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|  | MANAGING SHELLFISH TOXIN RISKS IN THE SCALLOP SECTOR  GUIDANCE FOR ENFORCEMENT OFFICERS SHELLFISH HARVESTERS AND SHELLFISH BUSINESSES |  |
|  | February 2017 |  |

**For all queries about this guidance —please use the number below.**

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| **CONTACT TELEPHONE** | 01224 285157 Jennifer Howie (POLICY)  07824 342187 Pat Smyth  (ENFORCEMENT) |

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**Summary**

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| **Intended audience:** | * Establishments handling and/or processing scallops including establishments approved for this activity * Local Authorities * Scallop fishermen * Caterers, retailers and distributers |
| **Purpose:** | This document provides information intended to assist enforcement officers and food businesses in the scallop sector in order to ensure compliance with toxin standards set out in EC regulation 853/2004. This guidance replaces the official controls for wild pectinidae guidance issued by Food Standards Agency in Scotland in 2004. |
| **Legal status:** | This document provides guidance on compliance with applicable food hygiene legislation contained within Regulations (EC) No 852/2004 and 853/2004. However only the courts can decide. |
|
| **Key words:** | * Shellfish, Live Bivalve Molluscs * Food law, monitoring and controls * Hygiene and food safety * Scallops * Shucking * Biotoxins * caterers |
| **Review date:** | This guidance will be reviewed in [] |

# Revision history

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| **Revision**  **No.** | **Revision date** | **Purpose of revision and paragraph number** | **Revised by** |
|  |  |  |  |

General Introduction

1. Shellfish contaminated with biotoxins can make people ill and in some cases can result in fatalities. That is why it is important that the risks associated with biotoxins in all live bivalve molluscs (LBMs; or filter-feeding shellfish) are managed appropriately by everyone involved in the supply chain.
2. The delivery of official controls applicable to the wild scallop (pectinidae) sector is usually land based. Unlike the active monitoring programmes in place for other LBM species which are required to be grown to maturity and harvested from areas classified by the competent authority, there is no offshore monitoring of scallop fishing areas by FSS. This is because the legislative framework for scallops harvested outside classified areas allows for a system of land-based controls for pectinidae. Unlike other species of LBM, the risks associated with biotoxins in scallops are significantly reduced by removing the gut of the animal – a process of evisceration known as shucking – which includes rigorous washing in order to remove any toxins left in the gut loop.
3. For food business operators (FBOs) selling whole scallops, rigorous end product testing **must** be in place as an integral part of their food safety management system. Essentially the regulations require that businesses ensure food safety “as **proved** by a system of own checks” [[1]](#footnote-2). All businesses, other than those to which specific exemptions apply (see Section 3), are assumed to require approval. This guidance document therefore outlines both the requirements for approval and for operators considered to qualify for non-approved status (direct sale to the local market).
4. This guidance is intended to provide a framework to assist all those involved in the production, processing and enforcement regarding the sale of **whole or shucked scallops** to assess the biotoxin risks associated with their products. The guidance will assist them in developing their HACCP system and design their supporting end product testing regime that will help ensure compliance with legal requirements and minimise the risks of placing harmful product on the market.

Intended audience

1. This guidance is primarily intended for scallop harvesters, retailers and caterers, handling and processing scallops as well as enforcement authorities.

Purpose of guidance

1. This guidance document is intended to help food businesses manage the inherent risk of biotoxins in scallops and to help local authorities (LAs) assess food safety management procedures in the businesses they inspect. It is anticipated that local authorities will utilise this guidance in order to assess compliance in food businesses handling or processing scallops. Where food businesses take a different approach to managing food safety risks then equivalence with the standard set out in regulation (EC) 853/2004 should be demonstrated by the FBO. Food Standards Scotland (FSS) will audit LAs against the standards set out in regulations, taking account of this guidance.

Legal status of guidance

1. These guidance notes have been produced to provide advice on compliance with toxin standards and therefore to help ensure compliance with

* the legal requirements of Regulations (EC) 852/2004 and 853/2004 (as amended) as enforced by the Food Hygiene (Scotland) Regulations 2006 (as amended). Specifically Chapter II, Article 5 (Hazard analysis and critical control points) of 852/2004 and Section VII, Chapter V (Health Standards for LBMs) of 853/2004.

1. These guidance notes cannot cover every situation and you may need to consider the relevant legislation itself to see how it applies in your circumstances.
2. Businesses with specific queries may wish to seek the advice of their LA. Details of relevant contacts in FSS are provided below.

