
STATUTORY INSTRUMENTS

1992 No. 3164

**FOOD
FOOD SAFETY**

**The Food Safety (Live Bivalve Molluscs
and Other Shellfish) Regulations 1992**

Made - - - - 11th December 1992

Laid before Parliament 11th December 1992

Coming into force in accordance with regulation 1

for certain purposes 1st January 1993

for other purposes 15th January 1993

The Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales and the Secretary of State for Scotland as respects Scotland, in the exercise of the powers conferred upon them by sections 6(4), 16(1), 17(1), 26(1)(b) and (3), 48(1), 49(2) and 59(2) of, and paragraphs 2(2), 5(1) and (2), 6(1) and 7(1) of Schedule 1 to, the Food Safety Act 1990⁽¹⁾ and of all other powers enabling them in that behalf, after consultation in accordance with section 48(4) of that Act with such organisations as appear to them to be representative of interests likely to be substantially affected, hereby make the following Regulations:

Citation and commencement

1.—(1) These Regulations may be cited as the Food Safety (Live Bivalve Molluscs and Other Shellfish) Regulations 1992.

(2) These Regulations shall come into force for the purposes of regulations 1 to 5, 7, 8, 9, and 14 on 1st January 1993 and for all other purposes on 15th January 1993.

Interpretation

2.—(1) In these Regulations, unless the context otherwise requires—
“the Act” means the Food Safety Act 1990;

(1) 1990 c. 16. Section 4(1) contains a definition of “the Ministers” which is relevant to the powers being exercised in these Regulations.

“batch” means a quantity of live bivalve molluscs collected from a production area and subsequently intended for delivery to an approved dispatch centre, purification centre, relaying area or processing plant;

“bivalve molluscs” means filter-feeding lamellibranch molluscs;

“clean sea water” means sea water or brackish water which is to be used under the conditions laid down in these Regulations and which is free from microbiological contamination and toxic and objectionable substances occurring naturally or after discharge in the environment, including those listed in the Annex to Directive [79/923/EEC\(2\)](#) (quality required of shellfish waters), in such quantities as may adversely affect the health quality of bivalve molluscs or other shellfish or impair their taste;

“conditioning” means storage in tanks or any other installation containing clean sea-water or in natural sites to remove sand, mud or slime;

“consignment” means a quantity of either live bivalve molluscs or other shellfish, or both, handled in a dispatch centre or treated in a purification centre and subsequently intended for one or more customers;

“the Council Directive” means Council Directive [91/492/EEC\(3\)](#) of 15th July 1991 laying down the health conditions for the production and the placing on the market of live bivalve molluscs;

“derogation” means the grant pursuant to the Derogations Regulations of a further period within which to comply fully with the conditions for the approval of dispatch centres and purification centres specified in the relevant section of the Schedule to the Derogations Regulations;

“the Derogations Regulations” means the Food Safety (Live Bivalve Molluscs) (Derogations) Regulations 1992(4);

“designated bivalve production area” has the meaning given in regulation 3;

“dispatch centre” means any on-shore or off-shore installation for the reception, conditioning, washing, cleaning, grading or wrapping of either live bivalve molluscs or other shellfish, or both, for human consumption;

“E.coli” means faecal coliforms which also form indole from tryptophan at $44^{\circ} \text{C} \pm 0.2^{\circ} \text{C}$ within 24 hours;

“establishment” includes a dispatch centre, a purification centre or a processing plant;

“faecal coliform” means facultative, aerobic, gram-negative, non-sporeforming, cytochrome oxidase negative, rod-shaped bacteria that are able to ferment lactose with gas production in the presence of bile salts, or other surface active agents with similar growth-inhibiting properties at 44°C plus or minus 0.2°C within at least 24 hours;

“final consumer” means a person who buys live bivalve molluscs or other shellfish(a)for his own consumption or consumption by his partner, family or other person in solely domestic context; (b)for direct transport to, and consumption on, premises either in his ownership or under his personal supervision or in the ownership or under the personal supervision of a person employed by him; or (c)for cooking on premises either in his ownership or under his personal supervision or in the ownership or under the personal supervision of a person employed by him for sale as take-away food for consumption off those premises;

“food authority” means an authority specified in regulation 20 which is to enforce and execute these Regulations;

(2) OJNo. L281, 10.11.1979, p.47.

(3) OJ No. L268, 24.9.1992, p.1.

(4) S.I.1992/1508.

“gatherer” means any person who collects live bivalve molluscs or other shellfish by any means from a harvesting area for the purpose of handling and placing on the market;

“healthmark” means a certificate in the form specified in paragraph 1 of Schedule 1 containing the information specified in that form and that Schedule as required by regulation 11(1)(h);

“laying” means a foreshore, bed, pond, pit, ledge, float or similar place including a relaying area where live bivalve molluscs or other shellfish are liable to be taken harvested or deposited;

“marine biotoxins” means poisonous substances accumulated by bivalve molluscs feeding on plankton containing toxin;

“means of transport” means those parts of road or rail vehicles, aircraft or ships, including containers and trailers used in conjunction with any such transport, constructed or adapted for the transport of goods;

“movement document” means a document in the form specified in Schedule 2 containing the information specified in that form and that Schedule, as required by regulation 11(1)(b);

“other shellfish” means live echinoderms, tunicates and marine gastropods;

“permanent transport authorisation” means a written authorisation issued pursuant to regulation 11(1)(b) and in accordance with the form and procedure prescribed in paragraph 6(8) of Schedule 2;

“placing on the market” means, in relation to live bivalve molluscs or other shellfish for human consumption, whether raw or for the purpose of processing, the holding, exposure, displaying for sale, offering for sale, selling, consigning, delivering or any other associated activities of marketing;

