

Circulation: See Annex 1

1 December 2008

Reference: FSH 0146

URGENT

Consideration of further amendments to the EU Hygiene Regulations: Live Bivalve Molluscs

Dear Stakeholder

You will be aware that (EC) Regulations 1019/2008, 1020/2008 and 1021/2008 amending certain provisions of (EC) Regulations 852/2004, 853/2004 and 854/2004 in so far as they relate to fishery products and live bivalve molluscs have been published and are now in force.

Further to this, the European Commission asked Member States at its working group meeting of 24th November to consider a further suite of proposed amendments to the current hygiene legislation in these areas and provide written comments by 19th December. Appendix 1 to this letter summarises the proposals relating to the provisions for live bivalve molluscs (LBMs) in Annex III of Regulation 853/2004 and, where appropriate, outlines the current FSA position. For information, a supplementary background note on marine gastropods, echinoderms and tunicates is included as Appendix 2.

Due to the short time available to respond to the Commission, we are carrying out a targeted consultation to seek the initial views of stakeholders to assist discussions at the next Commission Working Group meeting in January 2009. I should therefore be grateful for your comments on each of the proposals using the stakeholder response template in Appendix 3 no later than **10th December** to allow us time to prepare the UK response and subsequent negotiating lines.

This consultation is being sent to stakeholders in England, Wales and Northern Ireland. Separate consultation is being carried out in Scotland. We anticipate that further stakeholder consultation opportunities will be available during the development of these European proposals.

All correspondence should be sent to Karin Lemler, preferably by email at Karin.Lemler@foodstandards.gsi.gov.uk or by telephone on 0207 276 8955.

I look forward to your replies.

Yours faithfully

Mariam Aleem
Fish and Shellfish Hygiene Branch
Primary Production Division

Annex 1 – Circulation List

All Ireland Mussel Dredgers Producer Organisation
Aquaculture Initiative
Centre for Environment, Fisheries and Aquaculture Science
CIEH Cymru Wales
Conwy Mussel Fishermen's Association
Directors of Public Protection in Wales
Eastern Group Environmental Health Committee
Federation of Small Businesses
General Consumer Council for NI
LACORS
Local Authorities with classified harvesting areas in England, Wales and
Northern Ireland
NI Seafood Ltd
North Wales and Deeside Shellfish Liaison Group
Northern Group Systems
Seafish Industry Authority
Shellfish Association of Great Britain
South West Wales Shellfish Liaison Group
Southern Group Environmental Health Committee
UK NRL marine biotoxins
UK NRL microbiology and viral contamination
Ulster Shellfish Association
Welsh Consumer Council
Welsh Local Government Association
West Wales Shellfish Liaison Group
Western Group Environmental Health Committee

Appendix 1 - EU proposals on amendments to Regulation 853/2004, Annex III, Section VII

1. Contaminants in live bivalve molluscs

Proposed amendment: to clarify that live bivalve molluscs containing contaminants in excess of those permitted by Commission Regulation (EC) 1881/2006 must not be placed on the market for human consumption by amending the introductory part of Chapter V as follows:

“In addition to ensuring compliance with microbiological criteria adopted in accordance with Regulation (EC) 852/2004, and not exceeding the limits for contaminants laid down in the relevant legislation, food business operators must ensure that live bivalve molluscs placed on the market for human consumption meet the standards laid down in this Chapter.”

Proposed UK position: The additional wording strengthens the food safety principles of the Regulation. Welcome and support this clarification.

2. Packages of live bivalve molluscs for retail sale

Proposed amendment: to clarify that any packages of live bivalve molluscs for retail sale must be closed by amending point 2 of Chapter VI as follows:

“~~Individual consumer size~~ All packages of live bivalve molluscs destined for retail must be closed and remain closed after leaving the dispatch centre and until presented for sale to the final consumer.”

Proposed UK position: Support the proposed amendment, which clarifies the wrapping and packaging requirements for retail products.

3. Sale of Pectinidae

(i) **Proposed amendment:** to clarify the traceability requirements for pectinidae harvested from outside classified production areas by an auction market by amending point 4 of Chapter IX as follows:

“4. Food business operators handling pectinidae must comply:

*(a) with the documentary requirements of Chapter I, points 3 to 7, where applicable.
In this case, registration documents must clearly indicate the location of the area where the pectinidae were harvested;*

and

(b) ~~as regards packaged pectinidae and wrapped pectinidae if the wrapping provides protection equivalent to that of packaging, with the requirements of Chapter VI, Point 2 concerning the closing of all packages of live pectinidae destined for retail and~~ Chapter VII concerning identification marking and labelling.”

