Food Standards Scotland

For safe food and healthy eating

Managing Shellfish Toxin Risks in the Scallop Sector

Guidance for enforcement officers, shellfish harvesters and shellfish businesses

April 2021

foodstandards.gov.scot

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1. Summary

Intended audience

- Establishments handling and/or processing scallops including establishments approved for this activity
- Local Authorities (LA)
- Scallop fishermen/divers
- Caterers, retailers and distributers

Purpose

This document provides information intended to assist enforcement officers and Food Business Operators (FBOs) in the scallop sector in order to ensure compliance with toxin standards set out in Regulation (EC) 853/2004. This guidance replaces the official controls for wild pectinidae guidance issued by Food Standards Agency in Scotland in 2004.

Key points

- Anyone selling scallops must ensure that they are safe. This means that they must conform to all health standards set down in law, including health standards for toxins.
- Fishermen must not fish scallops from an area that any competent authority has closed.
- Registration documents are required for all batches of scallops that are intended for any approved establishment.
- Unless operating under the local market exemption, scallops can only be placed on the market via an approved dispatch centre.
- Caterers receiving king scallops sold directly to them by local fishermen (i.e. rather than from an approved dispatch centre) must ensure that the scallops are correctly shucked
- Fishermen and caterers supplying and receiving scallops through the local market exemption should inform their respective local authorities.
- Any FBO that either does not undertake appropriate levels of shucking (other than a primary producer) and/or fails to test their product before placing it on the market will be subject to enforcement action.

Legal status

This document provides guidance on managing toxin risks in the scallop sector as required by food law, and specifically Regulations (EC) No 852/2004 and 853/2004 .

The European Union (Withdrawal) Act 2018 provides that, from 1 January 2021, certain directly applicable legislation of the EU, including food feed and law, will be converted into UK law.

From 1 January 2021, any references to EU Regulations should be read as meaning retained EU law which can be accessed via the EU Exit Web Archive. Retained EU law should be read alongside any EU Exit legislation which was made to ensure that retained EU law operates correctly and is published on legislation.gov.uk

In publishing new and amended guided after the transition period, FSS will aim to ensure that cross-references are updated to accurately reflect the law which is then in force

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 legal requirement for offshore monitoring of scallop fishing areas by Food Standards Scotland (FSS). 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. FBOs selling whole scallops, appropriate end product testing (EPT) **must** be in place as an integral part of their Food Safety Management System (FSMS). Retained EU regulations require that FBOs ensure food safety "as proved by a system of own checks" [1].
   All businesses, other than those to which specific exemptions apply (see

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

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).

Intended audience

4. This guidance is intended for scallop harvesters, retailers and caterers handling and processing scallops as well as approved scallop establishments and their enforcement authorities.

Purpose of guidance

5. This guidance document is intended to help FBO 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 LAs will utilise this guidance in order to assess compliance in FBOs handling or processing scallops. Where FBOs 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. FSS will audit LAs against the appropriate regulations and guidance.

Legal status of guidance

6. 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). Article 5 (Hazard Analysis and Critical Control Points) of 852/2004 and Annex III Section VII, Chapter V (Health Standards for LBMs) of 853/2004.

7. This guidance is not intended to cover every situation and you may need to consider the relevant legislation itself to see how it applies in your circumstances.

8. FBOs with specific queries may wish to seek the advice of their LA. Contact details for LAs can be found at www.foodstandards.gov.scot/contact-us/local-authorities . Contacts details in FSS are provided in the final page of this guidance.

2. General obligations on scallop harvesters and businesses

Introduction

9. 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 will be subject to recall which can be costly for business and 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.

10. All FBOs are required to register with their LA prior to trading. This will enable a LA to make a determination as to whether or not that business requires to be approved and only businesses with a HACCP-based FSMS will be approved in line with the Approved Establishments National Protocol. Any business (including primary producers) that the LA considers to require approval but operates without the approval being granted may be subject to enforcement action.