“potable water” means water within the meaning of Directive [80/778/EEC\(5\)](#) (the quality of water intended for human consumption);

“private laying” means a laying where live bivalve molluscs or other shellfish are usually harvested or deposited by the owner or by a tenant of the laying and “tenant” includes any person authorised by the owner or by a tenant of that laying so to harvest or deposit;

“production area” means any sea, estuarine or lagoon area containing either natural deposits of bivalve molluscs or, sites used for the cultivation of bivalve molluscs, including relaying areas, from which live bivalve molluscs are taken;

“public laying” means a laying which is not a private laying;

“purification centre” means an establishment with tanks fed by naturally clean sea water or sea water that has been cleaned by appropriate treatment, in which live bivalve molluscs are placed for the time necessary to remove microbiological contamination, so making them fit for human consumption;

“relaying” means a transfer of live molluscs to an area of sea, estuary or lagoon for the purpose of removing any contamination, for the time necessary to remove such contamination, but does not include transfers to areas more suitable for further growth or fattening;

“relaying area” means any area of sea, estuary or lagoon within boundaries clearly marked and indicated by buoys, posts or any other fixed means and which is used exclusively for the natural purification of live bivalve molluscs;

“Sea Fisheries Committee” means a local fisheries committee for a sea fisheries district constituted under the Sea Fisheries Regulation Act 1966(6);

“wrapping” means the placing of a live bivalve mollusc in packaging material adequate for the purpose.

(5) OJ No. L229, 30.8.1980, p.11. Directive last amended by Directive [91/377/EEC](#) (OJ No. L377, 31.12.1991, p.48).

(6) [1966 c. 38](#).

(2) For the purpose of these Regulations a live bivalve mollusc or other shellfish shall be treated as if it is a food or food source even though it is usually supplied alive to the final consumer.

(3) In these Regulations—

- (a) a reference to a numbered regulation or Schedule is a reference to the regulation or Schedule in these Regulations which bears that number;
- (b) a reference in a regulation to a numbered paragraph is a reference to the paragraph of that regulation which bears that number.

(4) For the purposes of these Regulations the Schedule to the Derogations Regulations shall be construed as follows—

- (a) references to the competent authority in paragraph 4 of Section III and paragraph 1(a) of Section IV of that Schedule shall be taken to be references to the Ministers;
- (b) references to the competent authority in paragraph 11 of Section III and paragraphs 3 and 4 of Section IV of that Schedule shall be taken to be references to the food authority;
- (c) the reference to the competent authority in paragraph 12 of Section III of that Schedule shall be taken to be references to the food authority or a person authorised by the Ministers;
- (d) references to Chapter V shall be taken to be reference to Schedule 5 to these Regulations;
- (e) references to the registration document referred to in Chapter II, section 6 shall be taken to be references to a movement document or, where the requirements of paragraph 6 or Schedule 2 are met, to a permanent transportation authorisation;
- (f) the period laid down in paragraph 4 of Section IV for the preservation of data is six months.

Designation of certain 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 these Regulations, referred to in these Regulations as “designated bivalve production areas” and shall specify as respects each area of water designated by them whether it is—

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

and any such designation may be made subject to any limitation, condition or restriction as the Ministers think fit.

(2) Each food authority shall designate as a relaying area any area within its district which—

- (a) has been designated as being a class A or B area in accordance with Schedule 3, and
- (b) in its opinion is suitable for the relaying of live bivalve molluscs if the conditions specified in Parts 2 and 3 of Schedule 3 and in Schedule 4 are satisfied,

and, where the Ministers have notified the food authority that specified conditions relating to the matters mentioned in Schedule 4 should be complied with in operating 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.

(4) The Ministers shall maintain and publish—

- (a) a list of designated bivalve mollusc production areas, and
- (b) a list of any areas which food authorities have designated as suitable for relaying,

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

(5) The Ministers shall send a copy of the list, and of any amendments to it, to each food authority and to any other person of whom they are aware who, in its view, is directly affected by these Regulations.

(6) Each food authority shall take such action as it considers sufficient to bring the relevant part of such list to the attention of any harvester, handler, and operator of either a purification centre or dispatch centre in its area.

Areas unsuitable for production or harvesting

4. The Ministers may at any time designate any area as an area unsuitable for production or harvesting of live bivalve molluscs or other shellfish, or both, and any such area shall be described as appropriate as a “designated prohibited area for bivalve mollusc production”, a “designated prohibited area for other shellfish production”, or “designated prohibited area for live bivalve molluscs and other shellfish production”.

Alterations to designated areas

5.—(1) Subject to paragraph (3) the Ministers may at any time—

- (a) vary the boundary of any area designated under regulation 3(1) or 4,
- (b) impose limitations, restrictions or conditions on the use of any area designated under regulation 3(1) or 4,
- (c) alter the class of any area within a designated bivalve production area,
- (d) vary the designation of any area designated under regulation 4,

for such period as he thinks fit, and shall communicate such amendment to the food authority and to persons who appear to be affected.

(2) Subject to paragraph (3) the Ministers may at any time—

- (a) if the area is no longer suitable for the gathering of live bivalve molluscs in accordance with the requirements of Schedule 3, revoke the designation of a designated bivalve production area;
- (b) if the area is no longer suitable for the relaying of live bivalve molluscs in accordance with the requirements of Schedules 3 and 4, revoke the designation of a relaying area.

(3) The Ministers before exercising the power conferred by paragraph (1) or (2) shall invite representations from any food authority, gatherer or handler of whom they are aware and who appears to them to be likely to be affected by the exercise of that power.

