

Guidance on HACCP Plans for Bivalve Purification Operations

Seafood is a good source of protein, and shellfish have been shown to have many [health benefits](#). Farmed UK shellfish are one of the most [sustainable forms of food for us to eat](#), with very low impacts and increasingly recognised benefits to the wider environment.

Food Business Operators (FBO) have a legal duty to ensure the food placed on the market is safe. Because of their feeding methods, bivalves can accumulate microbial and viral pathogens, as well as biotoxins. As some species are consumed raw (oysters) or lightly cooked (mussels), they are considered high risk food product that requires control measures to eliminate or reduce to acceptable levels potential biological, chemical and physical hazards. Any FBO, handling or supplying live bivalves is required by law to put in place, implement and maintain permanent food safety management procedures based on Hazard Analysis Critical Control Point (HACCP) principles.

What is HACCP?

HACCP is an internationally recognised system of food safety management. HACCP involves:

- looking closely at your business practice to identify the food safety risks and what could go wrong;
- identifying any hazards that the business needs to focus on to ensure the risks are assessed and removed or reduced to safe levels;
- deciding what action to take if something goes wrong;
- making sure that your business procedures are followed and are working; and
- keeping records to evidence that your procedures are working.

In 2009, Seafish produced initial guidance on HACCP for bivalve purification. This guidance has now been updated and completely restructured (see example plan in annex 1) so that it reflects the practice and approaches used in other food industries.

The revised HACCP guidance is based on FBOs having appropriate policies and procedures in place to negate potential hazards and risks associated with bivalve purification operations. It is recognised that in a well-managed purification operation will ensure all hazards are controlled. By definition, a controlled hazard does not generate a critical control point (CCP).

Businesses using this revised HACCP guidance will need to put in place all the appropriate policies and procedures required. They will also need to monitor long term trends and develop a regime of active management of hazards.

Process Verification and Effective Permanent Management Procedures

Process verification and effective permanent management procedures are the essential underpinning to this approach. Businesses that are able to establish policies and procedures that can manage all anticipated eventualities AND which have effective monitoring procedures in place are unlikely to produce unsafe food. The management capability required to ensure that the pre-requisite policies and procedures are adequate and followed is significant, and should not be underestimated.

Where food business managers evidence that their systems are working consistently and safely, it is unlikely that they will need a system of positive release¹ or the more onerous approach to frequent batch testing and reliance on multiple CCPs. Instead, a system of process validation² can be used.

End product testing (EPT) is generally used to verify that a particular batch of product is safe to release – this is positive release. The purpose of bacteriological testing of depurated bivalves under this revised guidance is not to verify the safety of any particular batch of live bivalves. Rather, its purpose is to validate the long term efficacy of the process and the prerequisite procedures that underpin good manufacturing practices. An FBO that has good HACCP-based procedures in place and can provide historical evidence of the effectiveness of these procedures, is likely to undertake less EPT and may not need to depend on positive release to ensure consumer safety.

The Bivalve Critical Control Point

In this revised HACCP guidance, the CCP for live bivalves is the point at which they are ready to be dispatched to market. The hazard is that bivalves that are unsafe for human consumption are placed on the market. The control for this hazard is that all policies and procedures have been followed. This is monitored through some form of dispatch checklist that verifies this. Corrective actions in case of non-compliance include reject, relay, or restart the purification process. The effectiveness of the prerequisite operational policies and procedures must be verified by long term trends analysis using EPT and other appropriate measures.

Developing a HACCP Plan and Active Management Culture

The level of active management required to ensure the purified live bivalves that are put on the market are safe should not be underestimated. Annex 1 of this guidance provides an example HACCP plan for standard purification systems.

In order to develop and maintain an effective active management approach, businesses must underpin their HACCP plan with a series of standard operating procedures, policies and prerequisites to support the active management of food safety hazards. These procedures can be grouped into those required for the food industry in general and those required specifically for live bivalves.

The pre-requisite procedures or standard operating procedures may include, but are not limited to:

1. Standard Food Industry procedures

- Staff³ hygiene and work rules;
- Staff training⁴;
- Employee medical questionnaire;
- Staff sickness;
- Cleaning schedule;

¹ Positive release involves holding the animals in a way that will ensure they cannot be contaminated whilst waiting for the lab results.

² Process validation uses test results over a period of time to give confidence on the safety of the process and the product produced.

