

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.

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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:**

.....

<b>Name of gatherer</b>	<b>Signature of gatherer</b>
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<b>Food Authority where molluscs landed</b>	<b>Address of gatherer</b>
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<b>Date of gathering</b>	<b>Place of gathering</b>
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<b>Names of shellfish species being moved (common and scientific)</b>	<b>Class of production area (A, B, or C)</b>
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<b>Quantity of shellfish being moved</b>	<b>Name and address of proposed destination of shellfish being moved, including approval number</b>
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.....

**Date of receipt**  
**Place of receipt**  
**Approval number of recipient**

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**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—



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- (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.