
STATUTORY INSTRUMENTS

1998 No. 994

**The Food Safety (Fishery Products and
Live Shellfish) (Hygiene) Regulations 1998**

PART II

PRODUCTION AND PLACING ON THE MARKET OF LIVE SHELLFISH

Designation of areas as designated bivalve production areas

3.—(1) The Ministers shall designate sea waters and brackish waters from which live bivalve molluscs may be taken in accordance with the requirements of this Part and shall specify as respects each area of water designated by them whether it is—

- (a) a class A area from which live bivalve molluscs can be gathered as specified in Part 1 of Chapter I of Schedule 2;
- (b) a class B area from which live bivalve molluscs can be gathered as specified in Part 2 of Chapter I of Schedule 2;
- (c) a class C area from which live bivalve molluscs can be gathered as specified in Part 3 of Chapter I of Schedule 2,

and any such designation may be subject to such limitation, condition or restriction as appears to the Ministers to be called for by article 5(2) of the Live Bivalve Molluscs Directive.

(2) Each food authority shall, wherever possible, designate as a relaying area any area within their district which—

- (a) fulfils the conditions required for designation as a class A or B area specified in paragraph (1)(a) and (b); and
- (b) in their opinion is suitable for the relaying of live bivalve molluscs if the conditions specified in Parts 2 and 3 of Chapter I of Schedule 2 and in Chapter III of Schedule 2 are satisfied,

and, where the Ministers have notified the food authority that specified conditions relating to the matters mentioned in Chapter III of Schedule 2 should be complied with as respects the operation of the relaying area, the food authority shall make that designation subject to those conditions.

(3) The food authority shall notify the Ministers of any designation made under paragraph (2) and of its terms.

Designation of areas as prohibited areas for live shellfish production

4. The Ministers may at any time designate any area as an area unsuitable, for health reasons, for the production or collection of—

- (a) live bivalve molluscs;
- (b) live echinoderms, tunicates and marine gastropods;
- (c) live shellfish,

and any such area shall be designated, as appropriate, as a “designated prohibited area for live bivalve mollusc production”, a “designated prohibited area for live echinoderm, tunicate and marine gastropod production” or a “designated prohibited area for live shellfish production”.

Alterations to designated areas

- 5.—(1) The Ministers may in appropriate circumstances and at any time—
- (a) vary the boundary of any area designated under regulation 3(1) or 4;
 - (b) impose any limitation, restriction or condition on the use of any area designated under regulation 3(1) or 4;
 - (c) alter the class of any designated bivalve production area or any area within a designated bivalve production area;
 - (d) revoke the designation of a designated bivalve production area, if the area is no longer suitable for the gathering of live bivalve molluscs;
 - (e) vary or revoke the designation of any area designated under regulation 4.
- (2) A food authority may at any time—
- (a) in appropriate circumstances, vary the designation of a relaying area made under regulation 3(2);
 - (b) if a relaying area designated in accordance with regulation 3(2) is no longer suitable for the relaying of live bivalve molluscs, revoke the designation of that relaying area,

and shall communicate any such variation or revocation to the Ministers.

Lists of designated production and relaying areas

- 6.—(1) The Ministers shall maintain and publish—
- (a) a list of designated bivalve production areas; and
 - (b) a list of any areas which food authorities have designated as suitable for the relaying of live bivalve molluscs,

and amendments to these lists shall be published from time to time.

(2) The Ministers shall send a copy of the lists mentioned in paragraph (1), and any amendments to them to—

- (a) each food authority;
- (b) trade associations which appear to them to represent the interests of food businesses which are likely to be directly affected by this Part of these Regulations.

(3) Each food authority shall take such action as they consider sufficient to bring any part of the lists mentioned in paragraph (1) which relates to their area to the attention of any harvester, handler or operator of a dispatch or purification centre who is carrying out commercial operations with respect to live bivalve molluscs in their area.

Temporary prohibition orders concerning production areas

7.—(1) Subject to paragraph (4), a food authority may, if it is satisfied that the consumption of live shellfish taken from a production area is likely to cause a risk to public health, make a temporary prohibition order prohibiting the collecting of any live shellfish from that area.