³ Self-employed operators will still need some “staff-related” procedures as part of their food safety management systems.

⁴ Seafish offers a range of LBM training courses, pertinent to both FBOs and Environmental Health Officers (EHO) who approve s. For further information email Onshore Training (onshore@seafish.co.uk).

- Plant cleaning schedules;
- Pest control monitoring;
- General maintenance record log;
- Glass policy;
- Chiller temperature record;
- Safety of water;
- Waste disposal;
- Labelling;
- Chemical and physical contamination control; and
- Traceability and recall of product.

2. Bivalve purification procedures

- General live bivalves handling policy;
- Supplier selection and pre-reception policy and procures;
- Live bivalves reception procedure;
- Design, maintenance and control of purification plant structure and equipment⁵:
 - Pumps, valves, and pipework;
 - UV and/or other water treatments;
- Pre purification storage procedure;
- Pre-purification washing, grading, and handling procedure;
- Seawater procedures for the use / reuse of:
 - Natural seawater supply;
 - Artificial Seawater supply;
- Procedures for the filling, loading, draining, and unloading of purification systems, including stocking densities;
- Process monitoring guidance and records to include:
 - Aeration and oxygen levels;
 - Turbidity;
 - Water temperature and flow rates;
 - Live bivalve activity (visual indications);
 - UV lamp operation or similar for other types of treatment systems such as ozone;
- Post purification live bivalve handling, cleaning, and storage procedures;
- Packing, packaging, traceability, and labelling procedure;
- Conditioning or re-watering procedure;
- Dispatch procedures – Note: this is a CCP;
- Checklist for positive release;
- End product testing and HACCP verification policy; and
- Product recall policy and procedure.

The above list is provided for guidance only. FBOs have a responsibility to develop appropriate pre-requisite policies and procedures for their own businesses.

⁵ Seafish has produced guidance on how to build a shellfish purification system and also manuals on operating purification systems – see <https://www.seafish.org/responsible-sourcing/aquaculture-farming-seafood/bivalve-shellfish-purification/>

End Product Testing

The final safety net of any purification is End Product Testing (EPT). The current minimum standard is less than 230 *E.coli* per 100g of bivalve flesh and intravalvular using the MPN test. However, Seafish advise that in a correctly working purification system a level of less than 40 *E.coli* per 100g of bivalve flesh and intravalvular should be consistently achieved. Although aimed at Local Authorities, [FSA](#) and [FSS](#) have both produced guides on the inspection of purification systems which include some useful information for FBOs.

The standard purification cycle time across the UK is 42 hours. This was established under the previous Shellfish Regulations and has generally continued to be considered best practice. However, current policy allows FBOs to reduce this if they are able to demonstrate, in accordance with their HACCP plans, that all relevant risks (i.e. from bacteriological and viral contamination) have been considered and that any reduced purification time is effective and that their purification process⁶ is effective and remains protective of public health. There are Seafish guides available on [altering purification times](#) and [EPT](#).

Always remember - If there is a risk of shellfish becoming contaminated, you must take appropriate steps to ensure that any placed on the market are safe.

Effective end-product testing to ensure food safety is absolutely essential.

Resources

There are lots of resources available for developing HACCP plans and the management of safe seafood. These have been collated in the Seafood Training Academy [Bivalve Purification Library Guide](#) which include links to FAO, FSA, FSS and other relevant organisations.

⁶ Reduced purification times may be adopted where practices are validated and found to produce safer seafood. Local Authority approval may be required for reduced purification times.

Annex 1 - Example HACCP Plan for the Purification of Live Bivalve Molluscs (LBM)

This approach recognizes that in a well-managed operation that uses standard purification systems and operates within the limits set by various policies and procedures will ensure all of these hazards are controlled. By definition, a controlled hazard does not generate a CCP.

Note: 'GMPG' refers to the Seafood ['Good manufacturing practice guidelines. Live bivalves workbook'](#).