Proposed UK position: Support the proposed amendment and will also seek clarification that the proposed amendment similarly applies to processing establishments and dispatch centres.

(ii) **Proposal:** to clarify the wording of point 2 of Chapter IX on the classification of such fishing grounds.

The current wording is as follows:

“In addition, where data from official monitoring programmes enable the competent authority to classify fishing grounds – where appropriate, in cooperation with food business operators – the provisions of Chapter II, Part A, apply by analogy.”

Proposed UK position: The Agency is of the view that scallops harvested from sufficiently offshore areas that are at minimal risk from faecal pollution. Classification of

such areas is therefore neither practical nor necessary from a public health perspective. However, estuarine and coastal harvesting areas (for pectinidae) pose a greater public health risk due to their proximity to sources of microbiological contamination and consideration should be given to classifying these areas. Whilst no new text has been proposed by the Commission we support the Commission's proposal to clarify under what circumstances it considers that classification would be required.

Information on the number of landings of scallops from unclassified areas and the size of the UK market is unclear. We recognise this may not be possible in the time available. However, we would welcome data after the deadline as this would help with ongoing future discussions. All information will be treated as commercially confidential.

4. Hygiene rules for “other LBMs”, marine gastropods

Proposed amendment: to consider the extension of the ‘pectinidae regime’ in Chapter IX of Annex in Section VII to other live bivalve molluscs, marine gastropods (eg abalone) as specified in Article 11(7) of Regulation (EC) No 853/4004.. No text has been suggested by the Commission.

FSA Comment: This proposal has two distinct parts: “other LBMs” and “marine gastropods, etc”. With regard to “other LBMs”, the Agency is of the view that the current classification monitoring programme provides an appropriate level of consumer protection from the risks associated with the consumption of live bivalve molluscs. As such, we would not support the proposal to extend the provisions of Chapter IX to other live bivalve molluscs unless the clarification on pectinidae fishing grounds in the previous proposal limits these to such areas that are at a very low risk of faecal contamination.

While we welcome the opportunity to discuss the legislative position of marine gastropods etc., and support in principle amendment to the current requirements, we do not support the proposal as it stands to extend the provisions of Chapter IX to marine gastropods, echinoderms and tunicates. Although the legislation currently applies the same classification requirements as live bivalve molluscs to marine gastropods (etc.) placed on the market, the Agency is aware that some species (e.g. whelks) are being

commercially harvested in the UK without adherence to the specified conditions. However, we recognise that the provisions of the current legislation have practical difficulties with the application of official controls and enforceability and therefore it may not be possible logistically and technically to classify all such areas.

Marine gastropods (etc.) are quite different physiologically from LBMs and pose quite different risks to the consumer with respect to marine biotoxins and microbiological contamination. For these reasons, the Agency believes that they should be controlled in a more risk appropriate and proportionate manner. A technical background note on these matters is attached at Appendix 2 for information.

Proposed UK position: The UK considers that the legislation pertaining to gastropods (etc.) needs to be amended. The classification requirements for gastropods (etc.) should be removed, and that hygiene rules similar to those currently applied to fishery products (e.g. crabs) in Regulation 853/2004, Annex III, Section VIII, Chapter V (E) paragraph 2 are a more viable option in providing a proportionate level of consumer protection than equating gastropods with pectinidae.

Appendix 2

Technical background note

Classification and monitoring of Marine Gastropods, Tunicates and Echinoderms

Introduction

1. According to current Regulation (EC) No 854/2004, marine gastropods, tunicates and echinoderms are required to be treated in the same way as live bivalve molluscs (apart from the requirements for depuration). However, their environment, feeding habits and physiology are so different from the bivalve molluscs that full compliance with the requirements of the Regulation is very difficult and, in some cases, impossible.
2. Due to the feeding habitats of gastropod molluscs the risk to public health from the bioaccumulation of marine biotoxins is significantly different than for live bivalve molluscs. Additionally, the fact that they are generally cooked at higher temperatures and for a longer time prior to sale means the risk from microbial organisms is also lower. Further, there is no history of any particular public health problem reported in the UK with the consumption of marine gastropods.
3. This background note provides further detail on the differences between marine gastropods, tunicates, echinoderms and live bivalve molluscs and the impact on the ability to classify and monitor the former as well as the risk to public health. The technical considerations below support the proposed UK position outlined in Appendix 1 to the consultation letter.
4. Since, to our knowledge, there is little commercial harvesting in the UK of tunicates and echinoderms, this paper concentrates on marine gastropods, though our understanding is that many of the arguments presented can be applied equally to those products.

