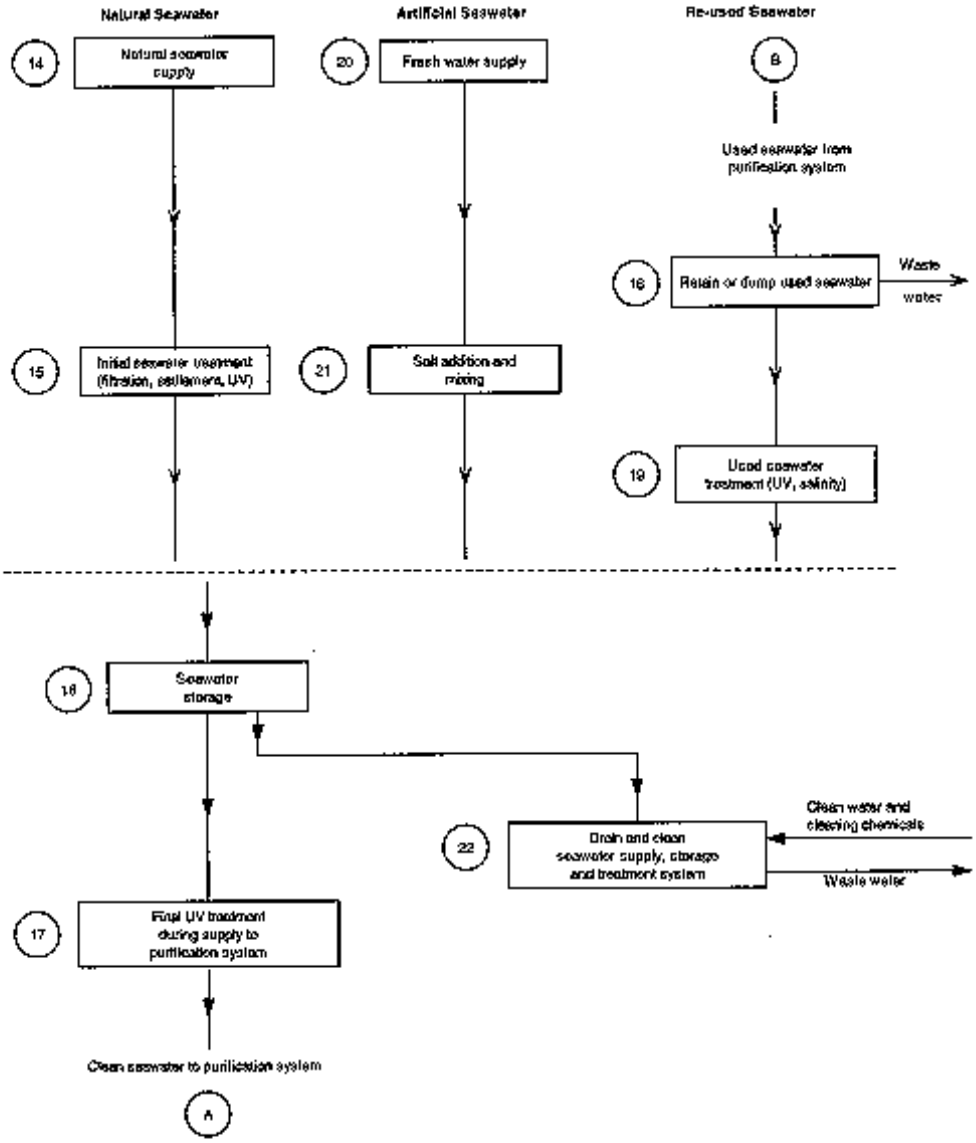
To ensure traceability of the product back to source, the record sheets are all 'keyed' to the original movement document numbers. If a permanent transport authorisation is in place, it may be necessary to allocate a batch number in order to identify each lot of molluscs received.

Example Flow Chart 1: Main Process Flow



Example Flow Chart 2: Seawater Process Flow

Note: the flow diagram includes options for natural or artificial seawater supply and for seawater re-use. The flow diagram will differ if the seawater is passed directly only once through the purification system and is not recirculated.



Example Checklist 1: Summary of the Main Hazards together with the General Hazards, Controls and Checks that Apply throughout the Operation of the Centre

Hazard	Control Measures	Checks
Molluscs supplied to Purification Centre in poor condition or with excessive contamination or viral or algal toxin or chemical contamination, such that they may fail to cleanse effectively.	Obtain molluscs only from reputable suppliers who can provide assurance of the source of the molluscs and of suitable conditions during harvesting, storage and transport. Accept molluscs only from category 'A' or 'B' areas with the necessary movement documents. Carry out the further particular control measures identified in the main process flow checklist.	Inspect deliveries and documents. Carry out regular bacteriological tests on samples of molluscs supplied. Record details of deliveries and the results of bacteriological tests, retain movement documents. Carry out the further particular checks identified in the main process flow checklist.
Seawater used for depuration or other purposes is contaminated or of unsuitable salinity or quality for effective depuration.	Comply with the Conditions of Approval. Take seawater only from a suitable area and at suitable states of tide. Treat the seawater as necessary to remove any low levels of contamination prior to use. Limit the re-use of seawater. Carry out the further particular control measures identified in the seawater process flow checklist.	Official and own checks on seawater cleanliness in the extraction area. Supervise and monitor the operation of the water treatment processes. Carry out regular bacteriological tests on samples of seawater input to the purification system . Carry out the further particular checks identified in the seawater process flow checklist.