(2) A temporary prohibition order shall cease to have effect at the expiration of a period of 28 days after it was made, unless earlier revoked by the food authority making the order.

(3) Forthwith after making such an order, a food authority shall—

- (a) in the case of a private laying, refer the matter to the Ministers and serve a notice on every owner and tenant of the laying whose name and address can with reasonable diligence be ascertained containing the following information—
 - (i) the reasons for the food authority making the order, and
 - (ii) any action which the food authority is requesting the Ministers to take pursuant to regulation 4 or 5(1), and in particular the detail of any proposed conditions or restrictions;
 - (b) in the case of any other production area, affix notices in the vicinity of the area and take any other steps it considers appropriate to bring the order to the attention of those affected, and in either case send a copy of the order and notice to the Ministers and to any Sea Fisheries Committee in whose district the production area is situated.
- (4) A food authority shall not make a temporary prohibition order in respect of any production area if they have made such an order in respect of that area within the preceding 28 days, unless the Ministers give consent to such action.

Collecting live shellfish from prohibited areas

8. No person shall collect—
- (a) live bivalve molluscs from a designated prohibited area for live bivalve mollusc production;
 - (b) live echinoderms, tunicates or marine gastropods from a designated prohibited area for live echinoderm, tunicate and marine gastropod production;
 - (c) live shellfish from—
 - (i) a designated prohibited area for live shellfish production, or
 - (ii) a laying which is the subject of a temporary prohibition order.

Requirements relating to the harvesting, transporting and relaying of live shellfish

9. No person shall—
- (a) harvest or transport from a production area to a dispatch centre or processing plant any live echinoderms, tunicates or marine gastropods otherwise than in accordance with Chapter II of Schedule 2;
 - (b) harvest or transport from a production area to a relaying area, dispatch centre, purification centre or processing plant any live bivalve molluscs otherwise than in accordance with Chapter II of Schedule 2; or
 - (c) relay any live bivalve molluscs otherwise than at a designated relaying area and in accordance with the applicable conditions for relaying in Chapter III of Schedule 2,

if they are intended for placing on the market for human consumption.

Requirement for the approval of dispatch or purification centres

10. No person shall operate a dispatch or purification centre unless it has been approved by the food authority for the area in which the centre is situated.

Approval of dispatch or purification centres

11.—(1) An application for an approval for a dispatch or purification centre shall be made to the food authority for the area in which the centre is situated.

(2) An application pursuant to paragraph (1) shall be—

- (a) made in writing; and
- (b) accompanied by such supplementary information, documents, plans, and diagrams as are necessary to enable the food authority to determine the application.

(3) An approval in respect of a dispatch centre may only be granted if the food authority is satisfied that it meets such of the conditions set out in Sections I, II and IV of Chapter IV of Schedule 2 as apply to it.

(4) An approval in respect of a purification centre may only be granted if the food authority is satisfied that it meets—

- (a) such of the conditions set out in Sections I, II and III of Chapter IV of Schedule 2 as apply to it; and
- (b) any additional conditions of which the food authority has been notified by the Ministers pursuant to paragraph (5).

(5) An approval for a dispatch or purification centre under this regulation may be granted subject to limitations as to the particular activities approved, the method of operation approved and intensity of use approved, and where the Ministers notify the food authority that specified conditions for the operation of a purification centre relating to matters mentioned in Chapter IV of Schedule 2 should be complied with, the food authority shall give their approval subject to those conditions.

(6) The food authority shall give written notification to each person who makes an application pursuant to paragraph (1) of the result of their application and, in the case of refusal, of the reasons for that refusal.

(7) If an application pursuant to paragraph (1) is approved, the food authority shall—

- (a) designate the dispatch or purification centre with a unique approval number; and
- (b) notify the Secretary of State of the approval and the approval number allocated.