11. In relation to shellfish toxins, the maximum permitted levels are set out in Regulation (EC) 853/2004 - see Fig 1. Compliance with these limits therefore applies to all batches of the product sold and whilst it is up to FBOs to define what constitutes a batch, a working definition of 'batch' is proposed – see Fig 2.

Fig 1. Shellfish toxins – Maximum permitted levels

- Amnesic shellfish poisoning (ASP) toxins - 20 milligrams of domoic acid per kilogram flesh

  - 160 micrograms okadiac acid (OA) / dinophysis toxins (DTX) / palitoxin (PTX) per kilogram flesh

  - 160 micrograms azaspiracids (AZA) per kilogram flesh

  - 3.75 milligrams yessotoxins (YTX) equivalent per kilogram flesh

- Paralytic shellfish poisoning (PSP) toxins - 800 micrograms per kilogram flesh.

12. Whilst the ASP toxins, (domoic acid and its isomers), have historically been more prevalent in Scottish king scallops, the animals are filter feeders and can accumulate other biotoxins, such as lipophilic toxins and PSP toxins.

Definition of a 'batch'

13. Bivalves are animals which can migrate, be at different stages in their life cycle and therefore may also accumulate toxins at different rates. Therefore FBOs should take reasonable steps in accordance with their own risk assessment to determine what constitutes a batch of scallops and what should form a representative sample of that batch.

Fig 2: The term '**batch'** is defined in 2073/2005 (micro criteria regulations), Article 2

(e) and means: "..*a group or set of identifiable products obtained from a given process under practically identical circumstances and produced in a given place within one defined production period*."

It is the responsibility of the FBO to ensure that their determination as to what a batch is in relation to their own product is backed up by evidence. For practical purposes, and in the absence of any other risk assessment which may have been undertaken by the FBO, it would seem reasonable for whole scallops with the same harvest date from the same harvest area were considered "a batch"[2]. In determining a batch, an "area" should be considered to be no bigger than an offshore box as outlined in Annex D, unless specific information is provided as to why any alternatives should be considered suitable

Practical considerations such as days at sea on single fishing trips may also be taken into account.

Shucking

14. Irrespective of whether scallops come from an approved or non-approved producer, scientific studies indicate that adequate shucking and a washing procedure, will

[2] In many other countries a 'batch' is defined as a consignment from the same area with the same harvest date.

Australia New Zealand Food Standards Code - Standard 4.2.1 - Primary Production and Processing Standard for Seafood (Australia Only)

http://www.fda.gov/downloads/Food/GuidanceRegulation/FederalStateFoodPrograms/UCM505093.pdf
http://www.seafish.org/media/Publications/FactsheetParalyticShellfishPoisoning_201110.pdf

significantly reduce the risk of shellfish toxins in scallops.

15. The term ‘shucking’ in this document therefore includes reference to the wash 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 always be washed in running water and not be left in static water baths where cross contamination can occur.

16. Seafish, the authority on the seafood industry, has provided more detailed advice on effective shucking practice here.

The key stages of effective shucking practice are:

- **Remove all traces of the gut loop**
- **rigorous washing for 10 minutes**

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

End product testing (EPT)

18. Approved FBOs are required to undertake EPT to validate and verify the effectiveness of their shucking procedure in minimising the levels of biotoxins in shucked scallop meat placed on the market. The frequency of EPT should be determined as part of the FBO’s FSMS. For example, increased levels of testing would be appropriate during periods when it is known that biotoxin levels were likely to be elevated, or where there were concerns around cross contamination risks during processing. In circumstances where there was evidence that continuously high standards of shucking were being maintained, FBOs would have the ability to reduce testing frequency to levels which were sufficient to allow background monitoring. FSS has produced the following information for harvesters and processors on the types of end product test kits 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 FSMS for shellfish toxins.

19. Where whole scallops are placed on the market – EPT is an essential tool and should be applied on a batch by batch basis.

