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| C:\Users\gmournia\Desktop\FSS_Pos_S_RGB.JPG | T: 01224-285157  F: 01224-285168  E: [jennifer.howie@fss.scot](mailto:jennifer.howie@fss.scot) |

19 February 2016

**LOCAL SALES OF SMALL QUANTITIES OF LIVE BIVALVE MOLLUSCS – REVIEW OF CURRENT CONTROLS**

**Summary and Purpose**

1. This letter has been produced following consideration of queries raised by industry sectors involved in the supply of whole scallops as well as enforcement officers within local authorities. It is also of relevance to other sectors of the shellfish catching and supply chain. The purpose of this letter is to invite views from: scallop fishermen, local authorities, caterers and other interested parties as to whether the current rules governing the sale by the producer of small quantities of bivalve shellfish to the final consumer or to local retail establishments are considered clear or adequate. And, if they are not considered to be clear or adequate, to invite suggested alternatives along with the rationale for their adoption.
2. Depending on the outcome of this consultation, consideration may be given to introducing a formal statutory measure, if it was considered that such a measure would be essential to better deliver public health protection for this sector. However, in any determination, in accordance with our commitment to better regulation principles, we will consider issues such as proportionality, consistency accountability and transparency of approach before reaching a final decision.
3. The issues discussed in this letter are necessarily detailed in terms of the EU regulatory framework applying to the supply of shellfish and also the technical nature of hygiene controls. Scallop fishermen, local authorities and caterers working in this sector will be familiar with current controls. However I have provided contact details for any recipients who have any further questions they may wish me to clarify.

**Introduction**

1. The requirement for all food businesses to ensure that the food they sell is safe is enshrined in both domestic and EU food safety legislation. For the vast majority of food businesses (e.g. caterers, food retailers), this requirement is principally met through implementation of effective risk management (‘HACCP’) procedures. In addition, for food businesses producing higher risk products of animal origin additional specified control measures are required to be met, including meeting critical food safety limits for a range of pathogens and chemicals. Business management controls for these specific measures may also be specified as part of the businesses’ HACCP plan or compliance demonstrated separately.
2. 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’. This provides for some member state flexibility in how the overall objectives of the hygiene rules can be met, whilst ensuring an equivalent level of public health protection.
3. Currently such national rules include domestic legislation such as the Food Safety Act 1990 and supporting guidance such as the Food Law Code of Practice and Practice Guidance, which cover all potentially ‘exempt[[1]](#footnote-1)’ activities.
4. However in recent years local authorities, caterers and fishermen with an interest in the scope of this exemption have raised a number of concerns regarding how specific food safety controls relating to live bivalve molluscs (LBMs), specifically scallops, should best be demonstrated and enforced.
5. The following principles will apply to any subsequent guidance or measures that are taken in the light of consultation responses:

* That any measures must fully protect public health and the interests of consumers;
* That the costs of applying any guidance or measures should be proportionate to their economic benefits;
* That the output from this consultation should not result in any market distortion;
* That any measures taken should set clear and practical boundaries as to when they will apply in general, and if possible, specific circumstances;
* That each party involved in the sale, receipt and enforcement of such activity will understand what is required of them;
* These measures will therefore set out the minimum requirements for each party in order for the ‘achievement of the regulation’ to have been met; and
* That, given FSS has legal competence to act within Scotland only, any revised guidance or measure will be restricted geographically to the boundaries of Scotland only.

**Detail**

1. 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) outlines the details of the local market exemption and the expected parameters in which it operates:

*“Regulation 853/2004 does not apply to the direct supply of small quantities of live bivalve molluscs to the final consumer or to local retail establishments directly supplying the final consumer. 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:*

*Extract from Food Law Code of Practice for Scotland (Practice Guidance) Section A.4.3*

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

1. These tonnage limits are consistent with limits agreed across the UK and are based on the levels which were prescribed in previous [Fish and Fishery Products](http://www.legislation.gov.uk/uksi/1998/994/regulation/20/made) regulations. The advice on ensuring product safety is also generally similar across the UK.
2. Other limits apply in guidance to other sectors, covered under similar but slightly different exemptions (e.g. for butchers, with marginal wholesale operations, and the supply of wild game and poultry); and there are also requirements relating to catch size under fish buyers and sellers’ legislation.