Checklist 1: Summary - continued

Hazard	Control Measures	Checks
Ineffective depuration.	Comply with the Conditions of Approval. Follow the recommendations for purification system operation in the Seafish Operating Manuals and Guidelines. Control the tank loading, the seawater temperature, flow and aeration and the period of depuration. Carry out the further particular control measures identified in the main process flow checklist.	Supervise and monitor the operation of the purification system. Carry out regular bacteriological tests on samples of purified molluscs. Record the details of operation of the purification system and the results of bacteriological tests. Carry out the further particular checks identified in the main process flow checklist.
Unsuitable premises and equipment for Purification/Dispatch Centre.	Follow the recommendations on design, construction and usage in the Seafish Guidelines and Operating Manuals. Seek further guidance if necessary. Obtain the necessary official approval of the Centre together with the issue of Conditions of Approval which limit usage. Comply with the Conditions of Approval and do not substantially change the Centre or its usage and particularly do not change the purification system, without official approval.	Official inspection. Supervision.
Inappropriate working practices for Purification/Dispatch Centre operation.	Comply with Conditions of Approval. Follow the recommendations in the Seafish Operating Manuals and Guidelines. Train, instruct and supervise staff.	

Checklist 1: Summary - continued

Hazard	Control Measures	Checks
General contamination from poor standards of maintenance and cleaning.	Maintain 'good housekeeping' standards of maintenance, tidiness and cleanliness. Establish a cleaning schedule.	Visual inspection. Supervision.
General contamination from waste.	Establish a hygienic system for removing waste from mollusc handling areas and for the separate storage and disposal of waste.	
General contamination from vermin.	Provide protection against vermin and take action against any infestation.	
General stress or damage to the molluscs from extremes of temperature or poor handling so that they may fail to depurate effectively and/or may die before reaching the consumer.	Do not subject molluscs to extremes of temperature or to impacts or other harmful physical actions. Follow the recommendations in the Seafish Guidelines on temperature control and on suitable equipment for mollusc handling, cleaning, declumping and debearding, etc.	Supervision.
Mixing or confusion between batches of molluscs at different process steps (e.g. purified and unpurified) resulting in cross-contamination or the incomplete treatment of some molluscs.	Keep batches separate throughout the operation of the Centre, by either physical or time separation.	
Loss of the necessary traceability of product, both back to source and forward through distribution.	Retain movement documents. Keep batches separate and identified. Put the necessary health mark on every pack of product. Keep records of the quantities and sources of batches of raw material received and the quantities and destinations of the product dispatched from those batches.	Supervision. Check the keeping of records.

Example Checklist 2: Particular Hazards, Controls and Checks for the Main Process Flow

Process Step	Hazards	Control Measures	Checks
1. Receive molluscs. (cont.)	Viral, gross bacterial, algal toxin, chemical or physical contamination of the molluscs in the harvesting area or similar contamination during harvesting, storage and transport to the Centre, that may not be removed by subsequent cleaning, sorting and depuration.	Obtain molluscs only from reputable suppliers who can provide assurance of the source of the molluscs and of hygienic conditions during harvesting, storage and transport. Accept batches of molluscs only from approved category 'A' or 'B' harvesting or relaying areas with the necessary movement documents. Do not accept batches of molluscs from areas for which there is a closure order resulting from toxic algal, chemical or other contamination. Reject any batch that is obviously suffering from unacceptable contamination.	Check the identity of every batch, date stamp and retain movement documents for at least 12 months. Inspect every batch. Inspect the hygiene of the transport vehicle prior to unloading. Regular bacteriological tests on samples of raw material to ensure compliance with harvesting area standards. The frequency of sampling should be based on risk assessment i.e. more frequently if there are numerous or new suppliers, numerous harvesting areas and large quantities, etc. Inform the EHO if bacteriological results are unsatisfactory. Investigate and correct the problem. Trace and recover the product if deemed necessary. Record details of every batch received, the results of bacteriological checks and any rejection of batches.

Checklist 2: Main Process Flow - continued

Process Step	Hazards	Control Measures	Checks
Receive molluscs (cont.)	Molluscs in weak seasonal condition or stressed, shocked or damaged by time delays, physical handling or extremes of temperatures during harvesting, storage and transport, such that they may not effectively depurate.	Obtain molluscs only from reputable suppliers who can provide assurance of suitable conditions during harvesting, storage and transport. Follow recommendations in Seafish Guidelines on maximum time delays between harvesting and depuration for sensitive species. Reject any batch that is obviously in poor condition (e.g. gaping).	Inspect every batch. Record the transport vehicle air temperature prior to unloading. Record any rejection of batches.
	Molluscs contaminated or subjected to temperature stress during reception.	Move molluscs directly from transport vehicle into storage or preparation area.	Supervise operations to ensure molluscs not left lying around outside.
	Loss of the necessary traceability back to source.	Record details of the batches received and retain the movement documents.	Check the keeping of records.