(4) A food authority may, having first invited and had regard to representations from any person likely to be affected, at any time vary the designation of a relaying area made under regulation 3(2), and shall communicate such amendment to the Ministers.

Restriction on production and harvesting of bivalve molluscs

6. No live bivalve molluscs produced or harvested in Great Britain shall be placed on the market for human consumption unless they are produced at or harvested from a designated bivalve production area and such production or harvesting is in accordance with the requirements of these Regulations.

Approval of dispatch centres and purification centres

7.—(1) Subject to the provisions of these Regulations any person who intends to operate a dispatch centre or a purification centre on or after 15th January 1993 shall before doing so apply to the food authority in whose area the dispatch centre is situated for approval of that centre.

(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 having regard to the matters specified in the relevant Parts of the Schedule to the Derogations Regulations.

(3) A person who has been granted a derogation by the Secretary of State in respect of a dispatch or purification centre may, when applying for approval of that centre, claim the benefit of that derogation in respect of any operations carried out during the period of that derogation subject to compliance with the conditions on which it was granted.

(4) No approval shall be granted for a dispatch centre or purification centre unless the food authority is satisfied—

- (a) in respect of an application for a dispatch centre, that the conditions specified in Parts 1, 2 and 4 of the Schedule to the Derogations Regulations are satisfied, or
- (b) in respect of an application for a purification centre, that the conditions specified in Parts 1, 2 and 3 of the Schedule to the Derogations Regulations are satisfied and that any operating conditions are in accordance with a system approved by the Ministers pursuant to regulation 7(5),

having regard to the effect of any derogation claimed by the applicant.

(5) An approval for the purposes of this regulation may be granted subject to limitations as to the particular activities approved and the intensity of use, and, where the Ministers have notified the food authority that specified conditions for the operation of a purification centre relating to the matters mentioned in Section III of the Schedule to the Derogations Regulations 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 in accordance with paragraph (1) of the result of the application and, in the case of a refusal, the reasons for that refusal.

(7) If such an application is approved the food authority shall—

- (a) designate the dispatch centre or purification centre by a unique approval number,
- (b) notify the Secretary of State of the approval and the approval number allocated, and
- (c) in a case where paragraph (3) applies specify that the approval will expire on the date on which the derogation is due to expire.

Operation of centres while appeal pending

8. Where an appeal against any decision taken by a food authority to refuse or to grant subject to any limitation or condition an approval under regulation 7 is made to a magistrates' court or a sheriff in accordance with section 37(1)(c) of the Act as applied by regulation 19, the applicant may continue to operate the centre the subject of the appeal, or operate it free of such limitation or condition, until such time as the appeal is finally determined.

Supplementary provisions about approvals

9.—(1) If before finally determining an application a food authority is minded to refuse the application it shall, and in any other circumstance where it considers it reasonable to do so it may, invite the applicant to make oral representations, on a date within 2 months of the invitation, on any matters specified by the food authority, in writing, which it considers relevant to its final determination.

(2) Before finally determining an application a food authority may in writing request an applicant to provide supplementary written information to enable it to properly determine the application.

(3) A person may at any time apply to a food authority to vary the terms or limitations of any approval.

Restriction on the operation of dispatch and purification centres

10.—(1) No person shall operate any dispatch centre or purification centre unless it has been approved by the food authority and the requirements of the approval, of the Schedule to the Derogations Regulations and of any applicable derogation are complied with.

(2) The proprietor of each dispatch centre or purification centre shall ensure that—

- (a) representative numbers of samples for laboratory examination are regularly taken and analysed so as to establish an historical record on the basis of the areas where batches come from and of the health quality of the live bivalve molluscs and other shellfish both before and after handling at a dispatch centre or purification centre, and
- (b) the sampling and recording as specified in the Schedule to the Derogations Regulations is undertaken.

Restrictions on marketing of molluscs and shellfish

11.—(1) Subject to the following provisions of these Regulations no person shall place live bivalve molluscs on the market for immediate human consumption unless they satisfy the following requirements—

- (a) except in the case of those pectinidae which are not aquaculture products within the definition in the Food Safety (Fishery Products) Regulations 1992(7) they originate from a designated bivalve production area of any class specified in Schedule 3 and any conditions or limitations specified in that Schedule in relation to that class have been complied with;
- (b) they have been harvested from such production area, kept and transported to an approved dispatch centre, approved purification centre, approved relaying area or approved processing plant in accordance with the requirements of Schedule 2 and are accompanied by a movement document in the form and containing the information prescribed in that Schedule or authorised by a permanent transport authorisation;
- (c) they have, where necessary, been relaid in accordance with Schedule 4;
- (d) they have been handled hygienically and where appropriate they have been purified or been subject to intensive purification at an approved purification centre;
- (e) they are as specified in Schedule 5;
- (f) ny wrapping is in accordance with Schedule 6;
- (g) they have been stored and transported under satisfactory conditions of hygiene and in particular in accordance with the requirements specified in Parts 1 and 2 of Schedule 7;
- (h) they bear the information comprising the healthmark in accordance with the requirements of Schedule 1 and, in particular, display the healthmark in the way prescribed in that Schedule.

(2) Subject to the following provisions of these Regulations, no person shall place any other shellfish on the market unless they satisfy the requirements in sub-paragraphs (e) to (h) in paragraph (1) and the following requirements—

- (a) after harvesting they have been transported to an approved dispatch centre or approved processing plant;

(b) they have been handled hygienically.

(3) A retailer who splits up the contents of a consignment of live bivalve molluscs or other shellfish which are not wrapped in individual consumer-size parcels shall keep the healthmark which was attached to the consignment for a period of not less than 60 days.

