1993 No. 52

FOOD

The Food Safety (Live Bivalve Molluscs and Other Shellfish) Regulations (Northern Ireland) 1993

Made . . . . . 9th February 1993

Coming into operation . . 17th March 1993

The Department of Health and Social Services in exercise of the powers conferred on it by Articles 15(1), 16(1), 25(1)(*b*) and (3), 26(3), 47(2), and 48(2) of, and paragraphs 2(2), 5(1) and (2), 6(1) and 7(1) of Schedule 1 to the Food Safety (Northern Ireland) Order 1991(**a**) and of all other powers enabling it in that behalf and after consultation in accordance with Article 47(3) of that Order with such organisations as appear to it to be representative of interests likely to be substantially affected by these Regulations, hereby makes the following Regulations:

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Food Safety (Live Bivalve Molluscs and Other Shellfish) Regulations (Northern Ireland) 1993 and shall come into operation on 17th March 1993.

(2) 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(**b**), (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 the storage in tanks or any other installation containing clean sea water, or in natural sites to remove sand, mud or slime;

(**a**) S.I. 1991/762 (N.I. 7). *See* Article 2(2) for the definitions of "regulations" and "the Department concerned"

(**b**) O.J. No. L281, 10.11.79, p. 47

"consignment" means a quantity of 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(**a**), 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 (Northern Ireland) 1992(**b**);

"designated bivalve production area" has the meaning given in regulation 2;

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

"E. coli" means faecal coliforms which also form indole from tryptophan at 44°C ± 0.2°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 ± 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 a 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;

"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;

(**a**) O.J. No. L268, 24.9.92, p. 1
(**b**) S.R. 1992 No. 295

"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 10(1)(*h*);

"laying" means a foreshore, bed, pond, pit, ledge, float or similar place including a relaying area where 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 10(1)(*b*);

"the Order" means the Food Safety (Northern Ireland) Order 1991;

"other shellfish" means live echinoderms, tunicates and marine gastropods;

"permanent transport authorisation" means a written authorisation issued pursuant to regulation 10(1)(*b*) and in accordanace 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(**a**) (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;

(**a**) O.J. No. L229, 30.8.80, p. 11. Directive last amended by Directive 91/377/EEC (O.J. No. 377, 31.12.91, p. 48)

"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;

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

(3) 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.

(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 Department;

(*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 district council;

(*c*) the reference to the competent authority in paragraph 12 of Section III of that Schedule shall be taken to be a reference to the district council or a person authorised by the Department;

(*d*) references to Chapter V shall be taken to be references to Schedule 5 to these Regulations;

(*e*) references to the registration document referred to in Chapter II, point 6 shall be taken to be references to a movement document or, where the requirements of paragraph 6 of Schedule 2 to these Regulations 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

2.—(1) The Department 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 it 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 Department thinks fit.

(2) Each district council 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 Department has notified the district council that specified conditions relating to the matters mentioned in Schedule 4 should be complied with in operating the relaying area, the district council shall make that designation subject to those conditions.

(3) The district council shall notify the Department of any designation made under paragraph (2) and of its terms.

(4) The Department shall maintain and publish—

(*a*) a list of designated bivalve mollusc production areas, and

(*b*) a list of any areas which district councils have designated as suitable for relaying,

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

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

(6) Each district council 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

3. The Department 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 a ''designated prohibited area for live bivalve molluscs and other shellfish production''.

Alterations to designated areas

4.—(1) Subject to paragraph (3) the Department may at any time—

(*a*) vary the boundary of any area designated under regulation 2(1) or 3,

(*b*) impose limitations, restrictions or conditions on the use of any area designated under regulation 2(1) or 3,

(*c*) alter the class of any area within a designated bivalve production area,

(*d*) vary the designation of any area designated under regulation 3,

for such period as it thinks fit, and shall communicate such amendment to the district council and to persons who appear to be affected.

(2) Subject to paragraph (3) the Department 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 Department before exercising the power conferred by paragraph (1) or (2) shall invite representations from any district council, 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 district council 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 2(2), and shall communicate such amendment to the Department.