Checklist 2: Main Process Flow - continued

Process Step	Hazards	Control Measures	Checks
2. Store Raw Material Note: there may also be intermediate storage of the unpurified molluscs after steps **3** or **4**.	Ingestion of contaminants by molluscs during any immersed storage.	Follow recommendations in Seafish Guidelines on immersed storage. Do not store molluscs in a natural area unless it is an approved category 'A' or 'B' harvesting or relaying area, or in a tank unless it is an approved storage facility operating under controlled conditions within the purification centre.	Monitor storage conditions. Bacteriological tests on samples of molluscs after immersed storage to ensure compliance with harvesting area standards. Note: this may replace the bacteriological tests at step **1**. Record details of all batches stored, the storage conditions and results of bacteriological checks.
	Contamination of molluscs during non-immersed storage.	Store molluscs raised off ground in a protected and well drained room or area within the purification centre.	Supervise operations to ensure molluscs not left lying around in unsuitable places.
	Molluscs stressed or shocked by time delays or temperature during non-immersed storage, such that they may not effectively depurate.	Follow recommendations in Seafish Guidelines on maximum time delays between harvesting and depuration for sensitive species and on storage temperatures.	Check stock rotation. Monitor and record storage temperature.

Checklist 2: Main Process Flow - continued

Process Step	Hazards	Control Measures	Checks
3. Clean and sort raw material Note: depending on the circumstances of growing and the operations carried out during harvesting of the molluscs, they may be supplied to the purification centre in an effectively cleaned and sorted condition. However, washing and inspecting the molluscs prior to purification is still considered necessary.	Ineffective cleaning and sorting of the molluscs leaving mud, other animals and rubbish or damaged, dying or dead molluscs that may contaminate the purification seawater.	Ensure that any cleaning and sorting equipment is cleared of molluscs and rubbish from previous use. Clean molluscs thoroughly using clean water and physical action as appropriate. Sort manually after cleaning or use sorting equipment followed by final manual sorting. Reject any batches which, at this stage, appear to be in an unsatisfactory condition.	Inspect every batch of raw material after cleaning and sorting, prior to loading into the purification system. Record any rejection of batches.
	Ingestion of contaminants by molluscs .	Do not immerse molluscs during cleaning. Clean rapidly with sprays and physical action as appropriate.	Supervise operations to ensure molluscs not immersed.
	Molluscs stressed or damaged by cleaning and sorting operations, such that they may not effectively depurate.	Follow recommendations in Seafish Guidelines on cleaning and sorting equipment. Do not subject molluscs to impacts and other potentially harmful physical actions.	Supervise operations to prevent abuse of molluscs.

Checklist 2: Main Process Flow - continued

Process Step	Hazards	Control Measures	Checks
4. Load molluscs into clean containers and tanks	Overloading of molluscs in deep layers which may inhibit their functioning. Exceeding the designed total loading of the purification system which may result in oxygen depletion.	Do not exceed container and tank loading specified in Conditions of Approval.	Supervise loading.
	Placing containers of molluscs in turbulent areas around water jets, aerators, etc, such that mollusc functioning may be inhibited or water flow impeded.	Follow recommendations in Seafish Guidelines and Operating Manuals on loading and comply with any Conditions of Approval.	
	Possible cross-contamination between batches of molluscs from different categories of harvesting area (A or B).	Do not mix batches from different categories of harvesting area in the purification system.	
	Cross-contamination between bivalve molluscs and other species of fish and shellfish including crustacea.	Do not mix other species of fish and shellfish with bivalve molluscs in the purification system.	
	Compromised purification conditions resulting from a mixture of bivalve mollusc species.	The law prohibits purifying different species together.	

Checklist 2: Main Process Flow - continued

Process Step		Hazards	Control Measures	Checks
5.	Fill purification system with clean seawater. Note: The supply, treatment, cleanliness and quality of the seawater is dealt with at steps **14 -22**.	Molluscs subjected to temperature shock on immersion that may inhibit their activity or which may induce spawning and death and spoil the seawater quality.	Follow recommendations in Seafish Guidelines on temperature control. Avoid large differentials between harvesting area, storage and initial seawater temperature.	Monitor and record seawater temperature.
		Incomplete filling of system with seawater which may leave molluscs exposed during depuration.	Fill to the levels specified in Conditions of Approval.	Monitor and record level in tanks.
6, 6a, 6b, and 6c	Depuration and seawater circulation (cont.)	Inadequate seawater flow and aeration resulting in low dissolved oxygen levels and low levels of mollusc activity. Excessive seawater flow and turbulence causing the resuspension of detritus and its ingestion by the molluscs.	Follow recommendations in Seafish Guidelines and Operating Manuals on dissolved oxygen levels, seawater flow and aeration. Operate seawater circulation pump and spray bars/cascades and any additional aeration system at the flow rates specified in Conditions of Approval and maintain any dissolved oxygen level specified.	Monitor and record seawater flow and also air flow in any direct aeration system. Visually check the activity of the top molluscs during depuration. Note: dissolved oxygen can be measured directly with specialised instruments and this should be done if there is doubt about purification system design and usage.