Exemptions for marketing molluscs and other shellfish within UK

12.—(1) Subject to paragraphs (2) and (3), during any calendar year, a coastal fisherman who has notified the food authority as specified in paragraph (2) may directly transfer to a retailer or final consumer within the United Kingdom for immediate human consumption a small quantity of any species of live bivalve molluscs gathered from a Class A area or of other shellfish, and where he does so, in the case of live bivalve molluscs regulation 11(1)(b), (c), (f) and (h) and, in the case of other shellfish, regulation 11(1)(f) and (h) and (2)(a) shall not apply to him.

(2) A coastal fisherman who proposes to transfer live bivalve molluscs or other shellfish in accordance with paragraph (1) shall—

- (a) prior to his gathering for the first time in the district of any food authority notify that food authority in writing of his intention to do so and shall at the same time supply the information specified in Schedule 8, and
- (b) similarly notify the food authority of any subsequent changes to the information originally supplied.

(3) For the purpose of paragraph (1) a “small quantity” means in relation to each species listed in column (a) in the table in this paragraph an amount not exceeding the maximum quantity specified in column (b) in that table—

Table

(a) species	(b) maximum amount
Cockles	25.0 tonnes
Oysters	5.0 tonnes
King Scallops	5.0 tonnes
Queen Scallops	10.0 tonnes
Mussels	20.0 tonnes
Marine Gastropods	20.0 tonnes
Other live bivalve molluscs	10.0 tonnes

Temporary prohibition orders concerning layings

13.—(1) Subject to paragraph (5) a food authority may, if satisfied that the consumption of live bivalve molluscs or other shellfish taken from a laying is likely to cause a risk to public health, make a temporary prohibition order prohibiting the placing on the market, including a placing in the circumstances of regulation 12, of any such molluscs or other shellfish from that laying.

(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.

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

- (a) in the case of a private laying serve a notice on every owner and tenant of the laying whose name and address can with reasonable diligence be ascertained containing the information specified in paragraph (4); or
 - (b) in the case of a public laying affix notices in the vicinity of the laying 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 any Sea Fisheries Committee in whose district the laying is situated.
- (4) The information referred to in paragraph (3)(a) is—
- (a) the reasons of the food authority for making the order;
 - (b) the action which the food authority is requesting the Ministers to take pursuant to regulation 5(1) and in particular the detail of any restrictions or conditions;
 - (c) the right of any person affected to make representations to the Ministers pursuant to regulation 5(2) before they finally determine the matter; and
 - (d) how a person may exercise such right.
- (5) A food authority shall not make a temporary prohibition order in respect of any laying if it has made such an order in respect of that laying within the preceding 28 days, unless the Ministers give consent to such action.
- (6) It is an offence to place on the market live bivalve molluscs or other shellfish taken from layings subject to the restrictions of a temporary prohibition order.

Monitoring by Ministers and food authorities

- 14.—(1) The Ministers shall perform the functions specified in paragraph 1 of Schedule 9.
- (2) Each food authority shall perform the functions specified in paragraph 2 of Schedule 9.

Imports

15. A person may only place on the market live bivalve molluscs or other shellfish which have been imported in the United Kingdom if subsequent to importation they have been handled in accordance with sub-paragraphs (b) to (h) of regulation 11(1) of these Regulations.

Food treated as failing to comply with food safety requirements

16.—(1) A food authority may certify any live bivalve molluscs or other shellfish in respect of which any of the requirements of these Regulations has not been complied with as being a food or food source which fails to comply with these Regulations.

(2) Any live bivalve molluscs or other shellfish which in accordance with these regulations is certified as being a food or food source which fails to comply with these Regulations may be treated for the purpose of section 9 of the Act as failing to comply with food safety requirements.

False information

17. Any person who for any purpose connected with these Regulations furnishes information which he knows to be false shall be guilty of an offence triable summarily and liable on conviction to a fine not exceeding the statutory maximum.

Offences and penalties

18.—(1) Any person who fails to comply with any provision of the Regulations specified in paragraph (2) below shall be guilty of an offence.

- (2) The Regulations specified for the purposes of paragraph (1) above are 6, 10 and 11.
- (3) Any person guilty of an offence under these Regulations shall be liable—
- (a) on summary conviction, to a fine not exceeding the statutory maximum; and
 - (b) on conviction on indictment, to a fine or imprisonment for a term not exceeding two years or both.
- (4) If the proprietor of any centre, an owner or tenant of any laying, a gatherer or a handler fails to take all reasonable steps to secure the compliance of any person employed by him or any person admitted to the place where the business is undertaken with any of the provisions referred to in paragraph (2) above he shall be guilty of an offence against these Regulations.

Applications of provisions of the Act

19.—(1) The following provisions of the Act shall apply for the purposes of the Regulations as they apply for the purposes of sections 8, 14 and 15 of the Act and unless the context otherwise requires a reference in them to the Act shall be construed as a reference to these Regulations: section 3 (presumptions that food intended for human consumption);

- section 20 (offences due to fault of another person);
- section 21 (defence of due diligence);
- section 30(8) (which relates to documentary evidence);
- section 32 (powers of entry);
- section 33 (obstruction etc of officers);
- section 34 (time limit for prosecutions);
- section 36 (offences by bodies corporate).

(2) Section 6(3) of the Act (discharge of duties of food authorities by Ministers) shall apply as respects functions imposed on food authorities under these Regulations as it does as respects a duty imposed on a food authority by section 6(2) of the Act.

(3) Section 37(1)(c) of the Act (appeals to magistrates' court or sheriff) shall apply in relation to a decision to refuse or grant subject to any condition or limitation an approval required by regulation 7 as it does to a decision to refuse, cancel, suspend or vary a licence required by Regulations under Part II of the Act.