### Contacts

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| --- | --- | --- |
| **FOOD STANDARDS SCOTLAND – SHELLFISH CONTACTS** | | |
| **Name** | **Topics** | **Contacts** |
| Pat Smyth | * Enforcement Advice | 🕿 07824 342187 |
| Jennifer Howie  Josep Campins | * Policy Advice | 🕿 01224 285157 |
| Caroline Thomson  Graham Ewen | * FSS LBM biotoxin monitoring programmes and contract management | 🕿 01224 285378 |
| Kasia Kazimierczak  Kelly White | * Scientific Advice | 🕿 01224 285111 |

SECTION 1: General obligations on scallop harvesters and businesses

### Introduction

1. All food businesses are required to register with their local authority prior to trading. This will enable a local authority to make a determination as to whether or not that business requires to be approved and only businesses with an effective hazard analysis and critical control point (HACCP) system will be approved. Any business (including primary producers involved in direct sale) that the local authority considers to require approval but operates without the approval being granted may also be subject to enforcement action[[2]](#footnote-3). This will allow enforcement officers to consider whether or not food safety management systems in place across the sector are sufficiently robust in order to protect public health. This is particularly important for shellfish toxins.
2. Marine biotoxins produced by phytoplankton can accumulate in the tissues of filter-feeding bivalve shellfish. Toxin related illness can occur, if contaminated shellfish are consumed by humans. In addition to the clear public health risks associated with shellfish toxins, any non-compliant product originating from Scotland has the potential to damage the reputation of the wider shellfish industry. This section outlines the general obligations of all those involved in the production of shellfish for both the wholesale and retail market.
3. In relation to shellfish toxins, the maximum permitted levels are set out in 853/2004. Compliance with these limits therefore applies to all batches of the product sold and whilst it is up to food businesses to define what constitutes a batch, a working definition of ‘batch’ is suggested at **Annex E.** This definition does not replace the legal definition of a batch as set out in EC regulation 178/2002[[3]](#footnote-4) which will form the legal test in determining food safety in any given instance.

### Shellfish toxins: Maximum permitted levels

* ASP - 20 milligrams of domoic acid per kilogram flesh

Lipophilic Toxins:

* + 160 micrograms OA/DTX/PTX per kilogram flesh
  + 160 micrograms AZA per kilogram flesh
  + 3.75 milligrams YTX per kilogram flesh

PSP - 800 micrograms per kilogram flesh.

1. Whilst the Amnesic Shellfish Poisoning toxin, domoic acid, has historically been more prevalent in Scottish king scallops than in other shellfish species, scallops are filter feeders and can accumulate other biotoxins, such as lipophilic toxins and PSP causing toxins too.

**Shucking**

1. Irrespective of whether scallops come from an approved or non-approved producer, scientific studies indicate that adequate shucking (which includes washing) will significantly reduce the risk of shellfish toxins in scallops.
2. The term ‘shucking’ in this document therefore includes reference to the wash step which is important in ensuring that toxins, which may be found within the gut loop, are removed. This means that eviscerated scallops should be subject to vigorous washing and agitation following careful removal of the non-edible parts. Scallops should not be left in static water baths where cross contamination can occur.
3. Seafish have provided the following advice on their [website](https://www.youtube.com/watch?v=PopQe9OozWU&list=PLjmL1YNydu1GVKF1UTHyMxk3y9BAYVSnx&index=2). Guidance will also be made available on the FSS website in due course
4. Effective shucking practice should therefore:

* Remove all traces of the gut loop
* Involve rigorous washing for 10 minutes
* Ensure cross contamination of the gut content to the edible flesh is minimised at all times.

1. **Annex A** provides shucking diagrams for reference.

### End product testing

1. Shucking is not a substitution for end product testing (EPT). However EPT can be reduced as part of a food safety management system, where for example, continuously high standards of shucking are maintained. FSS has produced the following information for harvesters and processors on the types of [end product test kits](http://www.foodstandards.gov.scot/shellfish-toxin-end-product-test) which are commercially available to detect these biotoxins. These kits are relatively inexpensive and easy to use and should be considered an integral part of any food safety management system for shellfish toxins.

SECTION 2: CONTROLS APPLICABLE TO SCALLOP ESTABLISHMENTS APPROVED UNDER 853/2004 AND HARVESTERS SUPPLYING SUCH ESTABLISHMENTS

### FBO obligations, official controls and action in the event of a failed sample or inadequate HACCP

1. In Scotland, scallop controls are applied in accordance with Chapter IX, Section VII, Annex III of 853/2004.. The regulations require that, for scallops outwith classified areas, food businesses must not place those products on the market unless they are harvested and handled in appropriately and are compliant with health standards “**as proved by a system of own checks**”.
2. A link to EC regulation 853/2004 can be found [here](http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02004R0853-20160401&qid=1462294525277&from=EN) but clearly, unless a system of own checks is demonstrated, scallops cannot be sold. End product testing must therefore be considered to be a significant feature of any food safety management system.
3. In relation to LBM biotoxins, these systems, **must** ensure that the product complies with the maximum permitted legal levels as set out in 853/2004.
4. Local Authorities are the competent enforcement authorities for approving shellfish processors and dispatch centres. In general terms LAs should follow guidance on inspection and sampling detailed within the [Food Law Code of Practice (Scotland) and Food Law Practice Guidance (Scotland).](http://www.foodstandards.gov.scot/food-law-code-practice-2015)
5. Only establishments with an effective HACCP system should be approved for the dispatch or processing of scallops (as for other commodities). If the HACCP system in any business is found to be subsequently deficient it is expected that LAs will consider appropriate enforcement action which should include consideration of serving a Remedial Action Notice or potentially suspension or withdrawal of approval.
6. If either a HACCP system is inadequate or an official control verification sample fails to meet regulatory toxin standards then the requirements of Regulation 27 of The Food Hygiene (Scotland) Regulations 2006Hygiene Regs apply. Steps to remove that product from the market, where evidence suggests it has not been processed in accordance with food safety requirements may be considered in which case LA’s should seek advice from the FSS Scottish Food Crime and Incident Unit at [incidents@fss.scot](mailto:incidents@fss.scot)
7. The General Food Law provisions of Article 19 require all food businesses to withdraw from the market products that do not comply with food safety requirements, therefore where there is evidence that products are not compliant they must be withdrawn.
8. Where appropriate, the issuing of a Food Alert, and RASSF (Rapid Alert System Food and Feed) will be undertaken by FSS in collaboration with the LA and the Food Business in order to withdraw non-compliant product
9. Routine official control verification samples should be taken from processors during normal inspection duties whose visit frequency should be determined by risk. However verification sampling should not be considered a pre-requisite to enforcement action.
10. Since specific frequencies of sampling have not been defined in legislation minimum sampling frequencies are suggested in **Annex B** as are supporting enforcing actions. These should be complimentary to the general direction given within the Code.
11. FSS currently provides funding for additional verification sampling to take place and advises local authorities to following the guidance at **Annex C** in relation to taking samples at approved establishments. FSS will communicate all results over the Maximum Permitted Level to industry representatives.
12. **Annex D** outlines the offshore box system which has been used by FSS to identify the areas in which shellfish has been harvested under previous offshore monitoring regimes. The registration document of the batch concerned should also identify the area where the scallops were fished using this or the National Grid Reference system in order to allow swift communication by FSS to relevant industry bodies of areas where there may be elevated levels of shellfish toxins.