Checklist 2: Main Process Flow - continued

Process Step	Hazards	Control Measures	Checks
Depuration and seawater circulation (continued).	Seawater temperature too low, resulting in low levels of mollusc activity. Seawater temperature too high, resulting in low dissolved oxygen levels and stressing the molluscs.	Follow recommendations in Seafish Guidelines and Operating Manuals on temperature control and operate above the minimum seawater temperature specified in Conditions of Approval. Operate heating/chilling systems as appropriate to keep the seawater temperature within the required range. Do not operate the purification system if, in seasonal conditions, the required seawater temperature range cannot be maintained.	Monitor and record seawater temperature. Visually check the activity of the top molluscs during depuration.
	Microbiological contamination in recirculated seawater ingested by molluscs.	Follow recommendations in Seafish Guidelines on UV treatment of recirculated seawater and operate treatment unit as specified in Conditions of Approval. Replace UV lamps at the intervals specified in Conditions of Approval (before their rated life expires).	Visually check that UV lamps are operating. Note: directly viewing UV lamps is harmful to the eyes. Record periods of operation of UV lamps and when they are changed.
(cont.)	Physical disturbance of the system causing the resuspension of detritus and its ingestion by the molluscs.	Do not add, move or remove molluscs or containers etc, whilst the molluscs are immersed or move, knock or shake the tank itself.	Supervise operation of the system to prevent interference

Checklist 2: Main Process Flow - continued

Process Step	Hazards	Control Measures	Checks
Depuration and seawater circulation (continued).	Contamination or dilution of the seawater in the purification tank by external factors such as seabirds or rainfall.	Install purification tanks within buildings or cover the tanks. Maintain 'good housekeeping' standards to prevent contamination by wash water spray, chemicals, etc.	Supervise operations to maintain 'good housekeeping' standards. Monitor and record the salinity in any outside tanks.
	High light level over tanks inhibiting mollusc activity.	Maintain low light level over tanks except when loading/unloading and cleaning or for safety reasons when working in the area.	Supervise operations to ensure lights turned off when not required.
(cont.)	Deterioration in seawater quality inhibiting mollusc activity.	If the seawater becomes discoloured or smells 'off'or if initial colouration or turbidity is not removed, despite the other conditions of seawater flow, aeration and temperature being satisfactory, then dump the seawater, wash the molluscs, clean the depuration system and restart the purification cycle with new seawater.	Check water colour, turbidity and odour and the activity of the top molluscs during depuration. Record any instances of the dumping of seawater.

Checklist 2: Main Process Flow - continued

Process Step	Hazards	Control Measures	Checks
Depuration and seawater circulation (continued). (Cont.)	Molluscs remain moribund as a result of stress or shock or weak seasonal condition and fail to function.	If the molluscs continue to show little sign of activity, despite the conditions of seawater quality, flow, aeration and temperature being satisfactory, then dump the molluscs (and the seawater as a further precaution).	Visually check the activity of the top molluscs during depuration. Record any instances of the dumping of molluscs.
	Inadequate period of operation resulting in incomplete depuration.	Operate purification system in correct operating conditions for at least 42 hours as specified in Conditions of Approval.	Record start and finish times and any periods of downtime**.**
	System failure (e.g. power cuts, pump breakdown, faulty thermostat, etc.) resulting in loss of the correct purification conditions and possibly stressing the molluscs.	Drain the seawater if the temperature rises excessively or if seawater flow and aeration are likely to be halted for a significant period of time, to avoid stressing the molluscs. Reappraise the situation after correcting the fault. Start a new purification cycle if the molluscs remain viable after a major incident or discount the downtime from the depuration period if the incident is minor.	Monitor the correct operation of the purification system and record any incidents and action taken.

Checklist 2: Main Process Flow - continued

	Process Step	Hazards	Control Measures	Checks
	Depuration and seawater circulation (continued).	Overall failure of depuration resulting from any or a combination of the above hazards.	All of the above control measures.	Regular bacteriological tests on samples of purified molluscs at the frequency recommended in the SAGB/DoH guidance document, to ensure compliance with the product standards. Inform the EHO if bacteriological results are unsatisfactory. Investigate and correct the problem. Trace and recover the product if deemed necessary. Record results of bacteriological tests.
7.	Drain seawater from purification system to below all the molluscs.	Changes in water flow rate and direction causing re-suspension of detritus and its ingestion by the molluscs.	Drain via the seawater circulation system or, where this is not feasible (e.g. in vertical stack systems), via the purpose designed low flow rate initial drainage system.	Supervise operations to ensure correct drainage procedure.
		Initial drainage incomplete, leaving molluscs immersed and subject to the ingestion of detritus when disturbed.	Locate seawater outlet below level of molluscs and drain until flow stops.	