Appeals against a refusal to grant an approval or against any conditions or limitation in approvals

12.—(1) A person who is aggrieved by a decision taken by a food authority—

- (a) to refuse to grant an approval for a dispatch or purification centre; or
- (b) to impose any limitation or condition in an approval granted for a dispatch or purification centre,

may appeal to a magistrates' court or, in Scotland, to the sheriff, and section 37(3) to (6) of the Act shall apply in relation to such an appeal as it applies in relation to an appeal under section 37(1)(c).

(2) Where an appeal against—

- (a) a limitation as to the particular activities approved, the method of operation approved or the intensity of use approved; or
- (b) a condition notified to the food authority by the Ministers in accordance with regulation 11(5),

is brought in accordance with paragraph (1)(b), the appellant may continue to operate the centre free of the limitation or condition which is being appealed against while the appeal is pending, and an appeal shall be regarded as pending for these purposes until it is finally disposed of, is struck out for want of prosecution or is withdrawn.

(3) Where an appeal is brought in accordance with paragraph (1)(b) against a condition notified to the food authority by the Ministers in accordance with regulation 11(5), the food authority shall inform the Ministers that such an appeal has been brought.

- (4) Where an appeal is brought in accordance with paragraph (1), the court may—
- (a) affirm any decision to refuse an approval;
 - (b) grant the approval either in its original form or with such modifications as the court may in the circumstances think fit;
 - (c) remit the matter to the food authority with the court's opinion on it; or
 - (d) make such other order in relation to the matter as the court thinks fit.

Obligations on food business proprietors operating dispatch or purification centres

13. A food business proprietor who is operating a dispatch or purification centre at which live shellfish which are intended for placing on the market are handled shall ensure that—

- (a) the requirements of the approval for his centre and of the applicable provisions of Chapter IV of Schedule 2 are complied with as respects his centre;
- (b) regular microbiological checks are carried out on—
 - (i) those of his shellfish which he is required to check for microbiological contamination in order to comply with the requirements set out in Chapter IV of Schedule 2, and
 - (ii) if he is a purification centre proprietor, the water for use in the purification system at this centre, by or in laboratories which meet the applicable requirements of Chapter IV of Schedule 2; and
- (c) the results of the checks mentioned in sub-paragraph (b)(i) are recorded in a historical record which, in relation to each area from which the shellfish come, gives details of the health quality of the shellfish from that area both before and after handling at the centre.

Variation of approvals for dispatch or purification centres

14.—(1) A person may at any time apply to a food authority for the authority to vary or revoke any term or limitation in any approval for a dispatch or purification centre granted to him, and subject to paragraph (2), the food authority may, in appropriate circumstances, vary any such term or limitation.

(2) A food authority may only vary or revoke any additional condition of which the food authority has been notified by the Ministers pursuant to regulation 11(5) with the consent of the Ministers.

(3) Any person who is aggrieved by a decision of a food authority to refuse to vary any term or limitation of any approval for a dispatch or purification centre may appeal to a magistrates' court or, in Scotland, to the sheriff, and section 37(3) to (6) of the Act shall apply in relation to such an appeal as it applies in relation to an appeal under section 37(1)(c) of the Act.

(4) Where an appeal is brought in accordance with paragraph (3) against a refusal to vary a condition notified to the food authority by the Ministers in accordance with regulation 11(5), the food authority shall inform the Ministers that such an appeal has been brought.

- (5) Where an appeal is brought in accordance with paragraph (3), the court may—
- (a) affirm any decision to refuse to vary the term or limitation in the approval;
 - (b) vary the term or limitation in the approval;
 - (c) remit the matter to the food authority with the court's opinion on it; or
 - (d) make such other order in relation to the matter as the court thinks fit.

Revocation of approvals for dispatch or purification centres

15.—(1) A food authority may revoke an approval of a dispatch or purification centre situated in its area if, after inspection of or any inquiry into the method of operation of the centre, they are satisfied that—

- (a) there has been a serious (on animal or public health grounds) and manifest breach of the conditions or limitations subject to which the approval was granted or of the applicable provisions of Chapter IV of Schedule 2;
- (b) the food business proprietor who is operating the centre is either unable or not prepared to ensure that the breach is remedied; and
- (c) there is in force in relation to that dispatch or purification centre—
 - (i) a prohibition order under section 11 of the Act, or
 - (ii) an emergency prohibition order under section 12 of that Act,and as a consequence of the order, commercial operations with regard to live shellfish which are for placing on the market for human consumption may not be carried out at that dispatch or purification centre.

