

FSS SUMMARY OF SUBSTANTIVE COMMENTS TO THE SHELLFISH REVIEW CONSULTATION ON THE DRAFT GUIDANCE ON SHELLFISH TOXIN CONTROLS FOR THE SCALLOP SECTOR

Question	Respondent	Comment	Response
1. Food Business Operators Obligations - Do you agree that the section on FBO obligations, official controls and action in the event of a failed sample or inadequate HACCP are clearly explained?	Keltic Seafare (Scotland) Ltd / Scottish Scallop Divers assc.	These steps are adequately explained in a clear manner.	Noted, thank you.
	Sea Fish Industry Authority	From the industry point of view, a more concise summary of the key points might be most useful (a quick reference guide(s)?).	The document has been redrafted to take into account these issues.
	Individual	It is quite difficult to find your way through these documents. Perhaps that is the intention, so I find it impossible to answer this unanticipated question.	The document has been redrafted to take into account these issues.
	Association of Scottish Shellfish Growers	<p>The definition of “local” is noted to cover the whole of Scotland. This logically means that the producer may have great difficulty in coming to a view whether the prospective catering buyers have an “effective food safety management system in place prior to sale”?</p> <p>“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”</p> <p>This seems to be a very weak chain of custody and it is unclear who the legal responsibility for compliance with this</p>	<p>The proposed guidance tries to provide additional clarity on the direct sale of small quantities of whole king scallops to the local market. Caterers are already required to put in place robust food safety management systems which includes HACCP – so there is a clear legal obligation for caterers to understand and mitigate the risks associated with all products used in food preparation. Primary producers working under the hygiene exemptions are covered by the general requirement that food sold must be safe. We are proposing</p>

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		<p>provision rests with – the caterer, the primary producer or the primary producer having to go to the caterers local EHO to seek such an assurance?</p>	<p>that a due diligence approach by all parties should be clearly articulated. The definition of 'local' under the hygiene exemptions is provided for in guidance only - but we consider that an all Scotland approach would simplify enforcement in this sector. Consideration will be given to introducing statute should any concerns be raised regarding application of the guidance in Scotland.</p>
	The Government Chemist	<p>The FSS guidance contains a hyperlinked document which is a very useful summary of the methods available for end product testing of shellfish for toxins. The majority of methods quoted are only suitable to be deployed by laboratories, and this should be reflected in the FBO HACCP plan. Moreover I suggest the guidance should advise that the laboratories be ISO/IEC 17025 accredited for the required methods. Without wishing unduly to lengthen the main document, it may be useful to repeat therein that of the methods described in the hyperlink only the lateral flow devices can easily be deployed in the 'field' and that ELISAs are probably</p>	<p>Thank you for these comments. We recognise that tests that are available commercially vary both in terms of complexity and cost. We have not changed the guidance in this regard, and continue to advise that the use of appropriate tests for toxins of concern must be considered acceptable to the competent authority under business specific food safety management plans.</p>

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		confined to highly skilled industry members, and no ELISAs or lateral flow devices are available for yessotoxins and azaspiracids.	
	Scottish Fisherman's Association	The controls outlined in this section seem clear and define the responsibilities of the whole supply chain	Noted, thank you.
	The Ethical Shellfish Company	Yes	Noted, thank you.
2. Small Quantities - Do you agree with the model framework for direct sales under the national market exemption? Please provide any information on possible impacts (positive and negative) as to how this proposal may affect you.	Keltic Seafare (Scotland) Ltd / Scottish Scallop Divers assc	I do not agree with the concept of "small amounts locally" What purpose does this derogation serve? the quantity allowed is immaterial, be it 10kg or 100'000kg? it makes little difference. It introduces "grey areas" into legislation which is intended to protect the health of consumers and simply provides wriggle room for small scale operators who will not be complying with any of the relevant legislation be that Marine or Health and Safety. If we are to be allowing for these local sales then surely if this is seen as a safe and legitimate system then it should be applied to all direct sales to end users? I do not see the distinction between locally and UK wide so long as the same rules are applied.	Noted. Current EU law already provides for direct sales to the local market – and there are already definitions for both outlined the Food Law Code of Practice . The revised guidance document proposes changes to these parameters and has also included reference to further restrictions as set out in The Shellfish (Restrictions on Taking by Unlicensed Fishing Boats) (Scotland) Order 2017 which restricts the numbers of certain shellfish species, including scallops, that can be taken by unlicensed fishing boats on a daily basis. With regards wider UK sales, FSS can only advise on conditions applicable to Scottish businesses . However this