### Communication and Notification Arrangements for OC Results

1. All official control sample results will be made available to FSS by the laboratory completing the analysis. These will be immediately made available to the LA who in turn may make these results available to the business where the sample was taken.
2. Every Tuesday the FSS will report all [OC biotoxin sample results](http://www.foodstandards.gov.scot/food-safety-standards/advice-business-and-industry/shellfish/shellfish-results). The summary report will be provided to all interested parties and published on the website.
3. Whilst within the same EU legislative framework, the controls that apply in UK waters with regard to scallops differ from those that apply for example in France and other EU member states. Unlike the UK, French scallop harvesting areas, for example, are classified and monitored and the French authorities will close areas and prohibit harvesting in their scallop beds. It is up to food businesses in the UK to make sure that they are aware of any statutory conditions and harvesting restrictions that apply in any sea area where they intend to operate. The French authorities provide regular updates via their website as to scallop area closures (**Annex F**).
4. **Any scallops caught from an area that any competent authority has closed should be seized and destroyed on arrival at port under section 9 of the Food Safety Act 1990.**
5. Harvesters who intend to supply their scallops to countries outside the UK must ensure that their product is compliant with all relevant requirements of the receiving country prior to sale. Further details are included in **Annex F**.

### Primary production: roles, responsibilities and registration documents

1. Everyone in the food supply chain is responsible for ensuring that controls are applied in accordance with legal obligations and that food safety issues are addressed. Existing regulations require that:

“Whenever a food business operator moves a batch of live bivalve molluscs between establishments, up to and including the arrival of the batch at a dispatch centre or processing establishment, a **registration document** must accompany the batch”[[4]](#footnote-5).

1. Primary producers, i.e. harvesters, must therefore ensure that a registration document is completed and that the risks associated with the harvest area have been assessed prior to landing a catch. The specific information required by law in a registration document is outlined below:
2. **Registration document requirement - From EC Regulation 853/2004 Annex II, Section VII, Ch. I Paragraph 4**.

|  |
| --- |
| (a) In the case of a batch of live bivalve molluscs sent from a production area, the registration document must contain at least the following information:  (i) the gatherer's identity and address;  (ii) the date of harvesting;  (iii) the location of the production area described in as precise detail as is practicable or by a code number;  (iv) the health status of the production area;  (v) the shellfish species and quantity;  **From EC Regulation 853/2004 Annex II, Section VII, Ch. I Paragraph 4.**  and  (vi) the destination of the batch.  5. Food business operators sending batches of live bivalve molluscs must complete the relevant sections of the registration document so that they are easy to read and cannot be altered. Food business operators receiving batches must date-stamp the document on receipt of the batch or record the date of receipt in another manner.  6. Food business operators must keep a copy of the registration document relating to each batch sent and received for at least twelve months after its dispatch or receipt (or such longer period as the competent authority may specify). |