(2) A proprietor who is aggrieved by a decision to revoke an approval for a dispatch or purification centre may appeal to a magistrates' court or, in Scotland, to the sheriff, and section 37(3) to (6) of the Act shall apply in relation to such an appeal as it applies in relation to an appeal under section 37(1) (c) of the Act.

(3) A revocation under this regulation shall take effect—

- (a) immediately after the time for appealing against it has elapsed; or
- (b) if an appeal is brought, immediately after the appeal is finally disposed of, struck out for want of prosecution or withdrawn,

and when a food authority informs the food business proprietor who is operating a dispatch or purification centre of a decision to revoke the approval for the centre, they shall explain to the proprietor in writing when the revocation will take effect (including when it will take effect if an appeal is brought).

Wrapping of live shellfish

16. A proprietor of a food business in the course of which live shellfish which are intended for placing on the market for human consumption are wrapped or repackaged shall ensure that the wrapping or repackaging of such shellfish is in accordance with the applicable requirements of those set out in Chapter VII of Schedule 2.

Storage and transportation of live shellfish after dispatch

17. A proprietor of a food business in the course of which live shellfish which are intended for placing on the market for human consumption are stored or transported after they have left a dispatch or purification centre, shall ensure that such shellfish are stored and transported in accordance with the applicable requirements of those set out in Chapters VIII and IX of Schedule 2.

Splitting consignments of live shellfish

18.—(1) A person other than the final consumer who splits the contents of a consignment of live shellfish which are not wrapped in individual consumer-sized parcels shall keep—

- (a) any healthmark which is attached to the consignment; or
- (b) a copy of any certificate required in accordance with regulation 45(2) which accompanied that consignment,

for a period of not less than 60 days from the date of the splitting of the contents of that consignment.

(2) A person who repackages a consignment of live shellfish in accordance with paragraph 3 of Chapter VII of Schedule 2 shall keep the original healthmark (if one was required) which was

attached to the consignment for a period of not less than 60 days from the date of the splitting of the contents of that consignment.

Placing live shellfish on the market

19.—(1) Subject to paragraphs (2) to (4), no person shall place on the market for immediate human consumption any live shellfish, unless—

- (a) they originate, if they are live bivalve molluscs, from a bivalve production area which—
 - (i) has been designated a class A area, a class B area or a class C area in accordance with regulation 3(1), and any condition or limitation specified in Chapter I of Schedule 2 in relation to that class of area has been complied with,
 - (ii) has been identified, pursuant to any law in force in Northern Ireland, the Channel Islands or the Isle of Man which is intended to give effect to the results to be achieved by Chapter I of the Annex to the Live Bivalve Molluscs Directive, as an area from which bivalve molluscs may be collected, and any condition or limitation derived from that Chapter which relates to that production area has been complied with, or
 - (iii) if they are imported for relaying, was of the same standard as an area designated as a class B area or a class C area in accordance with regulation 3(1)(b) or (c), and any condition or limitation specified in Chapter I of Schedule 2 for that production area has been complied with;
- (b) they have been harvested, kept and transported to any approved dispatch centre, approved purification centre or approved relaying area to which they are thereafter transferred in accordance with the applicable requirements of—
 - (i) Chapter II of Schedule 2, or
 - (ii) any law in force in Northern Ireland, the Channel Islands or the Isle of Man which is intended to give effect to the results to be achieved by Chapter II of the Annex to the Live Bivalve Molluscs Directive,accompanied by a valid movement document or a valid permanent transport authorisation;
- (c) if they are live bivalve molluscs, they have, where necessary, been relaid in accordance with—
 - (i) Chapter III of Schedule 2, or
 - (ii) any law in force in Northern Ireland, the Channel Islands or the Isle of Man which is intended to give effect to the results to be achieved by Chapter III of the Live Bivalve Molluscs Directive;
- (d) they have been handled hygienically and, if they are live bivalve molluscs, they have, where appropriate, been purified at a purification centre which has been approved in accordance with—
 - (i) regulation 11, or
 - (ii) any law in force in Northern Ireland, the Channel Islands or the Isle of Man which is intended to give effect to the results to be achieved in relation to the approval of purification centres by the Live Bivalve Molluscs Directive;
- (e) they are as specified in Chapter V of Schedule 2;
- (f) they have been wrapped in accordance with the applicable requirements of Chapter VII of Schedule 2;
- (g) they have been stored and transported in accordance with the applicable requirements of Chapter VIII of Schedule 2;
- (h) they comprise or form part of a consignment which bears a healthmark—