Public health considerations

5. Gastropods are susceptible to microbiological contamination by bacteria and viruses. Sporadic testing of periwinkles in the UK under the general microbiological

monitoring programme has yielded results from <20 to 16,000 *E. coli* per 100g, and whelks collected near an effluent outfall contained *E. coli* levels >1,000 per 100g. We are aware of only one microbial related outbreak (of typhoid) associated with the consumption of gastropods (in Canada in imported limpets; source unknown).

6. The normal practice in the UK is to cook whelks and periwinkles prior to consumption, and it is understood that higher temperature/time profiles are used than the minimum specified in the legislation for bivalves from class C areas¹, and therefore this should be sufficient to eliminate microbial pathogens. However, this is unlikely to eliminate spore forming bacteria or any heat resistant microbial toxins. While there is a lot of uncertainty with respect to the amount of raw and cooked product on the market, as much of the data are either incomplete or conflicting, our understanding is that most gastropods in the UK are cooked prior to sale, particularly whelks.
7. Although gastropods are not filter feeders, several studies² have demonstrated that they can bioaccumulate marine biotoxins through feeding on contaminated bivalve molluscs or toxic algae cysts. Reports³ suggest the contamination is mostly by PSP toxins and these have been detected in several species of gastropods worldwide, at levels sometimes exceeding the statutory European limit of 80 µg STX eq/100 g shellfish flesh. Whelks harvested in the UK have also been shown to contain some PSP toxins⁴, though at levels below the statutory limit. It is understood that periwinkles are unlikely to bioaccumulate large quantities of toxins due to their feeding habits.
8. Little information⁵ is available on the ability of gastropods to retain or excrete toxins or on the distribution of toxins within the different tissues. PSP toxins are not eliminated by heat treatment.
9. Nevertheless, we are not aware of any reports of poisoning caused by the consumption of gastropods containing marine biotoxins or microbial contaminants

¹ Not less than 90°C for not less than 90 seconds.

² FAO Food and Nutrition papers. Marine Biotoxins. Food and Agriculture Organisation of the United Nations, Rome 2004. Section 2.4 Occurrence and accumulation in seafood.

³ White et al. 1993. Recent Occurrence of Paralytic Shellfish Toxins in Offshore Shellfish in the Northeastern United States., In: Toxic Phytoplankton Blooms in the Sea, pp 435-440 (T.J. Smayda and Y. Shimizu, Eds.) New York: Elsevier Science Publishers.

⁴ UK monitoring data provided by the UK-NRL for Marine Biotoxins (only 13 whelks were tested, 6 of which contained PSP toxins).

⁵ Bravo et al. 1999. Paralytic shellfish poisoning in *Haliotis tuberculata* from the Galician coast: geographical distribution, toxicity by lengths and parts of the mollusc. *Aquatic Toxicology*. 46(2): 79-85.

in the UK. However, the consumption of gastropods contaminated with PSP toxins has been linked with reports of illnesses, including fatalities, in China⁶.

10. Separately, there are infrequent reports in the UK of outbreaks linked to the consumption of the *naturally* poisonous red whelk. The toxin secreted by the red whelk causes neurological symptoms which normally are resolved within 24 hours. The toxic whelks are distinguishable from the common whelks due to their larger size and smoother shell, with controls reliant on the harvester removing these from the catch.
11. DSP toxins have also been detected in gastropods, though this type of contamination is not currently widely reported.

Classification and monitoring of gastropods

12. The current EU food hygiene legislation requires marine gastropods (and tunicates and echinoderms) destined for human consumption to come from classified areas, and for such areas to be monitored by the Competent Authority in the same way as for bivalve molluscs. Classification of an area requires a sanitary survey for each new bed and subsequent *E. coli* sampling. In addition, once classified, the beds have to be sampled once per week (unless risk assessment indicates a reduced frequency) for 3 different groups of marine biotoxins.
13. However, gastropods and bivalve molluscs are different in many significant ways, meaning that it is not appropriate or always possible to apply the same criteria for classification and monitoring as for bivalve molluscs. Due to these differences it is necessary to consider a different approach to controlling any public health risk that may stem from these products.
14. The differences between the two molluscs that affect the ability to classify and monitor can be broadly grouped under 4 (albeit interrelated) headings: (i) feeding, (ii) physiology, (iii) mobility and (iv) habitat, and these will be dealt with in turn.