1. As offshore harvesting areas are not monitored in the UK, an attestation (based on official control sampling) by the harvester on the ‘health status of the production area’ will not normally be possible. Nevertheless, there is a requirement for harvesters to record the health status of the area fished, based on a requirement to ensure that fishing does not take place in an area which may be subject to fishing restrictions. Historical evidence from UK and French waters indicates that there is a significant risk of toxin contamination of whole scallops particularly during the summer months, and in the absence of definitive test results from harvesters this risk should be communicated to recipients of the registration document. It is imperative that receiving establishments understand the risks associated with the product received and that they are aware that the scallops have not been subject to any official control testing at that point.
2. Local Authorities will issue registration documents to producers on request in accordance with agreed copy control protocols. The registration document requirement applies to scallops as well as to other bivalves and **any live shellfish which is not accompanied by a registration document (or has not been appropriately labelled with an approval number) can be regarded as not complying with food law and can be seized by any Food Authority in Europe.**
3. Food Law Practice Guidance advises that authorities should familiarise themselves with the commercial activities within ports in their local area and implement some degree of monitoring of landings of scallops. This can be achieved through effective and periodic liaison with other statutory inspectorates e.g. Marine Scotland and Regional Inshore Fishery Groups[[5]](#footnote-6).
4. Food authorities responsible for establishments receiving batches of LBMs from outside their local area are encouraged to contact the issuing food authority when inspecting registration documents. In order to ensure efficiency in this verification process, food authorities are advised to keep a log of all registration documents that have been issued by them for at least one year, including details of the harvesters to whom they have been issued and the production areas which the harvester requires the registration documents for.
5. Food Business Operators must keep a copy of the registration document relating to each batch sent and received for at least 12 months after its dispatch or receipt (or such longer period as the competent authority may specify).[[6]](#footnote-7)
6. Clearly in order to deliver robust official controls for the scallop sector more generally, EC Regulation [882/2004](http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02004R0882-20140630&qid=1450085260827&from=EN) (the ‘official controls’ regulation) sets out an explicit requirement for competent authorities as follows:

“Article 6 - Staff performing official controls

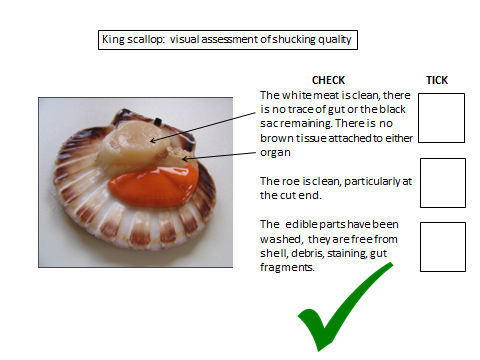
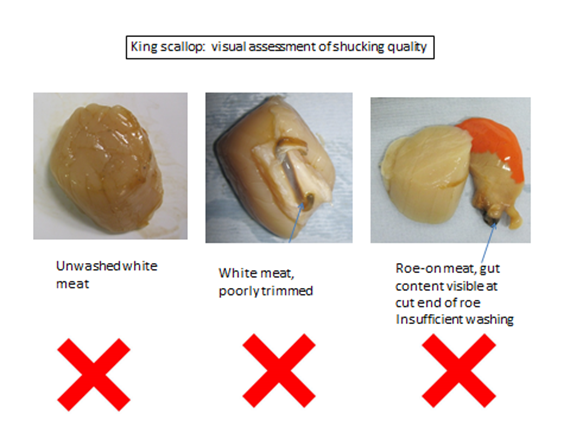
The competent authority shall ensure that all of its staff performing official controls …receive, for their area of competence, appropriate training enabling them to undertake their duties competently and to carry out official controls in a consistent manner.”

1. FSS will therefore continue to work with authorities in order to ensure the relevant skills and training is in place in order to ensure appropriate oversight of this sector.

SECTION 3 CONTROLS REGARDING The direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer[[7]](#footnote-8)

1. In EU food hygiene legislation there is an exemption from compliance with the detailed specified provisions of the Community law for food businesses solely involved in the direct supply of small quantities of primary products of animal origin to the final consumer or to local retail establishments directly supplying the final consumer. However, EC regulation 853/2004 states that ‘Member States shall establish, according to national law, rules governing such exempt activities and that such national rules ‘shall ensure the achievement of the objectives of this regulation’
2. It is the view of FSS that whole scallops should not be sold under the local market exemption unless the primary producer either tests each batch in order to ensure compliance with food safety criteria, or – for king scallops - puts in place other measures, as outlined in this document, that will ensure compliance prior to sale to the final consumer.
3. **Annex G** provides guidance on how primary producers can meet their obligations to provide safe food under the primary production exemption.

### ANNEX A – examples prepared scallops following good/bad shucking



### ANNEX B Frequency of official control sampling in relation to pecinidae and enforcement action

The controls outlined in this section should be delivered by personnel who are adequately trained and who understand the inherent risks associated with this product. This requirement is outlined in Article 6 of EC Regulation 882/2004.

Businesses should not be approved unless an effective HACCP system is in place. If any business is trading without adequate controls in place, consideration should be given to removing that approval and prohibiting sales until demonstrably robust and sustainable controls have been put in place by the business concerned.

Research indicates that the main critical control point in the shucking process is the adequate removal of the hepatopancreas, mantle and gill. Research has indicated that the removal of these tissues will remove much of the biotoxins which may be present in the animal, with vigorous washing also considered important in order to remove any toxins that may be present in the gut loop.

However it cannot be assumed that effective shucking practice alone will ensure the removal of all of the biotoxin that may be present.