- (i) unless head (ii) or (iii) applies, which is in accordance with Chapter X of Schedule 2,
- (ii) which, if they comprise or form part of a consignment which has been given a healthmark in accordance with any law in force in another EEA State, Northern Ireland, the Channel Islands or the Isle of Man which is intended to give effect to the results to be achieved by Chapter X of the Annex to the Live Bivalve Molluscs Directive, is in accordance with that law,
- (iii) which, if they comprise or form part of a consignment from a third country in respect of which the European Commission has adopted approved import conditions, is in accordance with those approved import conditions,

but a healthmark is not required in relation to live shellfish which originate from a third country in respect of which the European Commission has not adopted approved import conditions, unless those live shellfish have been repackaged in accordance with paragraph 3 of Chapter VII of Schedule 2;

- (i) if they are imported live shellfish, prior to importation such of the requirements specified in regulations 44 and 45 as are applicable to his case are satisfied in relation to those live shellfish which he places on the market.
- (2) Paragraph (1)(a) shall not apply to—
- (a) pectinidae, unless they are aquaculture products; or
 - (b) any imported live bivalve molluscs, unless they were harvested from seawaters or brackish waters within British fishery limits⁽¹⁾.
- (3) Paragraph (1)(b) and (c) shall not apply to imported live shellfish, unless their country of dispatch is part of the British Islands.

(4) Paragraph (1)(h)(ii) to (iii) shall not apply in circumstances where, in Great Britain, a person repackages live shellfish from a country or territory other than Great Britain in accordance with paragraph 3 of Chapter VII of Schedule 2.

Direct transfers of live shellfish on local markets

20.—(1) Regulations 9, 16, 17 and 19 shall not apply to a direct transfer to a retailer or final consumer in the United Kingdom of a small quantity of—

- (a) live bivalve molluscs gathered from a class A designated bivalve production area; or
- (b) live echinoderms, tunicates or marine gastropods,

which are as specified in Chapter V of Schedule 2 by a coastal fisherman who is part of the direct transfers scheme.

(2) A coastal fisherman is part of the direct transfers scheme for the purposes of paragraph (1) if, prior to gathering live shellfish for the first time in any calendar year in the district of a food authority, he notifies the food authority of his intention to do so and supplies them with the following information—

- (a) his name, address and telephone number;
- (b) the address where he keeps the equipment he uses for gathering;
- (c) the intended place of landing of gathered live shellfish;
- (d) the address where he intends to put the gathered live shellfish when landed;
- (e) if applicable, the name, address and approval number of any dispatch or purification centre to which he intends to send live shellfish after gathering,

(1) See sections 1(5) and 10(2)(b) of the Fishery Limits Act 1976 (c. 86).

and if he notifies the food authority of any changes to the information originally supplied.

(3) For the purposes of paragraph (1) a “small quantity” means an amount which comprises part of the coastal fisherman’s annual allowance.

(4) For the purposes of paragraph (3), a coastal fisherman’s annual allowance is a total amount of not more than 25 tonnes of live shellfish in a calendar year, and although that total amount may comprise of amounts of one or more species, in that total amount the amount of any species listed in column (a) of the table below shall not exceed the maximum amount for that species mentioned in column (b) of that table—

Table

<i>(a)</i> <i>Species</i>	<i>(b)</i> <i>Maximum amount</i>
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