Checklist 2: Main Process Flow - continued

Process Step	Hazards	Control Measures	Checks
8. Remove molluscs from purification tanks and containers.	Ingestion of detritus by molluscs.	Do not disturb molluscs until initial drainage is complete and ensure that containers of molluscs are tipped onto a well drained area so that any residual water runs away.	Supervise operations to ensure correct procedure.
9. Wash (declump and debeard if appropriate) and sort purified molluscs.	Ineffective cleaning and sorting of the molluscs leaving contamination that may subsequently be ingested or leaving rubbish or dead or dying molluscs unsuitable for sale.	Ensure that any cleaning, sorting and any other equipment used is cleared of molluscs and rubbish from previous use. Clean molluscs directly after removal from tanks. Clean thoroughly using clean water and physical action as appropriate. Sort manually after cleaning and any declumping and debearding or use appropriately designed sorting equipment followed by final manual sorting. Reject any batches which, at this stage, appear to be in an unsatisfactory condition.	Inspect every batch of cleaned and sorted molluscs prior to packaging. Record any rejection of batches.
(cont.)	Ingestion of contaminants by molluscs.	Do not immerse the molluscs during cleaning. Clean rapidly with sprays and physical action.	Supervise operations to ensure molluscs not immersed.

Checklist 2: Main Process Flow - continued

Process Step	Hazards	Control Measures	Checks
Wash (declump and debeard if appropriate) and sort purified molluscs (continued).	Molluscs stressed or damaged by cleaning, sorting and any associated operations such that they may die before sale to the consumer.	Follow recommmendations in Seafish Guidelines on cleaning, sorting and associated equipment. Do not subject molluscs to impacts and other potentially harmful physical actions.	Supervise operations to prevent abuse of molluscs.
10. Package and label molluscs. (cont.)	Contamination of product resulting from the use of unsuitable packaging.	Follow recommendations in Seafish Guidelines on packaging and carry out the packaging in a suitably hygienic area. Use a form of packaging that will provide adequate protection in the expected conditions of distribution. Provide drainage holes (or absorbent pads) in packaging to avoid the accumulation of liquor and the ingestion of contaminants by the molluscs.	Visually inspect the cleanliness of packaging materials, particularly any natural materials.

Checklist 2: Main Process Flow - continued

Process Step	Hazards	Control Measures	Checks
Package and label molluscs (continued.)	Contamination of product resulting from the use of unsuitable packaging (continued).	Use only suitable types of packaging materials that will not transfer contaminants to the molluscs. Use only clean packaging materials and store them off the floor in a protected clean area prior to use. Wash any natural materials such as seaweed in clean water prior to use. Obtain packaging materials, particularly any natural materials such as seaweed, only from reputable suppliers who can provide assurance of their origin, suitability and cleanliness.	Visually inspect the cleanliness of packaging materials, particularly any natural materials.
	Loss of the necessary traceability of the product back to source.	Label every package with the dispatch centre health mark. Note: separate purification centres must mark packages with the information that the molluscs have been purified and send them to a Dispatch Centre with a movement document. Twist tie, strap or otherwise enclose the packages.	Supervise operations to ensure correct labelling.

Checklist 2: Main Process Flow - continued

Process Step	Hazards	Control Measures	Checks
11. Store product (non-immersed). Note: there may also be intermediate storage of purified molluscs after step **9**.	Contamination of product.	Store product raised off the ground in a protected and well drained room or area within the purification centre. Do not use any immersed storage.	Supervise operations to ensure product not left lying around in unsuitable places.
	Molluscs stressed or shocked by time delay or temperature during storage such that they may die before they reach the final consumer.	Follow recommendations in Seafish Guidelines on storage temperature and storage lives. Hold in storage for only a minimum of time prior to dispatch.	Monitor stock rotation. Monitor and record storage temperature.
12. Dispatch (cont.)	Contamination of product during dispatch and distribution.	Move product directly from storage to transport vehicle. Use suitable hygienic transport vehicle (covered and clean) and ensure that the product is raised above the floor of the vehicle. Use reputable distributor who can provide assurance of hygienic conditions during distribution.	Supervise operations to ensure molluscs not left lying around in unsuitable places. Inspect the hygiene of the transport vehicle prior to loading.

Checklist 2: Main Process Flow - continued

Process Step	Hazards	Control Measures	Checks
Dispatch (continued)	Molluscs stressed or shocked by time delays or temperatures during dispatch and distribution such that they may die before they reach the final consumer.	Follow recommendations in Seafish Guidelines on holding temperatures and storage lives. Move product directly from storage to transport vehicle. Use temperature controlled transport vehicle. Use reputable distributor who can provide assurance of rapid distribution and temperature control during distribution.	Supervise operations to ensure molluscs not left lying around. Inspect suitability of transport vehicle prior to loading.
	Loss of traceability of product back to source.	Record details of the packs dispatched and their destinations.	Check the keeping of records.
13. Complete drainage and clean purification system and containers. (cont.)	Incomplete drainage and cleaning leaving contaminants in system.	Follow recommendations for cleaning in Seafish Operating Manuals.	Visually inspect cleanliness. Record completion of cleaning schedule.