* Evaluation of this process therefore, coupled with the general assessment of confidence in the processors’ own checks or EPT, (to check that the product does not exceed the statutory limits for PSP, ASP and lipophilic toxins) should allow a risk assessment to be determined for each processing establishment and the level of Official Control checks can be applied accordingly. For example a processor who conducts satisfactory EPT on product that is adequately shucked in conjunction with a full Hazard Analysis and Critical Control Points (HACCP) system may require little Official sampling.
* Official Control verification sampling is **not** always required prior to any enforcement action taking place and a sample that returns a negative result for any batch does not mean that the FBO has correctly identified or controlled the risks associated with his product. A food business placing whole scallops on the market without having undertaken adequate EPT for example, will be considered to be in breach of Regulation 27 of the Food Hygiene (Scotland) Regulations 2006.
* Any toxin positive result above permitted levels should result in the immediate seizure and detention of that product and notice to the FBO that in order to continue to trade, measures, as specified by the local authority, should be taken in order to ensure public health protection.
* It is also known that the quality of processor training, the actual quality of the shucking process, the HACCP system and end product testing as well as the environmental and biological factors affecting the biotoxin accumulation in the scallops are all important to the safety of the final product. Ensuring that the authorised officer is also adequately trained in order to make a determination as to the efficacy of the controls that are in place, is also vital.
* Decisions on batch size and sample frequency for EPT are the responsibility of individual food businesses and will need to be determined on a case by case basis using risk assessment criteria. For example, EPT plans should take into account the risks associated with a particular time of year, the area the product has been gathered from and the nature of the product to be offered for sale (i.e. shucked, adductor only, whole).
* **Table 1**. provides a suggestion as to how official control sampling might be scheduled within current arrangements promoting verification sampling during primary and secondary inspections and requiring follow up action where non-compliance is identified during initial verification checks.

### Table 1 Suggested frequency of official control sampling in relation to scallops and enforcement action

Please note that EPT is expected to be carried out for the entire 3 biotoxin categories on a batch basis unless the business HACCP system effectively demonstrates that a lesser frequency can be applied for any of these.

|  |  |  |  |  |  |  |
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|  | **Product sold/practice** | **EPT adequacy** | **HACCP adequacy** | **OC sampling frequency** | **OC enforcement action** | **Expectation at audit** |
| 1 | **SHUCKED**  **Good** evidence of shucking being carried out adequately by trained processors. E.g. attendance at Seafish courses | Frequency of testing demonstrated as compliant with risk assessment carried out in accordance with business HACCP procedures  with documentary evidence to this effect.  Full traceability systems in place.  EPT results can be shown. | Formally written, accurate and current HACCP plan that is understood by staff.  Evidence of its adequacy and compliance within the business.  Training records complete.  Full biotoxin risk assessment in relation to product in evidence.  Evidence of action plan in event of a failed sample. | During scheduled inspections with up to 2 samples during the course of a 12 month period) | No action | Evidence that LA enforcement policy, COP requirements and relevant guidance, including this guidance, has been followed. |
| 2 | **SHUCKED**  Shucking standards **poor or variable,** training for processors not complete or comprehensive | Sporadic or no EPT.  Little or no evidence that frequency of testing is compliant with risk assessment carried out in accordance with business HACCP procedures. Little or no documentary evidence of risk assessment to inform EPT.  Knowledge of risk assessment procedures inadequate.  Traceability ill defined. | General standard HACCP plan in evidence.  No evidence of biotoxin issue being adequately addressed within the plan.  Little evidence of action plan for use in the event of a failed sample. | No additional sampling required – remedial action required | Formal enforcement action. Consider remove approval unless immediate remedial is taken Remedial action and potential product recall required. | Evidence that LA enforcement policy, COP requirements and relevant guidance, including this guidance, has been followed. |
| 4 | **WHOLE** | **EPT every batch or in accordance with robust risk assessment** | Formally written accurate and current HACCP.  Evidence of its adequacy and compliance within the business.  Training records complete.  Full biotoxin risk assessment in relation to product in evidence.  Evidence of action plan in event of a failed sample. | Every scheduled visit (minimum 2 times per year) | No action | Evidence that LA enforcement policy, COP requirements and relevant guidance, including this guidance, has been followed. |
| 5 | **WHOLE** | **Sporadic or limited EPT** | HACCP plan, incomplete or inadequate. No real appreciation of biotoxin risk. No training records for staff, general lack of control. | Immediate intervention and suggest sample on site. | Immediate RAN. Seizure and detention, Product recall. Remove approval. | Evidence that LA enforcement policy, COP requirements and relevant guidance, including this guidance, has been followed. |

### ANNEX C – Sample collection protocol

The sampling protocol indicates how the OC sample should be gathered and details the method, amount and equipment required to fulfil this. The sample submission form must accompany the samples to the laboratory.

Please ensure that the protocol in the following link is followed. Cefas are contracted by FSS to provide logistical support for pectinidae sampling in Scotland.

