

## SCHEDULE 2

Regulations 2(1), 3(1) and (2), 9, 11(3) to (5), 13, 15 to 20 and 52

PRODUCTION AND PLACING ON THE MARKET CONDITIONS FOR LIVE SHELLFISH  
(BASED ON THE CORRESPONDING PROVISIONS OF THE ANNEX TO THE LIVE BIVALVE MOLLUSCS DIRECTIVE)

### CHAPTER I

#### CONDITIONS FOR PRODUCTION AREAS

##### PART 1

##### CLASS A AREAS

###### **Areas to be designated class A areas**

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

##### PART 2

##### CLASS B AREAS

###### **Areas to be designated class B areas**

2. An area from which live bivalve molluscs may be gathered but only placed on the market for human consumption—

- (a) after treatment in a purification centre or after relaying (followed, where necessary, by treatment in a purification centre); or
- (b) after heat treatment by an approved process in an approved establishment.

###### **Conditions in relation to a class B area**

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

- (a) a five-tube, three-dilution MPN-test of 6,000 faecal coliforms per 100 grams of flesh; or
- (b) 4,600 *E. coli* per 100 grams of flesh.

4. After any necessary relaying, purification and treatment, the live bivalve molluscs must satisfy the requirements of Chapter V.

##### PART 3

##### CLASS C AREAS

###### **Areas to be designated class C areas**

5. 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, followed, where necessary, by treatment in a purification centre; or
- (b) heat treatment by an approved process in an approved establishment.

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### Conditions in relation to a class C area

6. The live bivalve molluscs from these areas must not, prior to relaying and any periods of purification or heat treatment, exceed the limits of—

- (a) a five-tube, three-dilution MPN-test of 60,000 faecal coliforms per 100 grams of flesh; or
- (b) 46,000 *E. coli* per 100 grams of flesh.

7. After any necessary relaying, purification and treatment, the live bivalve molluscs must satisfy the requirements of Chapter V.

## CHAPTER II

### REQUIREMENTS FOR HARVESTING AND TRANSPORTATION OF BATCHES TO A DISPATCH OR PURIFICATION CENTRE, RELAYING AREA OR PROCESSING PLANT

1. Harvesting techniques must not cause excessive damage to the shells or tissue of live shellfish.
2. Live 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 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 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 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 shellfish 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 Chapter IX.
- 6.—(1) A movement document, as prescribed in this paragraph, for the identification of each batch of live shellfish 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.  
(4) A movement document shall be in the following form—

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**LIVE SHELLFISH  
MOVEMENT DOCUMENT**

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Movement Document No.

Issued by:

Date of Issue:

Name of gatherer

Signature of gatherer

Food Authority where shellfish landed

Address of gatherer

Date of gathering

Location of production area and, if live bivalve molluscs, class of production area (A, B or C)

Name of shellfish species being moved (common and scientific) and quantity of shellfish being moved

Place of destination, including (if applicable) approval number

Date of receipt

Place of receipt

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

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- (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 shellfish and of the person to whom the document was issued.
  - (7) The person receiving a movement document for each batch of live shellfish shall put on it the date the batch was received by either a dispatch centre, purification centre, relaying area or processing plant 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 food authority may, if satisfied that the gatherer will comply with the requirements of Part II concerning gathering and handling, issue to the gatherer a permanent transport authorization (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 authorization to a dispatch centre, purification centre, relaying area, or processing plant specified in that authorization.
7. If a production or relaying area is closed temporarily, pursuant to regulation 7, the food authority shall refrain from issuing further movement documents and permanent transport authorizations for that area and the food authority may suspend the validity of any such documentations or authorizations already issued for the area.

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## CHAPTER III

### CONDITIONS FOR RELAYING LIVE BIVALVE MOLLUSCS

The following conditions must be met—

1. live bivalve molluscs must be gathered and transported, under the supervision of the food authority, in accordance with the requirements of Chapter II;
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 Chapter V or the standards in Part 2 of Chapter I 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 situated, acting jointly, and be announced by the food authority;
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 Chapter II, unless a permanent transport authorization has been issued by a food authority.

## CHAPTER IV

### CONDITIONS FOR THE APPROVAL OF DISPATCH OR PURIFICATION CENTRES

#### *Section I*

#### *General conditions relating to premises and equipment*

Centres must not be located in areas which are close to objectionable odours, smoke, dust and other contaminants. The location must not be subject to flooding by ordinary high tides or run-off from surrounding areas.