Process Step	Hazards	Controls	Records and Policies
1. Receipt of molluscs.	<p>Contamination (viral, gross bacterial, biotoxin, chemical or physical) which is unlikely to be removed during subsequent sorting, washing or purification operations.</p> <p>Molluscs unlikely to deplete, e.g. due to stress or shock, damaged by time delays or temperature abuse, or in weak seasonal condition.</p>	<p>Apply Reception Procedure and General Handling Policy. All damaged or dead molluscs must be removed.</p> <p>Check the Registration documentation</p> <p>Check the status and history of harvesting area. This is extremely important for determining potential contamination levels.</p>	<p>1.1 Harvesting/supplier policy 1.2 Reception procedure 1.3 Bivalve handling procedure 1.4 Mollusc Reception Record See GMPG</p> <ul style="list-style-type: none"> • Steps 1 to 3 (Harvesting), • Step 4 (Landing/onshore reception), • Step 5 (Raw material transport), • Step 6 (Transport conditions), • Step 7 (Handling), • Step 17 (Example control measures) <p>1.5 Bacteriological testing record</p>
2. Storage of molluscs prior to purification.	<p>Contamination during non-immersed storage which is unlikely to be removed during subsequent sorting, washing or purification operations.</p> <p>Molluscs unlikely to deplete due to stress or shock as a result of time delays or temperature abuse.</p>	<p>Apply General Handling Procedure. All damaged or dead molluscs must be removed.</p>	<p>2.1 General Handling Procedure 2.2 Storage Procedure 2.3 Raw Material Storage Record 2.4 Chill store temperature record</p> <p>See GMPG Step 10 (Preparation for dispatch – handling)</p>

Process Step	Hazards	Controls	Records and Policies
<p>3. Clean, wash and grade molluscs prior to purification.</p>	<p>Ineffective cleaning that leads to the accumulation of mud and dead/dying molluscs. This leads to contamination of purification seawater.</p> <p>Ingestion of contaminants during cleaning, which might not be removed by purification.</p> <p>Molluscs stressed or damaged by cleaning and sorting operations, such that they may not effectively purify.</p> <p>Dead molluscs and mud balls within the biomass that need to be removed.</p>	<p>Apply Bivalve washing procedure – this will be business specific.</p> <p>Apply General Handling Procedure. All damaged or dead molluscs must be removed.</p> <p>During washing live bivalves must not be immersed in water.</p>	<p>3.1 Bivalve washing procedure 3.2 Dual use of equipment procedure 3.3 Bivalve cleaning record (Pre-purification)</p> <p>1.3 Bivalve handling procedure</p> <p>See GMPG Step 10 (Preparation for dispatch – handling)</p>

NB: Conditioning is not a routine process during purification and will require a separate HACCP.

Process Step	Hazards	Controls	Records and Policies
4. Load, fill and operate Purification system	<p>Overloading and improper operation of purification systems may result in:</p> <ul style="list-style-type: none"> • Oxygen depletion; • Impeded water flow; • Turbulent water flow; • Temperature shock or out of range; • Exposure of Bivalves; • Increased turbidity causing release of detritus by molluscs; • Reduced or inhibited bivalve activity; <p>Equipment failure during purification:</p> <ul style="list-style-type: none"> • UV lamp operation; • Pump operation; • Temperature control equipment; • Aeration; <p>Purification not carried out for required duration</p>	<p>Agree procedure on the loading, filling and operation of purification system.</p> <p>Follow any specific agreed guidance for operation of individual systems by the authorizing officer.</p>	<p>4.1 Load, fill and operate purification system Procedure</p> <p>4.2 Purification tank operation record</p> <p>4.3 UV Usage, cleaning and replacement record</p> <p>4.4 Water use and reuse record</p> <p>4.5 Daily hygiene audit</p> <p>1.3 Bivalve handling procedure</p> <p>See GMPG:</p> <ul style="list-style-type: none"> • Steps 12 (Purification - general) • Step 13 (Purification – structural hygiene) • Step 14 (Purification – loading tanks) • Step 15 (Purification – operational checks) • Steps 16 - 19 (Purification – HACCP systems) <p>See Seafish guidance document on EPT.</p>