Restriction on production and harvesting of bivalve molluscs

5. No live bivalve molluscs produced or harvested in Northern Ireland 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

6.—(1) Subject to the provisions of these Regulations any person who intends to operate a dispatch centre or a purification centre on and after 31st March 1993 shall before doing so apply to the district council 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 district council 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 Department 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 district council is satisfied—

(*a*) in respect of an application for a dispatch centre, that the conditions specified in sections I, II and IV 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 sections I, II and III of the Schedule to the

Derogations Regulations are satisfied and that any operating conditions are in accordance with a system approved by the Department pursuant to paragraph (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 Department has notified the district council 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 district council shall give their approval subject to those conditions.

(6) The district council 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 district council shall—

(*a*) designate the dispatch centre or purification centre by a unique approval number,

(*b*) notify the Department 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

7. Where an appeal against any decision taken by a district council to refuse or to grant subject to any limitation or condition an approval under regulation 6 is made to a court of summary jurisdiction in accordance with Article 37(1)(*c*) of the Order as applied by regulation 18, 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

8.—(1) If before finally determining an application a district council 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 district council, in writing, which it considers relevant to its final determination.

(2) Before finally determining an application a district council 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 district council to vary the terms or limitations of any approval.

Restriction on the operation of dispatch and purification centres

9.—(1) No person shall operate any dispatch centre or purification centre unless it has been approved by the district council 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

10.—(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 (Northern Ireland) 1993(**a**) 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*) any 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;

(**a**) S.R. 1993 No. 51

(*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

11.—(1) Subject to paragraphs (2) and (3), during any calendar year, a coastal fisherman who has notified the district council 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 10(1)(*b*), (*c*), (*f*) and (*h*) and, in the case of other shellfish, regulation 10(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 district council notify that district council 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 district council 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

12.—(1) Subject to paragraph (5), a district council 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 11 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 district council.

(3) Forthwith after making such an order a district council 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 Department.

(4) The information referred to in paragraph 3(*a*) is—

(*a*) the reasons of the district council for making the order;

(*b*) the action which the district council is requesting the Department to take pursuant to regulation 4(1) and in particular the detail of any restrictions or conditions;

(*c*) the right of any person affected to make representations to the Department pursuant to regulation 4(2) before it finally determines the matter; and

(*d*) how a person may exercise such right.

(5) A district council 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 Department gives 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 the Department and district councils

13.—(1) The Department shall perform the functions specified in paragraph 1 of Schedule 9.

(2) Each district council shall perform the functions specified in paragraph 2 of Schedule 9.

Imports

14. A person may only place on the market live bivalve molluscs or other shellfish which have been imported into the United Kingdom if subsequent to importation they have been handled in accordance with sub-paragraphs (*b*) to (*h*) of regulation 10(1).

Food treated as failing to comply with food safety requirements

15.—(1) A district council 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 Article 8 of the Order as failing to comply with food safety requirements.

False information

16. 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 £2,000.

Offences and penalties

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

(2) The regulations specified for the purposes of paragraph (1) are 5, 9 and 10.

(3) Any person guilty of an offence under these Regulations shall be liable—

(*a*) on summary conviction, to a fine not exceeding £2,000; 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) he shall be guilty of an offence against these Regulations.

Application of provisions of the Order

18.—(1) The following provisions of the Order shall apply for the purposes of these Regulations as they apply for the purposes of Articles 7, 13 and 14 of the Order and a reference in them to the Order shall be construed as a reference to these Regulations:

(*a*) Article 4 (presumptions that food intended for human consumption);

(*b*) Article 19 (offences due to fault of another person);

(*c*) Article 20 (defence of due diligence);

(*d*) Article 30(8) (which relates to documentary evidence);

(*e*) Article 33 (powers of entry);

(*f*) Article 34 (obstruction etc of officers);

(*g*) Article 35 (time limit for prosecutions).

(2) Article 26(2) of the Order (discharge of duties of district councils by the Department) shall apply as respects functions imposed on district councils under these Regulations as it does as respects a duty imposed on a district council by Article 26(1) of the Order.