3. Controls applicable to scallop establishments and harvesters supplying establishments

FBO obligations, official controls and action in the event of a failed sample or inadequate FSMS (whole or shucked product).

20. In Scotland, scallop controls are applied in accordance with Chapter IX, Section VII, Annex III of 853/2004. These regulations require that, for scallops harvested outwith classified areas, FBOs must not place those products on the market unless they are harvested and handled appropriately and are compliant with health standards laid down in Chapter V Section VII annex III "as proved by a system of own checks".

21. A link to Regulation (EC) 853/2004 can be found here but clearly, unless a system of FBO own checks is demonstrated, scallops cannot be sold. EPT must therefore be considered to be a significant feature of any FSMS for scallops.

22. In relation to LBM biotoxins, these systems, **must** ensure that the product complies with the maximum permitted legal levels as set out in Regulation (EC) 853/2004.

23. LAs are the enforcement authorities for approving shellfish processors and dispatch centres. In general terms LAs should follow the guidance on inspection and sampling detailed within the Food Law Code of Practice (Scotland) and the Food Law Practice Guidance (Scotland)[3].

24. Only establishments with an effective HACCP-based FSMS should be approved for the dispatch or processing of scallops (as for other commodities). If the HACCP-based procedures in any FSMS are 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 (RAN) or potentially suspension or withdrawal of approval as per Food Standards Scotland's Approved Establishments Scottish National Protocol[4].

25. If either a FSMS is inadequate or an official control verification sample fails to meet regulatory toxin standards then the food may be certified as not having been produced in accordance with the Hygiene regulations under Regulation 27 of the Food Hygiene (Scotland) Regulations 2006. Steps to remove the affected batch from the market, where evidence suggests it has not been processed in accordance with food safety

[3] Food Law Code of Practice (Scotland) and Food Law Practice Guidance (Scotland).
[4] FSS Approved Establishments Scottish National Protocol

requirements may be considered. In such cases LA's should seek advice from the FSS Scottish Food Crime and Incidents Unit at incidents@fss.scot

26. Article 19 of Regulation (EC) 178/2002 requires all FBOs to withdraw from the market any products that do not comply with food safety requirements. In determining which products would be affected by such an action, FBOs are required to ensure that all batches of affected products are identified accordingly.

27. 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 FBOs in order to withdraw non-compliant product.

28. 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**.

29. Since specific frequencies of sampling have not been prescribed 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 Food Law Code of Practice.

30. FSS currently funds scallop toxin verification analysis and advises LA to follow the guidance at **Annex C** in relation to taking samples at approved establishments.

Communication and Notification Arrangements for Official Control Results

31. All official control (OC) 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.

32. Every Tuesday the FSS will report all OC biotoxin sample results. The summary report will be provided to all interested parties and published on the website.

33. FSS notifies all results over the Maximum Permitted Level to industry representatives, with LAs responsible for following up sample failures with their individual businesses.

34. **Annex D** outlines the offshore box system which has been used by FSS to identify the areas in which shellfish have 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.

35. 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 are, for example, routinely monitored and the French authorities will close areas and prohibit harvesting in their scallop beds. It is up to FBOs 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 (for example) provide regular updates via their website as to scallop area closures (**Annex E**).

36. Any scallops caught from an area that any competent authority has closed should be seized by the competent authority on arrival at port and dealt with according to section 9 of the Food Safety Act 1990.

37. Harvesters who intend to supply their scallops to countries outside the UK must ensure that their product meets both UK and the country of destination statutory requirements prior to sale. This includes communication of all relevant information relating to toxin risks and information on any 'FBO own checks' which may or may not have been carried out. Further details are included in **Annex E**.

Primary production: roles, responsibilities and registration documents

38. 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"[5].

39. 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 as follows:

[5] EC Regulation 853/2004 Annex III, Section VII, Ch I, 3.