Checklist 2: Main Process Flow - continued

Process Step	Hazards	Control Measures	Checks
Complete drainage and clean purification system and containers (continued).	Incomplete drainage and cleaning leaving contaminants in system (continued).	At the end of each purification cycle and before residues dry, thoroughly flush out the tank and clean the tank and containers with clean water and physical action. Allow to drain completely. Drain any sections of the circulation system that do not drain naturally. Periodically clean any pump filter. Periodically clean the system with a suitable agent such as hypochlorite by loading the empty containers into the tanks and circulating diluted cleaning solution for a few hours. Follow by thorough rinsing with clean water. (Observe manufacturer's instructions for safe use of cleaning agent.)	Visually inspect cleanliness. Record completion of cleaning schedule.
	Accumulation of slime on UV glass reducing effectiveness.	Periodically dismantle units and clean the UV glass.	Record completion of cleaning schedule.

Example Checklist 3: Particular Hazards, Controls and Checks for the Seawater Process Flow

Process Step		Hazards	Control Measures	Checks
14.	Natural seawater supply.	Microbiological, algal toxin, chemical or physical contamination of the seawater that may not be removed by subsequent treatment.	Take seawater only from a suitable area without chemical contamination or unacceptable microbiological, algal toxin or physical contamination and comply with any Conditions of Approval. Ensure that the inlet pipe is well clear of any discharge pipe. Take water only at suitable states of tide and depth to avoid 'run off' from the land and surface contamination. Obtain any seawater in tanker vehicles only from reputable suppliers who can provide assurance of the source of the seawater and hygienic conditions during its transport.	Official and own checks on seawater cleanliness in the extraction area. Supervise pumping operations. Visually inspect the hygiene of tankers. Record the supply and source of seawater.
		Incorrect salinity.	Take water only at suitable states of tide and depth to avoid low salinity.	Check and record salinity.

Checklist 3: Seawater Process Flow - continued

Process Step	Hazards	Control Measures	Checks
15. Initial seawater treatment (filtration, settlement, UV). Note: The extent of any treatment required depends on the source of the seawater.	Survival of contamination.	Follow recommendations in Seafish Guidelines and comply with any Conditions of Approval. Use filter or settlement tank to reduce turbidity and UV treatment to inactivate microbiological contamination. UV treatment at step **17** may suffice. Regularly change or clean any filter as necessary. Replace UV lamps at the intervals specified in Conditions of Approval, before expiry of their rated life.	Supervise any settlement tank operation to ensure adequate settlement. Visually inspect the turbidity of the water after treatment. Check the correct operation of any filters and record when they are changed. Visually check that UV lamps are operating. Note: directly viewing UV lamps is dangerous to the eyes. Record periods of operation of UV lamps and when they are changed.
16. Seawater storage. (cont.)	Contamination or change of salinity of the seawater caused by outside factors such as seabirds, rainfall or evaporation.	Install storage tanks within buildings or cover tanks. Maintain 'good housekeeping' standards to prevent contamination by wash water spray, chemicals, etc.	Supervise operations to maintain 'good housekeeping' standards. Monitor and record salinity in any outside tanks.

Checklist 3: Seawater Process Flow - continued

Process Step		Hazards	Control Measures	Checks
	Seawater storage (continued).	Possible loss of water quality during storage caused by chemical or microbiological action.	Cover storage tanks and circulate/aerate water to maintain oxygen levels. Dump seawater if quality becomes suspect.	Check the appearance and the smell of the seawater in the tank. Record any dumping of seawater.
		Seawater temperature goes above or below that required for purification.	Protect storage tanks from the elements.	Check seawater temperature.
		Carrying over of any sediment from the storage tank.	Locate seawater outlet pipe and any aeration input clear of base of tank. Periodic cleaning of tank at step **22.**	Check accumulation of sediment in tank.
17.	Final UV treatment during supply to purification system.	Survival of any remaining microbiological contamination.	Pass through purification system seawater recirculation UV on supply to tank.	Regular bacteriological tests on samples of the seawater input to the purification system and the necessary keeping of records of those tests, at a frequency based on risk assessment i.e. more frequently if water is taken from areas with some contamination, or is supplied by tanker or is re-used. Inform the EHO if bacteriological results are unsatisfactory. Investigate and correct the problem. Trace and recover the product if deemed necessary.

Checklist 3: Seawater Process Flow - continued

Process Step		Hazards	Control Measures	Checks
18.	Retain or dump used seawater.	Seawater of poor quality through the accumulation of mollusc waste products.	Limit the extent of re-use to that prescribed in Conditions of Approval. Dump the seawater if it has become discoloured or smells 'off'.	Check the colour and odour of the seawater. Record the dumping of seawater.
19.	Used seawater treatment (UV, salinity).	Possible carrying over of microbiological contamination from one purification cycle to the next.	UV treatment at step **17** may suffice but where possible it is preferable also to pass the used seawater through the purification system UV when initially draining the tank. Replace UV lamps at the intervals specified in Conditions of Approval, before their rated life expires.	Visually check that UV lamps are operating. Note: directly viewing UV lamps is dangerous to the eyes. Record periods of operation of UV lamps and when they are changed.
		Evaporation during extended use increasing salinity.	Dilute with fresh water to reduce salinity if necessary.	Check and record salinity.
20.	Fresh water supply.	Possible contamination of the water.	Use public mains water supply or a supply complying with potable water standards.	Checks by Water Service Providers or own checks on potable water standards if private supply used.
		Residual chlorine in water harming molluscs.	Circulate or aerate water prior to use.	Check smell of water prior to supply to purification system.