(i) Feeding

- Bivalve molluscs are filter feeders, while gastropods are essentially omnivorous or herbivorous grazers, meaning that the feeding habits and patterns are quite different between the two groups.

⁶ Choi, Man-Chi, Yu, Peter K N, Hsieh, Dennis P H, and Lam, Paul K S. 2006. Trophic transfer of paralytic shellfish toxins from clams (*R. philippinarum*) to gastropods (*N. festivus*). Chemosphere (64) 1642-1649.

- Many gastropods thrive near effluent outflows but their feeding habits dictate that there is probably much more variation between individual animals than would be expected with bivalves. Whelks, for example, are scavengers and will eagerly seek out decaying flesh upon which to feed, and this may occur on quite a localised part of a 'classified' area. The decaying flesh may be bivalve molluscs already highly contaminated with toxins (this would be similar to the cause of the recent PSP outbreak in Norway in which crabs became highly toxic from eating contaminated mussels). Thus taking a few samples from an area for analyses will be less representative of the whole area with gastropods than with bivalves. On the other hand, bivalve molluscs, being filter feeders, are more likely to bioaccumulate both microorganisms and marine biotoxins than are gastropods.
- So, in essence, the feeding habits of gastropods make them *overall* a lower public health risk than bivalves and, with the chances of much greater variation between animals existing, it makes monitoring under our current schemes inappropriate.

(ii) Physiology

- Most marine gastropods, notably whelks which feed on mussels, clams etc., are liable to intoxication to some extent with DSP or PSP biotoxins. However, insufficient data are available to enable proper risk assessment with respect to which parts of the animals may become infected, how effectively the toxins are removed over time, or the rate of their uptake. Furthermore, as gastropods are not filter feeders, it is not possible at this stage to suggest depuration regimes. Given the differences in physiology (and the often quite different feeding areas and substrates) between bivalve and gastropod molluscs it is most unlikely that one could be used as a viable indicator of the other for the presence of toxins or microbial contamination, and certainly not without extensive studies being undertaken

(iii) Mobility

- Gastropod molluscs, on the whole, are far more mobile than bivalve molluscs making it more difficult to be sure that when harvested from a particular area that they have resided in that area for a significant amount of time (i.e. in

relation to a depuration period) and have not recently moved from an infected area. This is more of a problem with whelks (reported as being able to move at a rate of 10 cm per minute⁷) than periwinkles but it does raise questions of appropriateness since classified areas are required to be clearly fixed and delineated. Crustacea such as crabs are known vectors of marine biotoxins but, because of their mobility, the legislation does not require them to originate from classified areas. Similar considerations should be given to gastropods. Although, where gastropods can be grown in confined spaces, e.g. abalone in tanks, then mobility becomes less of an issue for classification.

(iv) Habitat

- Marine gastropods, especially periwinkles, are ubiquitous around the coastline of the UK. To classify the whole coastline would not be logistically possible given the prerequisite sanitary survey for each area and, once classified, the areas would need to be regularly monitored on a risk-based approach to maintain the classifications.
- Further, many whelks are harvested in deeper waters outwith the jurisdiction of Local Food Authorities (LFAs) and thus classification would be expensive and fraught with practical difficulties e.g. health and safety, availability of suitable boats or, in some instances, just not even possible.

⁷ Unpublished data

Appendix 3 - Stakeholder Response Template

Name: _____

Organisation: _____

E-mail: _____

Please indicate whether you agree or disagree with the UK position for each of the proposals. We would also welcome any additional comments you may have.

Proposal 1 - Contaminants in live bivalve molluscs

Agree Disagree

Comment

Proposal 2 - Packages of live bivalve molluscs for retail sale

Agree Disagree

Comment

Proposal 3 – Sale of pectinidae

(i) to clarify the traceability requirements for pectinidae harvested from outside classified production areas by amending point 4 of Chapter IX

Agree

Disagree

Comment

(ii) to clarify the wording of point 2 of Chapter IX on the classification of such fishing grounds. Data on the number of landings of scallops from unclassified areas and the size of the UK market is also requested. [NB. any data will be treated as ‘commercial in confidence’.]

Agree

Disagree

Comment

Proposal 4 – Hygiene rules for “other LBMs”, marine gastropods

Agree

Disagree

Comment

Please return completed responses by e-mail to:

Karin Lemler - Karin.Lemler@foodstandards.gsi.gov.uk