Enforcement and execution

- 20.**—(1) Subject to paragraph (2) these Regulations shall be enforced and executed—
- (a) as respects each London borough or district in England and Wales, by the council of that borough or district;
 - (b) as respects the City of London (including the Temples), by the Common Council;
 - (c) as respects each islands area or district in Scotland, by the islands or district council; and
 - (d) as respects the Isles of Scilly by the Council of the Isles of Scilly.
- (2) Where any functions are assigned—
- (a) by an order under section 2 or 7 of the Public Health (Control of Disease) Act 1984⁽⁸⁾ to a port health authority; or
 - (b) by an order under section 172 of the Public Health (Scotland) Act 1897⁽⁹⁾ to a port local authority;

⁽⁸⁾ 1984 c. 22.

⁽⁹⁾ 1897 c. 38.

these Regulations shall be enforced by that authority within its area and not by the food authority mentioned in paragraph (1).

Transitional provisions

21. A person shall not be prevented by regulation 11 from placing on the market any live bivalve mollusc or other shellfish—

- (a) by reason of any harvesting, transporting, relaying, handling, wrapping or storing of such mollusc or shellfish which took place before 15th January 1993;
- (b) where the mollusc or shellfish left a dispatch centre or purification centre before 15th January 1993, by reason of the failure of that batch of molluscs or shellfish to bear the healthmark,

and no person shall be regarded as having committed an offence in relation to such harvesting, transporting, relaying, handling, wrapping or storing or in relation to the failure of such batch of molluscs or shellfish to bear the healthmark,

(2) Until 1st January 1994 a person who has applied for approval in accordance with regulation 7 may continue to operate the dispatch centre or purification centre the subject of the application until the application is finally determined by the food authority, provided it was operating at any time during the period of 12 months ending on 14th January 1993 and it is not prohibited from operating by reason of any other legal requirement.

Amendment of Regulations

22.—(1) The Derogations Regulations shall be amended by the omission of regulation 3.

(2) The Public Health (Shell-Fish) Regulations 1934⁽¹⁰⁾ are hereby revoked.

(3) Article 10 of the Conway Mussel Fishery (Amendment) Order 1948⁽¹¹⁾ and paragraph 4 of the Schedule to the Conway Mussel Fishery (Variation) Order 1979⁽¹²⁾ shall be omitted.

In witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 10th December 1992.

L.S.

John Selwyn Gummer
Minister of Agriculture, Fisheries and Food

Signed by authority of the Secretary of State for Health

Department of Health
10th December 1992

Cumberlege
Parliamentary Under Secretary of State

⁽¹⁰⁾ SR & O 1934 No. 1342.

⁽¹¹⁾ S.I. 1948/1888 (as amended by S.I. 1979/1087).

⁽¹²⁾ S.I. 1979/1087.

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

10th December 1992

David Hunt
Secretary of State for Wales

Scottish Office
11th December 1992

Hector Monro
Parliamentary Under Secretary of State

SCHEDULE 1

Regulation 11(1)(h)

MARKING OF CONSIGNMENTS

1. All parcels in a consignment of live bivalve molluscs or other shellfish shall be provided with a healthmark so that the original dispatch centre may be identified at all times during transport and distribution until retail sale and shall be in the following form:

HEALTHMARK[LIVE BIVALVE MOLLUSCS/OTHER SHELLFISH]

Country of dispatch	Approval number of dispatch centre
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Species consigned (scientific name)	Species consigned (common name)
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Day and month of wrapping

[EITHER "WARNING THESE ANIMALS MUST BE ALIVE WHEN SOLD" OR DATE OF DURABILITY]

2.—(1) The healthmark may be—

- (a) printed on the wrapping material, or
- (b) affixed as a separate label to the wrapping material, or
- (c) put inside the wrapping, or
- (d) of a twist-tie or staple design.

(2) A self-adhesive healthmark must not be used, unless it is not detachable.

(3) All types of healthmark must be for single use only and are not transferable.

3. The healthmark must be durable and waterproof, and the information presented must be legible, indelible and in easily decipherable characters.

SCHEDULE 2

Regulation 11(1)(b)

REQUIREMENTS FOR HARVESTING AND TRANSPORTATION

1. Harvesting techniques must not cause excessive damage to the shells or tissues of live bivalve molluscs or other shellfish.

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

2. Live bivalve molluscs or other shellfish must be adequately protected from crushing, abrasion or vibration after harvesting and must not be exposed to extremes of hot or cold temperature.

3. Techniques for harvesting, transporting, landing and handling live bivalve molluscs or other shellfish must not result in additional contamination of the product, nor in a significant reduction in the quality of the product, nor in any changes significantly affecting their ability to be treated by purification, processing or relaying.

4. Live bivalve molluscs or other shellfish must not be re-immersed in water which could cause additional contamination between harvesting and landing.

5.—(1) The means of transport used for transporting live bivalve molluscs or other shellfish must be used under conditions which protect the latter from additional contamination and crushing of shells, and must permit adequate drainage and cleaning.

(2) In the event of bulk transport over long distances of live bivalve molluscs to a dispatch centre, purification centre, relaying area or processing plant, the means of transport must be equipped in such a way as to ensure the best survival conditions possible, and in particular must comply with the requirements laid down in paragraph 2 of Part 2 of Schedule 7.

6.—(1) A movement document, as prescribed in this paragraph, for the identification of each batch of live bivalve molluscs during transport from the production area to a dispatch centre, purification centre, relaying area or processing plant shall be issued by the food authority, on request, to the gatherer for completion by the gatherer in respect of each batch in a way which is both legible and indelible.

(2) The gatherer shall ensure the completed movement document accompanies each batch at all times.