REGISTRATION DOCUMENTS – requirements for all live bivalve molluscs

(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; and

(vi) the destination of the batch.

From Regulation (EC) 853/2004 Annex III, Section VII, Ch. I Paragraphs 4 and 5.

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).

40. As offshore harvesting areas are not classified in the UK, an attestation (based on official control sampling) by the harvester on the 'health status of the production area' in relation to biotoxin levels will not normally be possible. Nevertheless, this section of the registration document should be used to provide **any available** information which could be indicative of the potential risks associated with the batch of scallops which are accompanied by the document. This information will help to ensure the scallops are handled appropriately by the recipient, and that the necessary controls are put in place to ensure biotoxin risks are controlled before they are placed on the market. This information should include, but not be restricted to the following:

- confirmation that fishing has not taken place in an area which has been subject to restrictions
- indication of the potential for biotoxin risk at the point of harvesting, particularly in light of historical evidence that scallops harvested can become contaminated with high levels of biotoxins during the summer months
- confirmation as to whether or not the batch of scallops, or other shellfish harvested from the area have been subjected to testing, and if so, the levels that were detected.

41. LAs 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 <u>not</u> <u>accompanied</u> by a registration document (or has not been appropriately labelled with an approval number) can be regarded as not complying with food law and therefore may be subject to seizure and detention by the relevant Competent Authority.**

42. The Food Law Practice Guidance advises that LAs 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[6].

43. Local Authorities responsible for establishments which receive batches of LBMs from outside their 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 12 months, including details of the harvesters to whom they have been issued and the production areas which the harvester requires the registration documents for.

FBOs 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)[7].

[6] Regional Inshore Fishery Groups

[7] 853/2004, Section VII, Ch I .6

4. Controls regarding the direct supply of small quantities of primary products to the consumer[8]

44. In food hygiene legislation there is an exemption from compliance with the detailed specified provisions of the law for FBOs 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, Regulation (EC) 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'

45. 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 that will ensure compliance prior to sale to the final consumer. These other measures are outlined below.

46. The suggested scope of the exemptions from the requirements for approval under Regulation (EC) 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'

47. The Food Law Code of Practice, Practice Guidance for Scotland (FLCoP PG) outlines the details of the local market exemption and the expected parameters in which it operates. Given that the risks

[8] Article 1(3)(c) of EC Regulation 853/2004

associated with both king and queen scallops can be managed in similar ways, it is proposed that the limit for king scallops should match that for queen scallops (i.e. 10 tonnes per annum).

48. 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 tonnes
Oysters	5 tonnes
King Scallops	10 tonnes
Queen Scallops	10 tonnes
Mussels	20 tonnes
Other Live Bivalve Molluscs	10 tonnes
Marine Gastropods	20 tonnes

Please note these quantities only apply to licensed fishing vessels.

49. The Shellfish (Restrictions on Taking by Unlicensed Fishing Boats) (Scotland) Order 2017 , effective from 17 April 2017, restrict the numbers of certain shellfish species, including scallops, that can be taken by unlicensed fishing boats on a daily basis.

50. Unlicensed fishermen who intend to catch a small number of shellfish for their own consumption are not permitted to sell anything they catch for

profit and must comply with the set daily restrictions.

51. For further information please refer to Marine Scotland at Marine Scotland Information

Definition of 'local'

52. It is proposed that for scallops the definition of 'local' be considered to include the whole of Scotland.

For primary producers of scallops, the definition of 'local' is the whole of Scotland.

Definition of 'direct supply'

"Direct supply" includes the direct sale or provision of scallops by the harvester/fisherman to the final consumer. This would also 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

53. FBOs must be able to demonstrate that the food they have placed on the market to the final consumer is safe. Harvesters are only able to supply the primary product (i.e. the whole, live scallop), and these should not contain unsafe levels of biotoxins.