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			consultation and issues arising have been shared with Food Standards Agency.
	Sea Fish Industry Authority	<p>The definition of all markets within Scotland as 'local' is welcomed, although it only partly assists the industry in maintaining its financial viability. Access to the most lucrative and rewarding markets of London and the SE of England remains problematic for premium whole, live scallops. Should FSA follow this lead (i.e. define England as 'local'), it may significantly disadvantage Scottish producers in these markets as producers from SW England would have a marked marketing advantage.</p>	<p>Noted. As you will be aware FSS can only advise on conditions applicable to Scottish businesses in this area. However this consultation and issues arising have been shared with Food Standards Agency.</p>
	Individual	<p>Increasing the limit of small quantities of king scallops to 10 tonnes will have a positive effect.</p> <p>Definition of 'local' extending to include the whole of Scotland will have a positive effect on me.</p> <p>Regarding the conditions For Sale to Local Caterers: These are in general terms supported however the proposal that caterers should notify their local authority is</p>	<p>Noted, thank you. Whilst we consider the guidance on this matter reasonable, we will consider feedback as to how this provision works in practice. Ultimately enforcement of legal requirements in this sector falls to local authorities.</p>

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		<p>would have a negative impact. Suggest that all current customers are listed together on the producers' website, where the local authority can view it any time. Traceability can also be shown through invoicing.</p> <p>On the proposal to ensure that active documentary contact should be made between harvester/caterer/respective local authorities: sending letters would have a negative effect. I discuss shucking procedures with prospective customers and will inform them that I will be adding them to the customer list on my website where they may be viewed by the local authority. I will add links to shucking advise including the FSS Training Aid and the Seafish DVD. I believe the suggested letter would be onerous to customers and local authorities and that the 'Food Safety Warning' would be permanently on view.</p>	
	Individual	<p>It is quite difficult to find your way through the maze of documents and responses and consultations.</p>	<p>The document has been redrafted in a way which we hope provides clarity for this sector.</p>
	Association of Scottish Shellfish Growers	<p>This means that each batch should be tested for toxins prior to sale.</p> <p>It is considered that in order to maintain food safety in relation to potential biotoxin</p>	<p>Food placed on the market must be safe. We therefore agree that businesses, including primary producers, must ensure that they do not offer for sale to the final</p>

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		contamination small scale and local require to be redefined. The proposal to allow 10 tonnes of King scallop to be sold by a primary producer within Scotland without a reasonable biotoxin HACCP in place could potentially result in a serious food safety incident.	consumer any product that might be unsafe – testing is one way that product safety can be demonstrated particularly in relation to whole scallops.
	Scottish Fisherman's Association	The SFF agrees with the framework with the caveat that all sales of whole scallops should be subjected to the same rigorous testing in order to assure consumers of food safety. Raising the limit to 10T is not necessarily a risk worth taking with the testing regime.	The proposal regarding small quantity direct exempt sales is intended to tighten up existing practice in the non approved sector. This will be subject to review.
	The Ethical Shellfish Company	While in principle we are supportive of this measure, we have the following comments: <ol style="list-style-type: none"> 1. The proposal of this system illustrates that it is understood that there is no significant risk associated with the sale of live king scallops where sufficient measures and controls are in place to ensure that the caterer is aware of the need for correct shucking. 2. If this system is seen as safe and legitimate, why can't it be rolled out to the 	Thank you for your response. <p>Taking each point in turn:</p> <ol style="list-style-type: none"> 1. FSS recognises that a HACCP regime should mitigate the risks associated with shellfish toxins. 2. The proposal provides guidance covering sales considered exempt from more detailed hygiene requirements by the primary producer as permitted in law. Any wholesaling activities of products of animal origin