<https://www.cefas.co.uk/cefas-data-hub/food-safety/the-shellfish-partnership/>

* Shellfish samples should be collected from identified processors/dispatch centre/auction markets at a frequency determined by risk assessment.
* Ideally samples should be collected between Monday and Tuesday and posted to Cefas Weymouth using the boxes provided.
* Shellfish sample size should be such that at least 200g of meat can be provided for the ASP, DSP/LTs and PSP assays. This is usually achieved by the following minimum numbers of suitable commercial size animals:
  + Whole King Scallop 30 shells
  + Shucked King Scallop (adductor and gonad tissue) 30 pieces
  + Adductor (white) meat of King Scallop 30 pieces
  + Whole Queen Scallop 50 shells
  + Shucked Queen Scallop (whole or adductor/gonad) 50 pieces
  + Adductor (white) meat of Queen Scallop 50 pieces
* Shellfish must be placed in the polythene bags provided, closed with the cable ties and a completed self-adhesive label attached to each bag.
* A sample submission form [[8]](#footnote-9)must also be completed for every processor and the submission form placed in the document wallet in the box being sent to Cefas Weymouth.
* The bagged samples should be placed in the box provided along with pre-chilled cool packs. The boxes must be sealed with adhesive tape and a prepaid postage label attached to the boxes before being posted to **Cefas, Weymouth Laboratory, Barrack Road, The Nothe, Weymouth, Dorset, DT4 8UB (for purposes of Royal Mail Special Delivery, we have been assigned the postcode DT4 8BF)**
* Any queries or problems should be referred to:-
  + Cefas on: 01305 206713, fax 01305 206601.
  + [biotoxinmonitoring@cefas.co.uk](../../../../AppData/Local/Microsoft/Windows/Temporary%20Internet%20Files/Content.Outlook/RFK4HXSB/biotoxinmonitoring@cefas.co.uk)

### ANNEX D – Offshore map showing area ‘boxes’



### ANNEX E. What is a batch and what is a representative sample?

Bivalves are animals which can migrate, be at different stages in their life cycle and therefore may also accumulate toxins at different rates. Therefore a food business should take reasonable steps in accordance with their own risk assessment to determine what constitutes a batch of scallops and which shellfish should form a representative sample of that batch. In determining a definition for a ‘batch’ FSS considered definitions in use by international trading partners:

According to processing standards set out by the **Australian Government:**

**“batch”**  means a quantity of bivalve molluscs harvested from a particular harvesting area (e.g. marine farm, lease or designated wild shellstock harvest area) and with the same harvest date[[9]](#footnote-10).

The **Canadian Shellfish Sanitation Programme** applies the following definitions:

**“Harvest Lot”**: A collection of bulk shellstock or containers of shellstock from a defined growing area taken by one or more harvesters and removed from the water for delivery to the processing plant on the same day.

**“Lot of Shellstock” -** A collection of bulk shellstock or containers of shellstock of no more than one day's harvest from a single defined growing area by one or more harvesters. [[10]](#footnote-11)

The **US National Shellfish Sanitation Programme** Guide for the Control of Molluscan Shellfish also utilises similar definitions.as those applicable in Canada[[11]](#footnote-12)

The industry in the UK through Seafish have suggested that a *‘batch’ can be a bag, box or bin of shellfish or two days fishing. The decision as to what constitutes a batch can only be taken by the business placing the animals on the market in the light of the operators own risk assessment….”[[12]](#footnote-13).*

FSS agrees that batches should be determined by food businesses themselves following their own risk assessment, however given what we know about the rate at which toxins can accumulate in shellfish, FSS proposes the following definition could be considered appropriate:

“**Batch”: means a quantity of bivalve molluscs harvested from a particular harvesting area with the same harvest date**.” In determining a batch, an “area” should be considered to be no bigger than an offshore box as outline in Annex D.

### ANNEX F: Detail of Biotoxin closures in French waters and controls applicable to inter-EU trade

**French Scallop Bed Closures**

The controls that apply to scallops harvested in UK waters differ from those that apply for example in France and other EU member states. Unlike the UK, French scallop harvesting areas are classified and monitored and the French authorities will close areas and prohibit harvesting in their scallop beds. It is up to food businesses to make sure that they are aware of any statutory conditions that apply in any sea area where they intend to operate.

A new local geoportail is available and shows [open and closed areas in Baie de Seine](http://carto.geo-ide.application.developpement-durable.gouv.fr/950/Decisions_peche_memn.map).

Information relating to French scallop bed closures in The English Channel.

Click to open the following link [http://www.dirm-memn.developpement-durable.gouv.fr/peche-de-la-coquille-...](http://www.dirm-memn.developpement-durable.gouv.fr/peche-de-la-coquille-saint-jacques-a133.html)

Scroll down to open the last link at the bottom of this page which includes a map of open and closed sites. The scallop beds in dark blue are open. Those in grey are closed and must not be fished.

Make sure that you use a browser with a translation function (for example Google Chrome).

It should be noted that whilst this website is updated regularly industry should check with the relevant French Authorities prior to commencement of fishing activities. Any harvesting restriction which any competent authority has placed on any area of water must be adhered to.

Intra-EU trade

LBM species must be compliant with health standards set out in law at the point those products are ‘placed on the market’. The UK has interpreted the point at which scallops are placed on the market, other than for primary producers involved in direct sale to the final consumer’ to refer to product sold from any approved establishment.

Given that shucking can only take place in establishments approved for that activity, harvesters have an obligation to ensure that the risks associated with their product are fully communicated to receiving establishments in order that they can take all reasonable measure to ensure product safety.

The registration documentary requirement sets out the minimum amount of information that must accompany each batch from harvester/fisherman to approved establishment – and includes a requirement to provide information on the destination of the batch as well as information on the health status of the production area. If whole product is sent to an establishment that is not approved to process/shuck scallops then there is a significant risk that the product may be subject to recall unless either confirmatory testing on whole product takes place.

Harvesters that either do not carry out testing or do not clearly communicate the risks associated with their product to receiving establishments risk costly recalls and potentially put public health at risk.