Checklist 3: Seawater Process Flow - continued

Process Step		Hazards	Control Measures	Checks
21.	Salt addition and mixing.	Contamination of salts.	Obtain salts from reputable supplier. Store salts in a protected dry place.	Supervise operations to ensure salts supplied and stored in hygienic conditions.
		Incorrect mixture of the different types of salts required.	Follow recommendations on mixture in Seafish Guidelines and comply with Conditions of Approval. Obtain salts from reputable supplier.	Supervise operations to ensure correct and thorough mixing. Check and record salinity after mixing.
		Incomplete dissolving of salts.	Follow recommendations on mixing in Seafish Guidelines. Mix by agitation, aeration or circulation.	
		Incorrect salinity.	Follow recommendations for salinity in Seafish Guidelines and comply with Conditions of Approval. Use measured quantities of salts.	
22.	Drain and clean seawater supply, storage and treatment system.	Incomplete drainage and cleaning leaving contaminants in system.	Periodically drain, flush out and clean the system with a suitable cleaning agent such as hypochlorite. Follow with thorough rinsing with clean water. (Observe manufacturer's instructions for safe use of cleaning agent)	Record completion of cleaning schedule.
		Accumulation of slime on UV glass reducing effectiveness.	Periodically dismantle units and clean the UV glass.	

Example Checklist 4: Particular Hazards, Controls and Checks for Immersed Storage in the Purification System after Purification

Hazards	Procedures and Control Measures	Checks
Disturbance of the system causing the re-suspension of detritus and ingestion by the molluscs.	*For short-term storage of the entire purification load* it can be left undisturbed in the purification tank, continuing to operate in purification conditions after the end of the purification period: ▪ continue to operate the purification system (steps **6, 6a, 6b**, and **6c**). ▪ drain the seawater to below the level of all the molluscs before removing the molluscs (step **7**). Carry out the control measures identified in the main process flow at the relevant steps.	Carry out the checks identified in the main process flow at the relevant steps.
	For longer-term storage or if only part of the purification load is to be stored in a single tank system: ▪ drain the seawater to below all the molluscs at the end of the purification period (step **7**). ▪ remove all the molluscs from the tanks and containers (step **8**). ▪ wash and sort the molluscs (but do not necessarily declump and debeard) (step **9**). ▪ complete drainage and clean purification system and containers (step **13**). ▪ load molluscs for immersed storage into clean containers and tanks (step **4**). ▪ fill purification system with clean seawater (step **5**). ▪ operate purification system for immersed storage (steps **6, 6a, 6b** and **6c**). ▪ drain seawater to below the level of all the remaining molluscs at the end of storage before removing the molluscs (step **7**). Carry out the control measures identified in the main process flow at the relevant steps.	Carry out the checks identified in the main process flow at the relevant steps.

Checklist 4: Particular Hazards, Controls and Checks for Immersed Storage in the Purification System after Purification

Hazards	Procedures and Control Measures	Checks
Disturbance of the system causing the re-suspension of detritus and ingestion by the molluscs (continued).	*For 'order picking' during the period of storage* use a purpose designed (e.g. vertical stack) system which enables independent drainage and removal of molluscs from each container without disturbing the rest of the system: ▪ operate the purification system for immersed storage (steps **6, 6a, 6b** and **6c**). ▪ briefly halt the water flow for 'order picking'. ▪ drain the seawater to below the level of the molluscs in the container (step **7**). ▪ remove the container from the purification system and remove all the molluscs from the container (step **8**). ▪ wash and sort the molluscs (step **9**). ▪ complete drainage of container concerned and clean the container (step **13**). ▪ return any remaining cleaned molluscs to the container for further storage and return the container to the purification system (step **4**). ▪ restart the water flow (step **5**). Carry out the control measures identified in the main process flow at the relevant steps.	Carry out the checks identified in the main process flow at the relevant steps.
Molluscs stressed or exhausted by unsuitable seawater conditions or lengthy storage.	Follow recommendations in Seafish Guidelines on seawater temperature and aeration for immersed storage and on periods of immersed storage. Carry out the control measures identified in the main process flow at steps **6, 6a, 6b** and **6c** and in the seawater process flow.	Carry out the checks identified in the main process flow at steps **6, 6a, 6b** and **6c**.
Microbiological contamination in supplied or recirculated seawater,	Carry out the control measures identified in the main process flow at steps **6, 6a, 6b** and **6c** and in the seawater process flow.	Carry out the checks identified in the main process flow at steps **6, 6a, 6b** and **6c** and in the seawater process flow.
Unsuitable seawater quality.	Include any period of immersed storage in the total permissible period of re-use of seawater. Carry out the control measures identified in the main process flow at steps **6, 6a, 6b** and **6c** and in the seawater process flow.	