54. Given that a critical control for mitigating the risks toxins in king scallops exists – and has shown to be effective (in particular ASP) - small quantities of whole live king scallops may be sold direct by harvesters/fishermen under the following circumstances – see Fig 3:

Fig 3 - King scallop local market exemption conditions:

Small quantities of whole live king scallops may be sold direct by primary producers (harvesters/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 FSMS in place prior to sale. Primary producers selling whole king scallops should also notify their own LA of their intention to sell whole live product to such catering buyers.

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

c) Caterers should also notify their LA of their intention to process whole king scallops sourced directly from primary producers. Caterers should have an effective HACCP-based FSMS reflecting the risks associated with this product and should maintain traceability of all their suppliers in accordance with Regulation (EC) 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-based FSMS is effective at managing toxin risk, to the satisfaction of the local authority.

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

55. This system means that active documentary contact should be made between harvester and caterer prior to sale, and between harvesters/caterers and their respective LAs. Regular communication between the LAs for the harvester and the caterer entering into such arrangements is also critical to ensure official controls can be appropriately targeted and any issues dealt with as soon as possible. A model letter which a primary producer can send to prospective

customers, copying their LA lead food officer is available at **Annex F.**

56. Suggested instructions for use and labelling are provided at **Annex G**

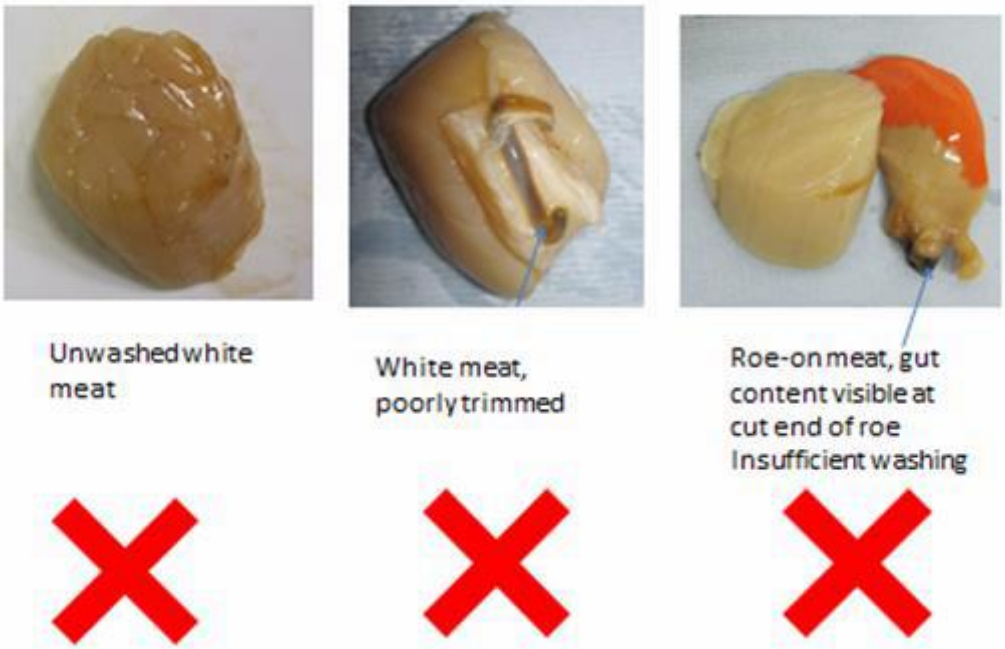
57. It should be noted that, in order to ensure public health is protected, shucking must take place in a controlled environment, which in this model should be confirmed by the primary producer prior to sale. Therefore, in all situations where it is not possible to confirm that shucking will be undertaken under an effective FSMS in a registered food establishment then all batches of whole king scallops (and all other bivalve shellfish placed on the market under exemption), **must** conform to the toxin standards set out in law. This means that each batch should be tested for toxins prior to sale.

58. 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. Therefore the exemption conditions summarised in Fig. 3 do not apply to the sale of queen scallops.