### ANNEX G: Guidance for the production of scallops on the national market. Model framework:

* 1. The suggested scope of the exemptions from the requirements for approval under Regulation 853/2004 fall into three categories of which the ‘primary production’ exemption is most relevant to shellfish. Article 1(3)(c) of EC Regulation 853/2004 exempts:

*“the direct supply, by the producer, of small quantities of primary products to the final consumer or to local retail establishments directly supplying the final consumer”*

***Definition of ‘Small quantities’***

* 1. The [Food Law Code of Practice, Practice Guidance for Scotland](http://www.foodstandards.gov.scot/food-law-code-practice-2015) (FLCoP PG) outlines the details of the local market exemption and the expected parameters in which it operates. Given that the risks associated with both king and queen scallops can be managed in similar ways, it is proposed that:

**The current limit for King Scallops (5 tonnes) be raised to match the current limit for Queen Scallops (10 tonnes).**

* 1. The following section therefore amends the relevant section A.4.3 of the FLCoP PG document as follows:

*“For live bivalve molluscs; a small amount is a total amount of not more than 25 tonnes of fishery products in a calendar year. The total amount may be made up of any species, with the exception that the total amount shall not exceed the maximum amount for the following species:*

|  |  |
| --- | --- |
| * **Allowances for small quantities of live bivalve molluscs** |  |
| * **Species** | * **Maximum amount** |
| * Cockles | * 25.0 tonnes |
| * Oysters | * 5.0 tonnes |
| * **King Scallops** | * **10.00 tonnes** |
| * **Queen Scallops** | * **10.0 tonnes** |
| * Mussels | * 20.0 tonnes |
| * Other Live Bivalve Molluscs | * 10.0 tonnes |
| * Marine Gastropods | * 20.0 tonnes |

***Definition of ‘local’***

* 1. It is proposed that for scallops, in line with existing guidance for the sale of wild game[[13]](#footnote-14), the definition of ‘local’ be extended to include the whole of Scotland.

**For primary producers of scallops, the definition of ‘local’ is the whole of Scotland.**

***Definition of ‘direct supply’***

* 1. “Direct supply” to the final consumer would include mail order or internet sales, as long as the supply is *direct* to the consumer. A courier service can therefore be used to transport the products directly from the primary producer to the final consumer or retailer supplier the final consumer – provided no intermediary transaction takes place.

***Managing toxin risks – for king scallops only***

* 1. Food businesses must be able to demonstrate that food placed on the market to the final consumer is safe.
  2. Given that a critical control exists which has been shown to be particularly effective for mitigating the risks toxins in King Scallops (in particular ASP), small quantities of whole live king scallops may be sold direct by fishermen under the following circumstances:
  3. *For sale to local caterers:*

**Small quantities of whole live king scallops may be sold direct by fishermen to local caterers provided all the following conditions (a-e) are met**

a). Primary producers selling whole king scallops should seek assurance from prospective catering buyers that they have effective food safety management systems in place prior to sale. Primary producers selling whole king scallops should also notify their own local authority of their intention to sell whole live product.

b). Caterers seeking to buy whole king scallops should be able to provide confirmation to primary producers that they have an effective HACCP system and trained staff in place prior to sale.

c) Caterers should also notify their local authority of their intention to process whole king scallops sourced directly from primary producers. Caterers should have an effective HACCP system reflecting the risks associated with this product and should maintain traceability of all their suppliers in accordance with EC regulation 178/2002, particularly for those supplying scallops under these arrangements.

d). Primary producers should provide appropriate instructions for use with each batch and that batches should be clearly labelled regarding intended use

e) Caterers need to be able to verify that their HACCP is effective and may be able to liaise with the primary producer who may be best placed to undertake testing of shucked product as part of that verification process.

f)Local authorities with caterers receiving product under these arrangements should ensure that the procedures outlined above are in place.

* 1. This system means that active documentary contact should be made between harvester and caterer prior to sale, and between harvesters/caterers and their respective local authorities. A model letter which a primary producer can send to prospective customers, copying their local authority lead food officer is available at **D1**. (**Annex D1)**
  2. Suggested instructions for use and labelling are provided at **Annex D 2**

* 1. *For sale to final consumers or caterers with unconfirmed scallop HACCP* It should be noted that the specific primary production exemption within the hygiene regulations extends to sales direct to final consumers. On the basis that shucking must take place in a controlled environment, which in this model should be confirmed by the primary producer prior to sale, it is proposed that *all batches of whole king scallops sold directly to the final consumer, retailers or to caterers that have not confirmed their food safety management and training systems must conform to the toxin standards set out in law.* This means that each batch should be tested for toxins prior to sale.
  2. All queen scallops sold on the local market, either to caterers, local retailers or final consumers must also be compliant with health standards set out in law. The specific conditions outlined at 1.7 therefore do not apply to the sale of queen scallops under the primary production exemption.
  3. Guidance on the traceability requirements set down in EC Regulation 178/2002 (the ‘General Food Law’ regulation) can be found [here](https://www.food.gov.uk/business-industry/guidancenotes/hygguid/generalfoodlaw). It is expected that local authorities should be able to cross reference lists of producers and receivers of scallops handled under these arrangements.