Process Step	Hazards	Controls	Records and Policies
<p>5. Drain seawater from purification system to below all the molluscs.</p> <p>Rinse bivalves to remove detritus.</p> <p>Remove molluscs from purification tanks and containers.</p>	<p>Changes in water flow rate and direction causing re-suspension of detritus and ingestion by the molluscs.</p> <p>Initial drainage incomplete, leaving molluscs immersed and subject to ingestion of detritus when disturbed.</p> <p>Inadequate separation of unpurified and purified molluscs, enabling unpurified to go to packing.</p>	<p>Follow the drain and removal procedure.</p> <p>Maintain separation and traceability of bivalves</p> <p>During rinsing, live bivalves must not be immersed in water.</p>	<p>5.1 Drain tank and remove bivalves Procedure</p> <p>4.4 Water use and reuse record</p> <p>4.5 Daily hygiene audit</p>
<p>6. Wash and sort purified molluscs.</p> <p>De-clump and de-beard if appropriate</p>	<p>Ineffective clean down of same washing and or de-clumping machine used for purified and un-purified animals. Dual use of equipment may be a hazard</p> <p>Ineffective cleaning and sorting of molluscs, resulting in contamination of bivalves.</p>	<p>Document Cleaning Schedule.</p> <p>Apply General Handling Policy. Any damaged or dead molluscs must be removed.</p> <p>Apply Post Purification Cleaning Procedure.</p>	<p>6.1 Post depuration cleaning procedure</p> <p>6.2 Bivalve cleaning record (post)</p> <p>1.4 Bivalve Handling Procedure</p> <p>3.2 Dual use of equipment procedure</p> <p>Update Process Verification Checklist.</p>

Process Step	Hazards	Controls	Records and Policies
7 Pack and label molluscs.	<p>Damage to, or contamination of, molluscs during packing operations.</p> <p>Contamination of molluscs during transit, from use of inappropriate packaging system.</p> <p>Loss of traceability.</p> <p>Bivalves are incorrectly handled by customer.</p>	<p>Apply General Handling Policy. All damaged or dead molluscs must be removed.</p> <p>Document Packing Area Cleaning Schedule.</p> <p>Use of appropriate packaging systems.</p> <p>Traceability and other appropriate information must accompany the batch.</p> <p>Use of appropriate labelling, e.g. mollusc and allergen information.</p>	<p>7.1 Packing and wrapping policy 7.2 Packing and wrapping procedure 7.3 Packing and wrapping record(s)</p> <p>See also GMPC:</p> <ul style="list-style-type: none"> • Step 20 (Wrapping) • Step 21 (Labelling)

Process Step	Hazards	Controls	Records and Policies
8 Store packed molluscs.	<p>Contamination of molluscs being stored for dispatched and distribution.</p> <p>This hazard may occur if storage systems are used for other products or packaging systems are not a guaranteed method of avoiding contamination.</p>	<p>Apply General Handling Policy.</p> <p>Compliance with appropriate storage and dispatch procedures.</p>	<p>8.1 Storage and dispatch procedure 8.2 Chill store temp and cleaning record 8.3 Dispatch record.</p> <p>See GMPG:</p> <ul style="list-style-type: none"> • Step 22 (Storage) • Step 23 (Dispatch) • Step 24 (Handling after dispatch)
9. Possible brief rewatering or immersed storage in clean seawater.	<p>Water used is contaminated.</p>	<p>Follow approved procedure for rewatering bivalves.</p>	<p>9.1 Update Process verification Checklist.</p> <p>This activity may not be relevant to your depuration process.</p> <p>See GMPG:</p> <ul style="list-style-type: none"> • Step 22 (Storage) • Step 24 (Handling after dispatch)

Process Step	Hazards	Controls	CCP	Critical Limits	Monitoring Procedures	Corrective Actions	Verification
10. Dispatch of molluscs to market.	<p>Bivalves unsafe for consumption are placed on the market.</p> <p>Any unpurified bivalves dispatched to market must be verified as originating from class A waters and otherwise handled to ensure that they are fit for consumption.</p>	Verify that all policies and procedures have been followed.	Yes	Adherence to all procedures	Completion of Process Verification Checklist	Reject, relay or restart purification as appropriate.	<p>The effectiveness of the pre-requisite operational policies and procedures should be verified by long term trends analysis using EPT and other appropriate measures and records.</p> <p>Accurate and reliable EPT requires lab facilities and are therefore valuable for determining trends through time that can be used for active hazard management. Lateral flow EPT is considered less reliable, but provides quick real time results that are more suitable for positive release of a perishable product.</p>

NB: This example HACCP plan is appropriate for [purification systems](#) that are operated in accordance with agreed policies and procedures that reflect good manufacturing practices and current authoritative guidance. Verification of the effectiveness of these policies and procedures must be monitored continually to demonstrate that an effective regime of active management of known hazards has been put in place.

For newly established purification systems, evidence for the effectiveness of the policies and procedures to manage the known hazards will need to be gathered in order to demonstrate that best practice is being adhered to and that the bivalves are safe for human consumption.