(3) If a batch in respect of which a movement document has been issued is split for any reason the person having control of the original batch at the time of the splitting shall ensure that the information accompanying the original batch accompanies each sub-batch in the same form as the movement document together with the full name and address of the person splitting the batch and the additional information concerning the subsequent movement of the sub-batches.

(4) A movement document shall be in the following form—
LIVE BIVALVE MOLLUSCS MOVEMENT DOCUMENT

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.....

Movement Document No.

Issued by:

Date of issue:

.....

Name of gatherer	Signature of gatherer
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.....

Food Authority where molluscs landed	Address of gatherer
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.....

Date of gathering	Place of gathering
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.....

Names of shellfish species being moved (common and scientific)	Class of production area (A, B, or C)
---	--

.....

Quantity of shellfish being moved	Name and address of proposed destination of shellfish being moved, including approval number
--	---

.....

Date of receipt
Place of receipt
Approval number of recipient

.....

REMINDER – This document is to be kept by the person receiving the shellfish for a period of not less than 60 days.

- (5) Each movement document must be numbered permanently in sequence by the food authority.
- (6) Each food authority shall keep a register indicating the number of each movement document together with the name of the person collecting the live bivalve molluscs and of the person to whom the document was issued.
- (7) The person receiving a movement document for each batch of live bivalve molluscs shall put on it the date the batch was received by either a dispatch centre, purification centre or relaying area and shall keep it available for inspection for a period of at least 60 days.

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(8) If gathering is or is to be, carried out by a person employed by the person who operates the dispatch centre, purification centre, relaying area or processing plant of destination, the food authority may, if satisfied that the gatherer will comply with the requirements of these Regulations concerning gathering and handling issue to the gatherer a permanent transport authorisation (which may be withdrawn at any time) absolving the gatherer from the requirement to use movement documents for transfers from a production area specified in that authorisation to a dispatch centre, purification centre, relaying area, or processing plant specified in that authorisation.

7. If a production or relaying area is closed temporarily, pursuant to regulation 4 or 13, the food authority shall refrain from issuing further movement documents and permanent transport authorisations for that area and the food authority may suspend the validity of any such documents or authorisations already issued for the area.

SCHEDULE 3

Regulation 3

CONDITIONS FOR PRODUCTION AREAS

PART 1

class a areas

An area from which live bivalve molluscs can be gathered for direct human consumption provided such molluscs satisfy the requirements specified in Schedule 5.

PART 2

class b areas

An area from which live bivalve molluscs may—

- (a) be gathered but only placed on the market for human consumption after treatment in a purification centre or after relaying, or
- (b) used for relaying providing such relaying is followed by purification, or
- (c) be heat treated by an approved process in an establishment approved for the purposes of the Food Safety (Fishery Products) Regulations 1992.

Conditions in relation to a class B area

1. Prior to relaying or treatment in a purification centre or heat treatment, live bivalve molluscs from these areas must not exceed in 90% of samples the limits of either—

- (a) a five-tube, three-dilution MPN-test of 6000 faecal coliforms per 100 grammes of flesh, or
- (b) 4,600 E.Coli per 100 grammes of flesh.

2. After relaying or purification such molluscs must satisfy the requirements specified in Schedule.

PART 3

class c areas

An area from which live bivalve molluscs can be gathered but placed on the market for human consumption only after—

- (a) a relaying period of at least 2 months, whether or not such relaying is combined with purification, or
- (b) intensive purification.
- (c) heat treatment by an approved process in an establishment approved for the purposes of the Food Safety (Fishery Products) Regulations 1992.

Conditions in relation to a class C area

1. Such molluscs must not, prior to relaying and any periods of purification or heat treatment, exceed the limits of a five-tube, three-dilution MPN-test of 60,000 faecal coliforms per 100 grammes of flesh.
2. For the purpose of this Schedule “intensive purification” means purification at an approved purification centre for a period and in accordance with such operating conditions as may have been previously approved by the Ministers.
3. Such molluscs must, after relaying and any period of purification, satisfy the requirements specified in Schedule 5.

PART 4

relaying areas

An area of either Class A or Class B areas from which live bivalve molluscs can be gathered.

SCHEDULE 4

Regulation 11(1)(c)

CONDITIONS FOR RELAYING LIVE BIVALVE MOLLUSCS

The following conditions must be met:

1. live bivalve molluscs must be gathered and transported in accordance with the requirements of Schedule 2;
2. techniques for handling live bivalve molluscs intended for relaying must permit the resumption of filter-feeding activity after immersion in natural waters;
3. live bivalve molluscs must not be relaid at a density which does not permit purification;
4. live bivalve molluscs must be immersed in seawater at the relaying area for an appropriate period which must exceed the time taken for levels of faecal bacteria to become reduced to the levels permitted by these Regulations and in particular either the standards specified in Schedule 5 or the standards in Part 2 of Schedule 3 where relaying is to be followed by purification;
5. the minimum water temperature for effective relaying must, where necessary, be determined for each species of live bivalve mollusc and each approved relaying area, by the Minister and the food authority for the area where the laying is situate, acting jointly, and be announced by the food authority;

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6. the boundaries of the sites must be physically delineated by buoys, poles or any other fixed means; there must be a minimum distance of 300 metres between relaying areas, and also between relaying areas and production areas;

7. sites within a relaying area must be well separated to prevent mixing of batches; the “all in, all out” system must be used, so that a new batch cannot be brought in before the whole of the previous batch has been removed;

8. permanent records of the source of live bivalve molluscs, relaying periods, relaying areas and subsequent destination of the batch after relaying must be kept by the operators of relaying areas for inspection by the food authority;

9. after harvesting from the relaying area, batches must, during transport from the relaying area to the approved dispatch centre, purification centre or processing plant, be accompanied by the movement document referred to in paragraph 6 of Schedule 2, unless a permanent transport authorisation has been issued by a food authority.