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		<p>whole of the UK?</p> <p>3. Why must it only apply to direct sales to the end user? The same measures could easily be put in place when sold through a 3rd party (e.g. wholesaler)</p> <p>4. The limit of 10 tonnes annually is not realistic and not sufficient to support a business of any size or ambition.</p>	<p>including scallops are subject to legal approval requirements. A wholesaler receiving whole scallops would require to be approved as a dispatch centre, and an ID mark applied indicating compliance with the health standards set out in law.</p> <p>3/4. The exemption is intended to apply to sales by the producer of small quantities of product direct to the local retailers, in line with the general flexibility accorded in law. As outlined above any wholesaling draws down a de facto requirement to be approved in law, as does sales that go beyond what is deemed to be 'small quantity'.</p>
	The Highland Council	<p>No objection to increase as proposed. If there is no science / public health basis for the proposed limit, consideration should be given to increasing beyond 10T, but not to exceed the 25T combined total amount listed.</p> <p>The amended definition of 'local' is welcome as provides a greater consistency for industry. Existing definition does not appear to have any science basis.</p>	<p>Thank you for these comments.</p> <p>We consider the proposed limit for king scallops a reasonable increase at this point. This will be kept under review.</p> <p>Noted. The definition of "local" is intended to take into account practical enforcement considerations.</p>

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		<p>The amended definition of 'direct supply' is welcome as being more reasonable.</p> <p>The proposed obligations placed on the primary producer appear to be at odds with other primary production sectors. It is considered entirely appropriate that instructions for use be provided by the primary producer, but 1.8a (<i>primary producers should seek assurance from caterers</i>) appears to require more than this. Is placing an obligation on the primary producer such as this enforceable? Is it not only the receiving FBO's legal obligation to ensure they have a valid HACCP?</p> <p>Welcome is the fact that the proposal will allow the LAs to keep a database of which FBOs receive scallops via this route, but question whether the reporting requirements can be enforced.</p> <p>It is suggested that a definitive statement be included, to avoid any misinterpretation, that if 1.8a-e (in whatever form it ultimately takes) is met there is no requirement for EPT. If this is correct, it would appear to be at odds with the main section of the guidance.</p>	<p>We consider it important that all parties are sighted as appropriate on activities which may have a bearing on controls applied elsewhere. The guidance is intended to provide some practical solutions to food safety management in this sector and will be kept under review.</p> <p>We have revised the guidance with a view to providing greater clarity both on the requirements set out in law, and the practical approach suggested for direct sales. It will be kept under review and we would welcome feedback from all parties.</p>

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		1.11 is not clear - the guidance should confirm the legal position - can a primary producer legally sell whole king scallops to any final consumer (individual, caterer, etc) as long as they provide appropriate instructions for use?	
3. Frequency of Official Controls - What would improve the proposed guidance on an enforcement approach outlined in the document (Annex B)?	Keltic Seafare (Scotland) Ltd / Scottish Scallop Divers assc	<p>This is a matter for FSS to decide upon themselves and I have no relevant input to add other than to say that this is yet another pointless exercise in applying an inherently unsafe system which is based on incorrect and now outdated assumptions surrounding the batch testing regime.</p> <p>We could test every animal and get a vastly different result from each one! In my opinion the current system is dangerously flawed and FSS/FSA are failing miserably in their obligation to protect consumers and fostering massive costs on Industry in the process.</p>	<p>Inter-animal variability is an issue across the live bivalve sector and batch testing should try to take into account the potential for variability within the batch in so far as it is practicable to do so. However for volume sales of whole live bivalves (including, but not exclusively scallops), we consider batch testing to be one element within a food safety management system that can help provide the necessary due diligence for operators as required by law. The alternative to batch testing, for scallops, is a meat only processing approach, unless operating under the exemption in law. The enforcement approach outlined in the guidance does not add to the testing obligations required by each party, rather it attempts to articulate a risk based approach more clearly.</p>