**Are these volume limits for each group of LBMs reasonable? If not what limits should apply? Please explain your answers.**

***Definition of ‘local’***

1. The definition of “local” for the purposes of the current exemption has also been described in domestic guidance. [EU Guidance](http://ec.europa.eu/food/food/biosafety/hygienelegislation/docs/guidance_doc_853-2004_en.pdf) is quite clear that ‘localised’ trade, in the case of larger member states should not refer to the entirety of that member state, and given that this letter applies to Scotland only it would be inappropriate to propose that definitions of “local” be extended beyond Scotland at this stage.

***Ensuring the achievement of the objectives of this regulation – for scallops***

1. Current EU regulation recognises the potential role of shucking as a critical control in the management of shellfish toxins in scallops and that is why, instead of routine offshore controls which apply to other LBM sectors, there is potential for derogation to allow controls to take place in a controlled environment on land. For non-exempt trade this control is applied at an approved establishment and all product leaving such an establishment must be compliant with regulatory food safety standards outlined in Regulation 853/2004. For the vast majority of scallops sold in Scotland, shucking takes place prior to the product being placed on the market. The risk management procedures applied by businesses responsible for placing shucked scallops on the market place emphasis on demonstrating product safety through a process of visual checks (to ensure removal of the hepatopancreatic tissues) with risk based verification testing carried out to confirm the efficacy of the shucking process in reducing the microbiological and biotoxin contamination from the edible meat (adductor muscle and gonad) to safe levels. Non-exempt businesses wishing to place live scallops on the market must ensure that the whole animal complies with the legal microbiological and biotoxin standards.

We would be interested to hear your views on what sort of guidance and/or controls should apply to the *direct supply by the producer, of* ***small quantities of whole scallops*** *to the final consumer or to local retail establishments directly supplying the final consumer,* that would ensure the achievement of the objectives of the regulations are met.

***Ensuring the achievement of the objectives of this regulation – for LBMs other than scallops***

1. All LBM production areas (with the exception of scallops) are required to be classified by Food Standards Scotland, and monitored for microbiological and shellfish toxin risk. This monitoring indicates the level of potential risk to consumers, and as such local authorities are required to close any areas where statutory food safety limits have been breached. Monitoring does not guarantee the safety of product placed on the market, so even when a classified production area is open, food businesses are also required to undertake a programme of end product testing to ensure that the product they sell is compliant with the regulations. The frequency of end product testing to be carried out by food businesses will depend on the biotoxin risk associated with the area and the time of year.
2. Unlike scallops, other species of LBMs cannot be ‘shucked’ to remove the microbiological and toxin risk.

We would be interested to hear your views on what sort of guidance and/or controls should apply to the *direct supply by the producer, of* ***small quantities of LBMs other than scallops*** *to the final consumer or to local retail establishments directly supplying the final consumer,* that would ensure the achievement of the objectives of the regulations are met.

1. For each of the questions asked above we would be particularly interested to hear the views of:

* primary producers supplying or seeking to supply LBMs (please describe which species you supply);
* caterers seeking to source such ‘exempt’ supply; and
* enforcement authorities for both primary production and caterer sectors.
* The non-exempt trade (ie the approved establishment sector).

**Next steps and outcomes from this review**

Depending on the outcome of this consultation, consideration may be given to introducing a formal statutory measure, if it was considered that such a measure would be essential to better deliver public health protection for this sector. However, in any determination, in accordance with our commitment to better regulation principles, we will consider issues such as proportionality, consistency accountability and transparency of approach before reaching a final decision. Your views and response to the content of this letter would be most welcome. In your response, please describe the capacity in which you are responding e.g. as a fisherman, caterer, local authority, private individual, shellfish processor or dispatch centre etc.

A list of people and organisations who has been sent this letter directly by FSS is included at **Annex 1.** Please see **Annex 2** for further details on how we handle consultation responses. **Annex 3** contains a consultation feedback form and **Annex 4** contains a Public information form, which you will need to fill in if you do not want your details to be made public when responding to this consultation.

Please provide the information requested by **19th May 2016** to me at the address below; copying [adminpool@fss.scot](mailto:adminpool@fss.scot).

Thank you on behalf of Food Standards Scotland for your assistance with this request for information and please do not hesitate to contact me if you have any questions.

Yours sincerely

**Jennifer Howie**

Food Standards Scotland

[Jennifer.howie@fss.scot](mailto:Jennifer.howie@fss.scot)

1. It should also be noted that whilst certain fishing activities may be considered ‘exempt’ for the purposes of food hygienelegislation, other fishery management legislation may still apply (for example regarding vessel registration etc). [↑](#footnote-ref-1)