59. It is expected that local authorities should be able to cross reference lists of producers and receivers of scallops handled under these arrangements.

Annex A: Examples of prepared scallops following good/bad shucking

King scallop: visual assessment of shucking quality



King scallop: visual assessment of shucking quality

CHECK	TICK
The white meat is clean, there is no trace of gut or the black sac remaining. There is no brown tissue attached to either organ	☐
The roe is clean, particularly at the cut end.	☐
The edible parts have been washed, they are free from shell, debris, staining, gut fragments.	☐

Annex B: Frequency of official control sampling in relation to pectinidae 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 5(4) of Regulation (EU) 2017/625.

Businesses should not be approved unless an effective HACCP-based FSMS 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.

EPT plays an important role in the FSMS of scallop processors, whether they are placing whole or shucked scallops on the market. EPT is necessary to either demonstrate that biotoxin levels in whole scallops are within safe limits, or, to validate the ability of their shucking process to reduce biotoxins to acceptable levels and verify the on-going effectiveness of this process.

- Evaluation of the shucking 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 Control 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. An FBO 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 LA, 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 EPT 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 FBOs 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 (OC) 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.

	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 representative 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.	Shucking standards visibly deficient by the Authorised Officer. No need for samples to be taken in this instance.	Formal enforcement action. Consider suspension or withdrawal of approval unless immediate remedial action 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.
3	**Whole**	EPT every batch or in accordance with robust risk assessment.	Formally written accurate and current HACCP plan. 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.

4	**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.	Consider serving a RAN. Seizure and detention, Product recall.	Evidence that LA enforcement policy, COP requirements and relevant guidance, including this guidance, has

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.

Cefas are contracted by FSS to provide logistical support for pectinidae sampling in Scotland. Please ensure that the sampling protocols are followed[9].

- 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.

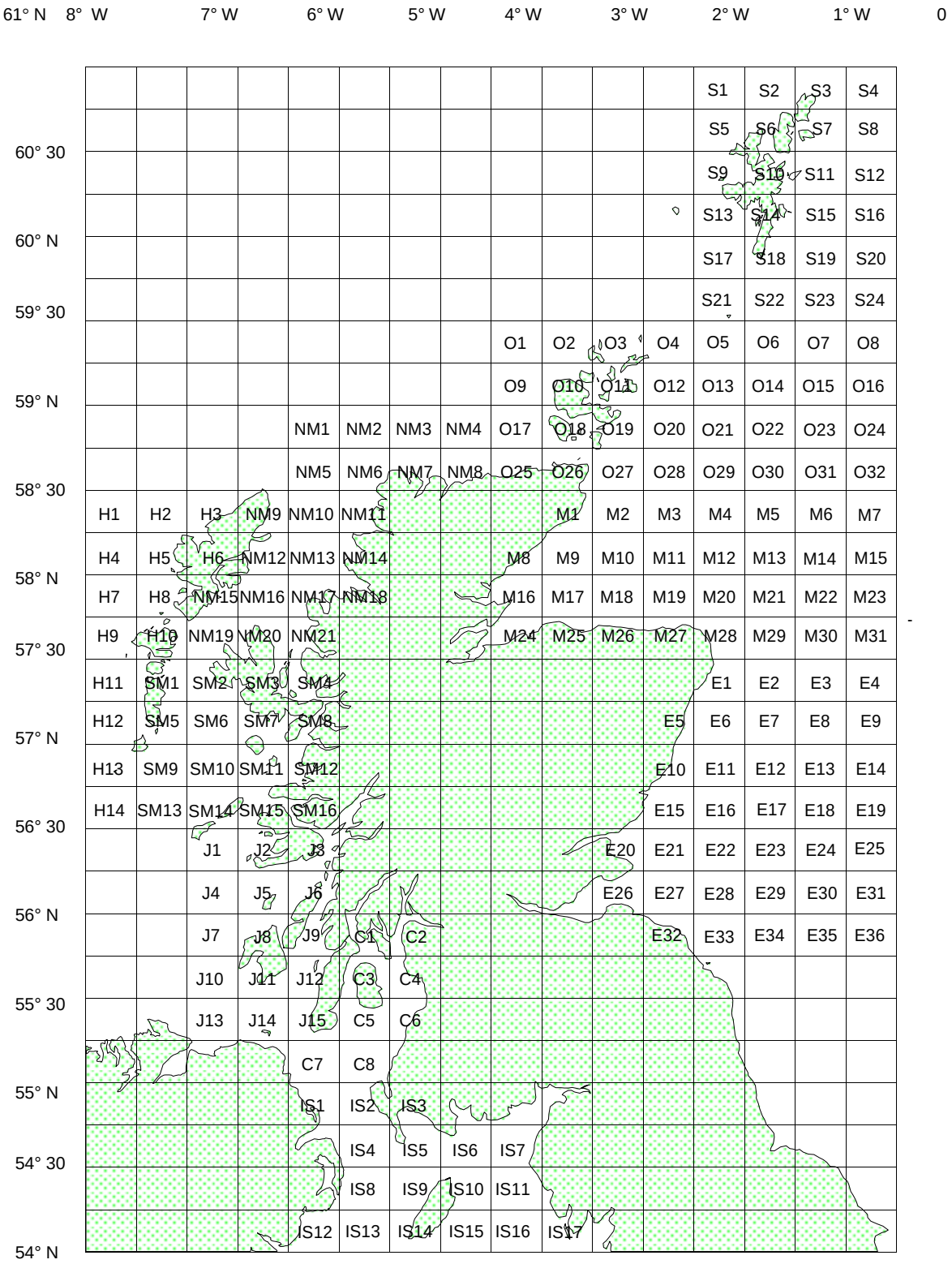
- A sample submission form must also be completed for every processor and the submission form placed in the document wallet in the box being sent to Cefas Weymouth.