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	Sea Fish Industry Authority	The guidance is adequate for LA EHOs, but industry would benefit from a clearer, bulleted list of what it should do to ensure and demonstrate compliance.	The guidance has been revised to try and set out the requirements more clearly.
	Individual	As far as I am aware there has never been a health issue such as food poisoning associated with Pectin Maximus, therefore it is not clear why there should be any controls at all, except in the creation of more jobs for bureaucrats.	Toxin related illness associated with the consumption of bivalves both in the UK and worldwide are well known. Non-compliance with health standards for bivalves - which are also agreed at an international level could lead not only to illness – but to reputational damage for the Scottish shellfish industry.
	The Government Chemist	<p>Regarding the application of Regulation 27 of The Food Hygiene (Scotland) Regulations 2006. Guidance states that 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.</p> <p>Both EC regulation 178/2002 and EC regulation 853/2004 require the entire <i>batch</i> to be condemned in the event of a non-compliant sample result and whilst a lot of guidance exists on the need to traceability systems to exist in terms of</p>	<p>Thank you for your comments. Taking each in turn:</p> <p>We hope that the revision to the document provides greater clarity regarding obligations in relation to batches.</p> <p>Consistency across guidance documents is important and the point is noted.</p>

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		<p>'products', I wonder whether the guidance would benefit from a statement indicating that the FBO needs to make the link between <i>product</i> and <i>batch</i>.</p> <p>It is very helpful that Annex B of the FSS guidance suggests minimum sampling frequencies for <i>official control sampling</i>. The sample collection protocol provided in Annex C gives good detailed guidance on how official control samples should be gathered which will help the consistency of sampling, for example, I am pleased to see that it is clearly stated that one sample should be comprised of 200g of meat and minimum numbers of suitable commercial size animals required to achieve this weight are given. I note that these minimum numbers of suitable commercial size animals are the same as those given in the CEFAS 'Algal Toxin Monitoring and Surveillance Programme Wild Pectinidae Sample Collection Protocol' but differ from those given in CEFAS 'Sample Submission Form: Wild Pectinidae Biotoxin Monitoring'</p> <p>In addition, no provision has been made for sample collection in accordance with regulation 7 of the Food Safety (Sampling and Qualifications) (Scotland) Regulations</p>	<p>As you note, the guidance does not cover samples taken in accordance with the Food Safety (Sampling and Qualifications) (Scotland) Regulations. We consider that this is adequately covered in other guidance for local authorities.</p>

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		2013 and the Code (Section 38.6) which stipulates that the sample should be divided into three parts. A case, of course, could be made for the taking of a single sample on the basis that wild pectinidae falls under section 6.1.7.4 of the Food Law Practice Guidance (Scotland) "Samples which Present Difficulties in Dividing into Parts" if this is what FSS intends.	
	The Ethical Shellfish Company	There is an undue focus on monitoring batch testing systems by scallop producers, when it is an inherently unsafe system. Research has shown that toxin levels can vary dramatically between individual scallops tested within one batch. The only way to ensure safety for the consumer is to focus on safe shucking by food establishments, which is easily monitored by the network of EHOs throughout the UK.	Inter-animal variability is an issue across the live bivalve sector and batch testing should try to take into account the potential for variability within the batch in so far as it is practicable to do so. However for volume sales of whole live bivalves (including, but not exclusively scallops), we consider batch testing to be one element within a food safety management system that can help provide the necessary due diligence for operators as required by law. The alternative to batch testing, for scallops, is a meat only processing approach, unless operating under the exemption guidance.
4. "Batch" Definition - Do you agree with the proposed	Keltic Seafare (Scotland) Ltd / Scottish Scallop	It is pointless to try to define a "batch" of Scallops for testing purposes. It has been	We agree that for scallops shucking is a critical control and

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working definition of a batch ? Please explain the rationale behind your answer.	Divers assc	<p>scientifically proven that all Scallops living on a small area of seabed will have widely variable tissue toxin contents. We do not seem to understand the reasons for this, maybe it is genetic and some animals are simply predisposed to accumulate toxins? Scallops are a mobile species and do not adhere to boundaries and any attempt to define "areas" is futile. For these reasons "batch testing" to protect consumer health is a costly and frankly pointless exercise in futility. The only way to protect consumers is to ensure correct shucking techniques are applied at the end user. It must be said that Scallop businesses such as ours are not selling a food product, we are selling a live animal which only becomes a food product once the end user applies steps to make it such. During these steps simple controls can be used to ensure food safety in relation to Toxins. Food businesses prepare and handle many foods which can be hazardous to Human health should proper procedures not be applied so why should Scallops be any different? This hysteria over toxins in Scallops and the overly restrictive regulations that have sprung up in response to this issue have placed massive costs both on industry and regulators.</p>	<p>that is why we have set out explicit guidance for the exempt trade in order to manage this risk. However as stated earlier, for whole live bivalve sales, risk based batch testing is an important component of a food safety management system. Inter animal variability is an issue for all live animal sales (including mussels, oysters etc) and that is why sampling should try to take into account the potential for variability within the batch in so far as it is practicable to do so.</p> <p>Unlike microbiological risks associated with meat, shellfish toxins are heat stable and shucking to an industry standard is a processing step that cannot reasonably be expected of final consumers . In addition, the law requires that live bivalve molluscs meet certain health standards prior to sale to final consumers.</p>