Record Sheet 1: Mollusc Reception

Note: Movement Documents must be date stamped and retained

Date/time of reception		/ /	: hrs	/ /	: hrs	/ /	: hrs	/ /	: hrs
Movement Document No. or allocated Batch No.								
Species								
Quantity			kg		kg		kg		kg
Supplier								
Source *(harvesting area and category)*								
Delivery vehicle inspection	**Hygiene OK**	YES	NO	YES	NO	YES	NO	YES	NO
	Temp		°C		°C		°C		°C
Mollusc inspection OK		YES	NO	YES	NO	YES	NO	YES	NO
Batch accepted		YES	NO	YES	NO	YES	NO	YES	NO
Comments: *(any further detail/explanation, etc)*									
Signature of receiver									

Record Sheet 2 : Purification Tank No. _____ Operation

PURIFICATION TANK LOADING	**Species**		
	Quantity of molluscs	kg	boxes
	Movement Document Nos./Batch Nos.		
	Seawater use No.		
	Date of original supply of seawater	/ /	
	Seawater salinity		‰
	Period of UV use to date		hrs
	Signature of operator		

DURING PURIFICATION	**Start of cycle**		**2-3 hours after start**		**Mid-cycle**		**End of cycle**	
Date	/ /		/ /		/ /		/ /	
Time	: hrs		: hrs		: hrs		: hrs	
Water level OK	YES	NO			YES	NO	YES	NO
Water (& air) flow OK	YES	NO			YES	NO	YES	NO
UV lamps OK	YES	NO			YES	NO	YES	NO
Water temp	°C				°C			°C
Water appearance and odour OK			YES	NO	YES	NO	YES	NO
Mollusc activity OK			YES	NO	YES	NO	YES	NO
Signature of operator								

AFTER PURIFICATION	**Seawater dumped or retained**	DUMPED	RETAINED
	Tank and containers cleaned	YES	NO
	Cumulative total of UV use		hrs
	Signature of operator		

Comments: (record of breakdowns, spawning in tanks, failure of molluscs to function, addition or changing of water, dumping of molluscs, etc).

Signature of operator	

Record Sheet 3: Product Dispatch

Note: If practicable, it would be useful to include the purification tank Nos. as well as the Movement Document/Batch Nos.

Date/time of dispatch		/ /	: hrs	/ /	: hrs	/ /	: hrs	/ /	: hrs
Species								
Quantity		packs of	kg	packs of	kg	packs of	kg	packs of	kg
Original Movement Document Nos. or Batch Nos.								
Carrier								
Destination								
Delivery vehicle inspection	**Hygiene OK**	YES	NO	YES	NO	YES	NO	YES	NO
	Temp control operational	YES	NO	YES	NO	YES	NO	YES	NO
Comments: *(any further detail/explanation, etc*)									
Signature of dispatcher									

Record Sheet 4: Bacteriological Testing

Note: Laboratory reports should be retained

Date sample taken		/ /		/ /		/ /		/ /	
Mollusc samples	**Reception or purification sample**	RECEPTION	PURIFIED	RECEPTION	PURIFIED	RECEPTION	PURIFIED	RECEPTION	PURIFIED
	Purification Tank No. *(if purified)*								
	Species								
	Harvesting area and category								
	Movement Doc. No. or Batch No.								
Or water samples	**Purification Tank No. water supplied to**								
	Date of original supply of seawater	/ /		/ /		/ /		/ /	
Laboratory									
***E. Coli* count**		per 100g or ml		per 100g or ml		per 100g or ml		per 100g or ml	
Comments (any further action taken,etc)									
Signature of person responsible									

FURTHER SOURCES OF ADVICE AND INFORMATION

Advice can be sought directly from the local Environmental Health Officer.

Further advice is available from Seafish Technology, Seafish House, St. Andrews Dock, Hull, HU3 4QE, Tel. 01482 327837, Fax. 01482 223310.

Seafish have also published further advisory documents including:

Guidelines

Guidelines for the Facilities and Equipment Required for Handling Bivalve Molluscs from Harvesting through to Distribution to Retail Outlets

Purification System Operating Manuals

Operating Manual for the Medium Scale Multi-Layer System (95/31/FT)

Operating Manual for the Vertical Stack System (95/32/FT)

Operating Manual for the Large Scale Multi-Layer System (95/33/FT)

Operating Manual for the Small Scale Shallow Tank System (95/34/FT)

Operating Manual for the Bulk Bin System for Mussels (95/35/FT)

General Operating Manual for Purification Systems of Non-Standard Design (95/36/FT)

Data Sheet

The Use of Artificial Seawater in Mollusc Purification (1994/25/FT)

Advice is also available from the Shellfish Association of Great Britain (SAGB), Fishmonger's Hall, London Bridge, London, EC4R 9EL, Tel. 0171 283 8305, Fax 0171 929 1389.

A further advisory document is also available from SAGB:

Guidance on the Frequency of Microbiological Sampling of Purified Molluscs by Operators of Purification Centres.