- 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)**

[9] CEFAS - The Shellfish Partnership - Sampling Protocols and Forms

- Any queries or problems should be referred to: Contact - Cefas (Centre for Environment, Fisheries and Aquaculture Science)

Annex D: Offshore map showing area ‘boxes’



Annex E: Controls applicable to 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 FBOs to make sure that they are aware of any fishing/harvesting restrictions that apply in any sea area where they intend to operate.

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-

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.

EU exports

As of 1st January 2021 the UK became Third Country for the purposes of trading and exporting to the EU. FBOs that make the commercial decision to export their scallops to the EU must ensure that their product meets both UK and the country of destination statutory requirements prior to sale. This includes communication of all relevant information relating to toxin risks and information on 'FBO own checks'. It is therefore imperative that FBOs follow this guidance if exporting to the EU and that the LA uses the guidance as the basis for provision of attestations and Export Health certification.

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 an 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 document 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 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 F: 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

IMPORTANT FOOD SAFETY

NOTICE: SUPPLY OF WHOLE KING SCALLOPS

Dear Chef / Manager, DATE

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 and 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 the 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
- Training Aid '**Preparation of king scallops and visual checks of**

shucking quality' available at ANNEX A of Food Standards Scotland Managing Shellfish Toxin Risks in the Scallop Sector document

- SeaFish DVD (3.5 min long), '**Scallop Preparation'** published Jan 5th 2013 and available on YouTube[10]
- SeaFish 'Scallop handling and shucking practices' 2nd Edition Seafish Industry authority 2006[11]

[10] YouTube - Scallop Preparation
[11] SeaFish - Scallop handling and shucking practices

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 G 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 in food preparation.

Food Standards Scotland

For safe food and healthy eating

Contact details

Food Standards Scotland
Pilgrim House,
Old Ford Road,
Aberdeen,
AB11 5RL.

T: 01224 285100

E. Enquiries@fss.scot

www.foodstandards.gov.scot