(3) Article 37(1)(*c*) of the Order (appeals) shall apply in relation to a decision to refuse or grant subject to any condition or limitation an approval required by regulation 6 as it does to a decision to refuse, cancel, suspend or vary a licence required by Regulations under Part II of the Order.

Enforcement and execution

19. These Regulations shall be enforced and executed by each district council within its district.

Transitional provisions

20.—(1) A person shall not be prevented by regulation 10 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 17th March 1993;

(*b*) where the mollusc or shellfish left a dispatch centre or purification centre before 17th March 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 6 may continue to operate the dispatch centre or purification centre the subject of the application until the application is finally determined by the district council, provided it was operating at any time during the period of 12 months ending on 16th March 1993 and it is not prohibited from operating by reason of any other legal requirement.

Amendment of Regulations

21.—(1) The Derogations Regulations shall be amended by the omission of regulation 2.

(2) The Shellfish Regulations (Northern Ireland) 1973(**a**) are hereby revoked.

Sealed with the Official Seal of the Department of Health and Social Services on 9th February 1993.

(L.S.) *J. Scott*

Assistant Secretary

(**a**) S.R. & O. (N.I.) 1973 No. 453

SCHEDULE 1 Regulation 10(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

.....

Species consigned (scientific name)

Species consigned (common name)

.....

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 10(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.

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 district council 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

.....

Movement Document No.

Issued by:

Date of issue:

.....

Name of gatherer | Signature of gatherer

.....

District council where molluscs landed | Address of gatherer

.....

Date of gathering | Place of gathering

.....

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 district council.

(6) Each district council 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.

(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 district council 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 withdrawm 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 3 or 12, the district council shall refrain from issuing further movement documents and permanent transport authorisations for that area and the district council may suspend the validity of any such documents or authorisations already issued for the area.

SCHEDULE 3 Regulation 2

Conditions for Production Areas

PART I

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*) be 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 (Northern Ireland) 1993.

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 5.

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,

(*b*) intensive purification, or

(*c*) heat treatment by an approved process in an establishment approved for the purposes of the Food Safety (Fishery Products) Regulations (Northern Ireland) 1993.

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 Department.

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 10(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 Department and the district council for the area where the laying is situate, acting jointly, and be announced by the district council;
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 district council;
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 district council.

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 Department.

SCHEDULE 6 Regulation 10(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 10(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 execpt 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.

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 mighht 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 11

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 13

Public health control and monitoring of production

1. The Department shall undertake or may require district councils to undertake on its 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 district council shall undertake periodic monitoring of live mollusc relaying and production 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 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*) 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 results;

(*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 district council 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 Section III of the Schedule to the Derogations Regulations;

(*f*) on the correct use of health marks.

(2) The checks referred to in paragraph (1) may include the taking of samples for laboratory tests.

(3) The results of such tests must be notified to the persons responsible for the establishments.

6. A district council shall check on the storage and transport conditions for consignments of live bivalve molluscs and other shellfish.

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 (Northern Ireland) 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 2 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 3 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 4 provides for the alteration of designated areas and relaying areas and for designations to be revoked in certain circumstances.

Regulation 5 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 6 and 8 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 7 permits the operation of such a centre pending an appeal against a decision to refuse an approval of a centre.

Regulation 9 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 10 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 11 provides for an exemption from regulation 10 where a coastal fisherman places a small quantity of products on the market (see Article 2.16 of the Directive).

Regulation 12 provides for the district council to make a temporary prohibition order in relation to a laying.

Regulation 13 provides for monitoring by the Department (see Article 5.1(*b*) and 5.2(*b*) of the Directive).

Chapter III of the Directive relates to imports from third countries. Most of this part of the Directive is being implemented elsewhere, but regulation 14 makes provision for certain requirements relating to live bivalve molluscs and other shellfish imported into the United Kingdom (whether from a third country or from a member State).

Regulations 15 to 21 provide for offences, the application of certain provisions of the Food Safety (Northern Ireland) Order 1991, enforcement and execution of the Regulations, amendment of inconsistent or spent Statutory Rules and for transitional provisions.