**Annex D1: Confirmation of HACCP and king scallop handling requirements**

(Applies only to small quantities sold directly by the primary producer to local retail establishments)

Company letterhead

16 February 2017

Dear Chef / Manager,

**IMPORTANT FOOD SAFETY NOTICE:**

**SUPPLY OF WHOLE KING SCALLOPS**

**The edible part of the scallop is the white meat and orange roe.**

**The other parts comprising the gut and frill**

**must NOT be consumed or used in food preparation.**

Scallops may contain algal toxins derived from naturally occurring phytoplankton on which the scallops feed. The gut (particularly the black sac or hepatopancreas), and the frill (skirt or mantle) contain the highest proportion of these toxins. These are the inedible parts must always be discarded and never used in food preparation, e.g. for soups, stock, sauces, etc.

The edible parts should also be washed after removal in order to remove any remaining small pieces of the gut.

If you obtain whole king scallops from us you must agree to undertake the effective removal of the inedible parts. Your staff must be adequately trained in accordance with the requirement set out in EC regulation 852/2004, and your HACCP must reflect the hazard and process steps required to mitigate THIS RISK. You should inform your local authority of your intention to process scallops in this way.

The cutting out of the edible parts is termed shucking. Advice on safe shucking can be obtained from

* Us, your supplier
* FSS Training Aid ‘**Preparation of king scallops and visual checks of shucking quality’[[14]](#footnote-15)** available from [SEE ANNEX A]……………….and on line at ……………..
* SeaFish DVD (3.5 min long), ‘**Scallop Preparation’** published Jan 5th 2013 and available on YouTube [www.**youtube.com/watch**?**v**=**7jZrviH\_z5E**](http://www.youtube.com/watch?v=7jZrviH_z5E)
* SeaFish ‘Scallop handling and shucking practices’ 2nd Edition Seafish Industry authority 2006 <http://www.seafoodacademy.org/LinkedDocuments/scallops/Scallop%20Coaching%20Pack%202nd%20Ed.pdf>
* Additional information for your inclusion in your HACCP **PREPARATION OF KING SCALLOPS *Pecten maximus* RECEIVED WHOLE (LIVE IN SHELL)[[15]](#footnote-16)** is available on line at……………………………………….

**We would be grateful if you would sign below and return this letter (*email address)* to enable us to know that all our customers are aware of this safety advice – we suggest you keep a copy for your own records. Please note we will also advise our EHO of customers who receive whole scallops. Please send a signed copy of this letter to your EHO.**

If you have any queries or wish to discuss any aspect of the above then please do not hesitate to contact me. A copy of this letter has been sent to our local authority.

Yours sincerely,

Signed \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Print Name**

**Position Company Managing Director or Head Chef**

Restaurant: Name……………………………………………………….

Restaurant Address

I have read the accompanying food safety notice regarding the supply, shucking and consumption of scallops.

Signed: ……………………………………………………………

Print Name ……………………………………………………

Position Held: ……………………………………………….

Date: ……………………………………………………………..

**Annex D2 –Suggested Food safety notice**

|  |
| --- |
| Food Safety Warning  Whole king scallops *Pecten maximus*  **The edible part of the scallop is the white meat and orange roe**  **The other parts, the gut and frill, must NOT be consumed or used to in food preparation.** |

1. Chapter IX, Section VII, Annex III of EC regulation 853/2004

   <http://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:02004R0853-20160401&qid=1462294525277&from=EN> [↑](#footnote-ref-2)
2. Local Authorities are obliged to follow the Food Law Code of Practice when undertaking enforcement functions: <http://www.foodstandards.gov.scot/food-law-code-practice-2015> [↑](#footnote-ref-3)
3. http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1478003169873&uri=CELEX:02002R0178-20140630 [↑](#footnote-ref-4)
4. EC Regulation 853/2004 Annex II, Section VII, Ch I, 3. [↑](#footnote-ref-5)
5. <http://ifgs.org.uk/> [↑](#footnote-ref-6)
6. 853/2004, Section VII, Ch I .6 [↑](#footnote-ref-7)
7. Article 1(3)(c) of EC Regulation 853/2004 [↑](#footnote-ref-8)
8. Please see Cefas sampling protocols webpages for details: <https://www.cefas.co.uk/cefas-data-hub/food-safety/the-shellfish-partnership/> [↑](#footnote-ref-9)
9. [Australia New Zealand Food Standards Code - Standard 4.2.1 - Primary Production and Processing Standard for Seafood (Australia Only)](https://www.legislation.gov.au/Details/F2012C00775) [↑](#footnote-ref-10)
10. [Definitions - Canadian Shellfish Sanitation program - Manual of Operations - Food - Canadian Food Inspection Agency](http://www.inspection.gc.ca/food/fish-and-seafood/manuals/canadian-shellfish-sanitation-program/eng/1351609988326/1351610579883?chap=3) [↑](#footnote-ref-11)
11. <http://www.fda.gov/downloads/Food/GuidanceRegulation/FederalStateFoodPrograms/UCM505093.pdf> [↑](#footnote-ref-12)
12. <http://www.seafish.org/media/Publications/FactsheetParalyticShellfishPoisoning_201110.pdf> [↑](#footnote-ref-13)
13. [↑](#footnote-ref-14)
14. See section 7 this report [↑](#footnote-ref-15)
15. See section 6 this report [↑](#footnote-ref-16)