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		<p>Better results in terms of food safety and consumer protection could be achieved by simply ensuring that the product is prepared to the correct standard. This would of course mean that regulators would have to admit that they were wrong to follow the path which they have done in the past and require a rethink of how they would apply controls to Live Scallops.</p>	<p>There has been considerable changes to the approach taken to scallop controls by the competent authority in recent years. Prior to 2006, sampling was undertaken from 'offshore boxes' in a tiered analysis regime. In recognition that shucking is a critical control for scallops, the legislation now explicitly recognises that land based controls can apply and that only the edible parts need to conform to the health standards, which has drastically changed the official control and scallop industry landscape in Scotland.</p>
	Sea Fish Industry Authority	<p>The Seafish definition of a batch is more realistic in terms of how sectors of the industry operate. The proposed definition is more restrictive and less permissive of FBO discretion in defining a batch to meet its operating requirements.</p>	<p>Noted, we think that the revision proposed remains suitably flexible.</p>
	The Government Chemist	<p>I note the FSS guidance states that "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" and</p>	<p>Noted.</p>

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		agree that the FSS proposed definition of batch is appropriate.	
	Scottish Fisherman's Association	The proposed definition of a batch seems sensible in that a single location and date can be attributed to the batch, thus simplifying the data required in the chain of custody	Noted.
	The Ethical Shellfish Company	We do not agree with the working definition of a batch. The sea is by its nature not divided into boxes and animals can migrate between different sea areas. We repeat that this is an inadequate system - there is no consistency across sea areas or between individual animals. The only way to ensure every scallop is below agreed toxin levels is to have them safely and correctly shucked, which every food operator is entirely capable of.	All food businesses must put in place traceability systems and such systems are predicated on batch management. We do however agree that shucking is a key control for toxin management for the scallop sector, but that is a separate issue.
5. Other EU countries - Do you consider the guidance regarding controls that can be used in relation to product harvested in non-UK waters within the EU to be sufficiently clear?	Sea Fish Industry Authority	The guidance is there and explained, but, once again, the industry would benefit from a clearer, bulleted quick reference guide.	Noted. The guidance has been revised to try and set out the requirements more clearly.
	Individual	We will soon leave the EU so this is not a long-term consideration.	Irrespective of whether the UK is or is not a member of the EU, exported product will have to conform to the legal requirements set out by the importing party.

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	Scottish Fisherman's Association	The Scallop industry has many international links, especially with fishing in the Channel, thus it is essential for UK fishers to be aware of the French management regime, so this section is helpful for the present. Post Brexit we believe that there will be a need for a review of management and evidence being used in the French sector, in order to avoid the scenario where the UK fleet is permanently excluded from the area for no good reason.	Noted.
Do you have any suggestions on how the consultation package could have been improved?	Individual	Too many layers of documents all with similar names, no real conclusion reached on previous consultations, after filling in many response documents one despairs and gives up.	Noted. The document has been revised for greater clarity.
Do you have any other comments about this consultation exercise?	Individual	Why can't someone just act and get on with things instead of endless consultation?	FSS is required to consult those who may be affected by the decisions we make, before we make them. We welcome all views from all stakeholders which help ensure that requirements in law are delivered in a way that takes into account potential impacts on businesses and other organisations.

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Respondents

2 fishing and industry organisations, 2 shellfish businesses, 2 individuals, 1 local authority and 2 public bodies responded to this consultation.