SCHEDULE 5

Regulation 11(1)(e)

REQUIREMENTS CONCERNING LIVE BIVALVE MOLLUSCS AND OTHER SHELLFISH

Live bivalve molluscs and other shellfish intended for immediate human consumption must comply with the following requirements:

1. The possession of visual characteristics associated with freshness and viability, including shells free of dirt, an adequate response to percussion, and normal amounts of intravalvular liquid.

2. They must contain less than 300 faecal coliforms or less than 230 E.Coli per 100g of mollusc flesh and intravalvular liquid based on a five-tube, three-dilution MPN-test or any other bacteriological procedure shown to be of equivalent accuracy.

3. They must not contain salmonella in 25g of mollusc flesh.

4. They must not contain toxic or objectionable compounds occurring naturally or added to the environment such as those listed in the Annex to Directive [79/923/EEC](#) in such quantities that the calculated dietary intake exceeds the permissible daily intake (PDI) or that the taste of the molluscs may be impaired.

5.—(1) The total Paralytic Shellfish Poison (PSP) content in the edible parts of molluscs that is the whole body or any part edible separately must not exceed 80 micrograms per 100g of mollusc flesh in accordance with the biological testing method-in association if necessary with a chemical method for detection of Saxitoxin.

(2) If the results of such tests are challenged, the reference method shall be the biological method.

6. The customary biological testing methods must not give a positive result to the presence of Diarrhetic-Shellfish Poison (DSP) in the edible parts of molluscs that is the whole body or any part edible separately.

7. In the absence of routine virus testing procedures and the establishment of virological standards, health checks must be based on faecal bacteria counts.

8. Any examinations for checking compliance with the requirements of this Schedule must be carried out in accordance with methods which may from time to time be approved for the purpose of these Regulations by the Ministers.

SCHEDULE 6

Regulation 11(1)(f)

WRAPPING

1.—(1) Live bivalve molluscs and other shellfish must be wrapped under satisfactory conditions of hygiene.

(2) The wrapping material or container of such molluscs or shellfish shall—

- (a) not impair the organoleptic characteristics of the live bivalve molluscs or shellfish,
- (b) not be capable of transmitting substances harmful to human health to the live bivalve molluscs or shellfish,
- (c) be strong enough to give adequate protection to the live bivalve molluscs or shellfish.

2. Oysters must be wrapped with the concave shell downwards.

3. All wrappings of live bivalve molluscs must be sealed and remain sealed from the dispatch centre until delivery to the consumer or retailer but wrappings may be unwrapped and repackaged provided that—

- (a) the person who unwraps the product keeps records of the origin of all live bivalve molluscs and other shellfish received and of the place of dispatch, and
- (b) live bivalve molluscs and other shellfish from different dispatch centres are not mixed when repackaging, and
- (c) a healthmark is provided on the repackaging showing the same information as required by Schedule 1 together with the original dispatch details plus the registration number of the market, or in the case of a different intermediary, the full name and address of that person, and
- (d) the person who unwraps the product keeps the healthmark for a period of not less than 60 days.

SCHEDULE 7

Regulation 11(1)(g)

PART 1

preservation and storage

1. In any storing rooms, live bivalve molluscs and other shellfish or both must be kept at a temperature which does not adversely affect their quality and viability; the wrapping must not come into contact with the floor of the store room, but must be placed on a clean, raised surface except in the circumstances provided in paragraph 3 of Schedule 6.

2. Re-immersion in or spraying with water of live bivalve molluscs or other shellfish must not take place after they have been wrapped and have left the dispatch centre except in the case of retail sale at the dispatch centre.

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PART 2

transport from the dispatch centre

1. Except where paragraph 3 of Schedule 6 applies, consignments of live bivalve molluscs or other shellfish intended for human consumption must be transported wrapped in sealed parcels from the dispatch centre until offered for sale to the consumer or retailer.
2. The means of transport used for consignments of live bivalve molluscs or other shellfish or both must have the following characteristics:
 - (a) their interior walls and any other parts which might come into contact with the live bivalve mollusc or other shellfish must be made of corrosion-resistant materials; the walls must be smooth and easy to clean;
 - (b) they must be suitably equipped to provide efficient protection of the live bivalve molluscs or other shellfish against extremes of heat and cold, contamination with dirt or dust, and damage to the shells from vibration and abrasion;
 - (c) the live bivalve molluscs or other shellfish must not be transported with other products which might contaminate them.
3. Live bivalve molluscs or other shellfish must be transported and distributed using closed vehicles or containers which maintain the product at a temperature which does not adversely affect their quality and viability.
4. The parcels containing live bivalve molluscs or other shellfish must not be transported in direct contact with the floor of the vehicle or container but must be supported on raised surfaces or by some other means which prevents such contact.
5. Where ice is used in transporting consignments of live bivalve molluscs or other shellfish, it must have been made from potable water or clean sea water.

SCHEDULE 8

Regulation 12

NOTIFICATION REQUIREMENTS

1. Name of person notifying.
2. Address of person notifying.
3. Telephone number of person notifying.
4. Address of premises where person notifying keeps the equipment he uses for gathering.
5. Address of premises where notifier intends to put gathered live bivalve molluscs or other shellfish when landed.
6. If applicable, name address and approval number of any dispatch or purification centre to which the notifier intends to send live bivalve molluscs after gathering.
7. Intended place of landing of gathered bivalve molluscs or other shellfish.

SCHEDULE 9

Regulation 14

PUBLIC HEALTH CONTROL AND MONITORING OF PRODUCTION

1. The Ministers shall undertake, or may require food authorities to undertake on their behalf, the periodic monitoring of bivalve mollusc relaying and production areas to determine—

- (a) whether toxin producing plankton are present in production and relaying waters or biotoxins are present in live bivalve molluscs; and
 - (b) whether chemical contaminants are present.
2. A food authority shall undertake periodic monitoring of live bivalve mollusc relaying and production in areas in order to—
- (a) preclude any malpractice with regard to the origin and destination of the live bivalve molluscs;
 - (b) determine the microbiological quality of the live bivalve molluscs in relation to the production and relaying areas.
- 3.—(1) Sampling plans for the purposes of paragraphs 1 and 2 of this Schedule shall in particular take account of:
- (a) likely variations in faecal contamination at each production and relaying area;
 - (b) possible variations in production and relaying areas in the presence of plankton containing marine biotoxins;
 - (c) possible contamination of the molluscs in the production and relaying area.
- (2) Sampling plans referred to in sub-paragraph (1)(b) above shall be carried out as follows—
- (a) in relation to monitoring, periodic sampling shall be organized to detect changes in the composition of the plankton containing toxins and the geographical distribution of the plankton,
 - (b) where periodic sampling leads to a suspicion of accumulation of toxins in mollusc flesh, intensive sampling shall be carried out and molluscs from the relevant area shall not be placed on the market until new sampling has provided satisfactory toxicity test result;
 - (c) where intensive sampling is to be carried out, it shall consist of—
 - (i) monitoring plankton in the growing and fishing waters by increasing the number of sampling points and the number of samples, and
 - (ii) the carrying out of toxicity tests using the molluscs from the affected area which are most susceptible to contamination.
- 4.—(1) Laboratory tests shall be carried out to check compliance with the requirements for the end product as laid down in Schedule 5.
- (2) A control system shall be established to verify that the level of marine biotoxins does not exceed safety limits.
- 5.—(1) A food authority shall inspect establishments at regular intervals and those inspections shall include, in particular, checks—
- (a) to determine whether the approval conditions are still being complied with;
 - (b) on the cleanliness of the premises, facilities, equipment and on staff hygiene;
 - (c) to determine whether the live bivalve molluscs and other shellfish are handled and treated correctly;
 - (d) on the correct application and functioning of purification or conditioning systems;
 - (e) on the ledger books referred to in paragraph 12 of Part 3 of Schedule 1;
 - (f) on the correct use of health marks.
- (2) The checks referred to in paragraph (1) above may include the taking of samples for laboratory tests.

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- (3) The results of such tests must be notified to the persons responsible for the establishments.
6. A food authority shall check on the storage and transport conditions for consignments of live bivalve molluscs and other shellfish.
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EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations implement parts of Council Directive 91/492/EEC of 15th July 1991 (“the Directive”) which lays down health conditions for the production and placing on the market of live bivalve molluscs. Part of the Directive was implemented by the Food Safety (Live Bivalve Molluscs) (Derogations) Regulations 1992 (“the Derogations Regulations”).

The Derogations Regulations specify the procedure to be followed on an application for a derogation from some of the requirements of the Directive in relation to purification centres which requirements are set out in the Schedule to those Regulations.

The Directive makes provision in relation to live bivalve molluscs and also to echinoderms, tunicates and marine gastropods (in these Regulations referred to as “other shellfish”). Provisions relating to purification do not relate to other shellfish.

Regulation 3 provides for the designation of areas called “designated bivalve production areas” for the harvesting and production of live bivalve molluscs and for the designation of areas for the relaying of live bivalve molluscs, and for the keeping of lists of such areas in accordance with article 5.2(a) of the Directive.

Regulation 4 provides for the designation of areas unsuitable for the production and harvesting of live bivalve molluscs and other shellfish in accordance with article 5.3 of the Directive.

Regulation 5 provides for the alteration of designated areas and relaying areas and for designations to be revoked in certain circumstances.

Regulation 6 prohibits the production and harvesting of live bivalve molluscs unless they are from a designated bivalve production area (see article 5.2(a) of the Directive).

Regulations 7 and 9 are about the approval of dispatch and purification centres (see article 5.1(a) of the Directive) subject to the effect of any derogation under the Derogations Regulations.

Regulation 8 permits the operation of such a centre pending an appeal against a decision to refuse an approval of a centre.

Regulation 10 prohibits the operation of a dispatch or purification centre except in accordance with the requirements specified in the Schedule to the Derogations Regulations and any other limitations imposed under the Regulations (article 5.1(a) of the Directive).

Regulation 11 implements article 3.1 of the Directive and requires that live bivalve molluscs for immediate consumption should be placed on the market only where the requirements specified are satisfied. It also imposes some requirements for other shellfish.

Regulation 12 provides for an exemption from regulation 11 where a coastal fisherman places a small quantity of products on the market (see article 2.16 of the Directive).

Regulation 13 provides for the food authority to make a temporary prohibition order in relation to a laying.

Regulation 14 provides for monitoring by the Ministers (defined in section 4(1) of the Food Safety Act 1990)-see article 5.1(b) and 5.2.(b).

Chapter III of the Directive relates to imports from third countries. Most of this part of the Directive is being implemented elsewhere, but regulation 15 makes provision for certain requirements for the transport and handling to apply to live bivalve molluscs and other shellfish imported into the United Kingdom (whether from a third country or from a member State) are met.

Regulations 16 to 22 provide for offences, the application of certain provisions of the Food Safety Act 1990, enforcement and execution of the Regulations, amendment of inconsistent or spent statutory instruments and for transitional provisions.