Centres must have at least—

1. on premises where live shellfish are handled or stored—

- (a) buildings or facilities of sound construction, designed and maintained adequately for the purpose of preventing contamination of live bivalve molluscs by any type of waste, dirty water, fumes, dirt or by the presence of rodents or other animals;
  - (b) flooring which is easy to keep clean and is laid in such a way as to facilitate drainage;
  - (c) adequate working space to allow for satisfactory performance of all operations;
  - (d) durable walls which are easy to clean;
  - (e) adequate natural or artificial lighting;
2. access to an appropriate number of changing rooms, wash basins and lavatories; there must be a sufficient number of wash basins close to the lavatories;
  3. adequate equipment for washing tools, containers and equipment;
  4. facilities for the supply and, where appropriate, storage of exclusively potable water or facilities for the supply of clean seawater. Facilities supplying non-potable water may be authorised. The water concerned may not come into direct contact with live shellfish or be used for cleaning or disinfecting containers, plant or equipment which come into contact with live shellfish. Pipes and outlets carrying non-potable water must be clearly distinguished from those carrying potable water;
  5. equipment and instruments or their surfaces which are intended to come into contact with live shellfish must be made of corrosion-resistant material which is easy to wash and clean repeatedly.

## ***Section II***

### ***General hygiene requirements***

A high degree of cleanliness and hygiene must be required of staff, premises, equipment and working conditions—

1. staff who treat or handle live shellfish must in particular wear clean working clothes and, where appropriate, gloves which are suitable for the work in which the person is engaged;
2. staff are obliged to refrain from personal behaviour, such as spitting, which could result in contamination of live shellfish; any person suffering from an illness which can be transmitted by live shellfish must be temporarily prohibited, until recovery, from working with or handling these products;
3. any rodents, insects or other vermin found must be destroyed and further infestation prevented. Domestic animals must not enter the facilities;
4. premises, equipment and instruments used for handling live shellfish must be kept clean and in a good state of repair; equipment and instruments must be thoroughly cleaned at the end of the day's work and at such other times as may be appropriate;
5. premises, instruments and equipment must not be used for purposes other than the handling of live shellfish without authorization by the food authority;
6. waste products must be stored hygienically in a separate area and, where appropriate, in covered containers suitable for the purpose intended. Waste material must be removed from the vicinity of the establishment at appropriate intervals;
7. the finished products must be stored under cover and must be kept away from the areas where animals other than live bivalve molluscs, echinoderms, tunicates or marine gastropods— such as crustaceans—are handled.

### **Section III**

#### **Requirements for purification centres**

In addition to the requirements under Sections I and II, the following conditions must be met—

1. the floors and walls of the purification tanks and any water storage containers must have a smooth, hard and impermeable surface and be easy to clean by scrubbing or use of pressurised water. The base of the purification tanks must be sufficiently sloped and be equipped with drainage sufficient for the volume of work;

2. live bivalve molluscs must be washed free of mud with pressurised clean seawater or potable water before purification. The initial washing may also be carried out in the purification tanks before purification commences, the drainage pipes being kept open during the entire initial washing and sufficient time being allowed thereafter for the system to be flushed clean before the purification process begins;

3. the purification tanks must be supplied with a sufficient flow of seawater per hour and per tonne of live bivalve molluscs treated;

4. clean seawater or seawater cleaned by treatment must be used for purifying live bivalve molluscs; the distance between the seawater intake point and the waste water outlets must be sufficient to avoid contamination; if treatment of the seawater is necessary, the process shall be authorised once its effectiveness has been verified by the Ministers; water used to prepare seawater from its major constituent chemicals must be potable water;

5. operation of the purification system must allow live bivalve molluscs to rapidly resume filter feeding activity, remove sewage contamination, not to become recontaminated and be able to remain alive in a suitable condition after purification for wrapping, storage and transport before being placed on the market;

6. the quantity of live bivalve molluscs to be purified must not exceed the capacity of the purification centre; the live bivalve molluscs must be continuously purified for a period sufficient to allow the microbiological standards laid down in Chapter V to be met. This period starts from the moment at which the live bivalve molluscs in the purification tanks are adequately covered by the water until the moment when they are removed. The purification centre must take account of the data relating to the raw materials (the type of bivalve mollusc, its area or origin, microbe content, etc.) in case it is necessary to extend the purification period so as to ensure that the live bivalve molluscs meet the bacteriological requirements of Chapter V;

7. should a purification tank contain several batches of molluscs, they must be of the same species and come from the same production area or different areas conforming to the same health conditions. The length of the treatment must be based on the time required by the batch needing the longest period of purification;

8. containers used to hold live bivalve molluscs in purification systems must have a construction which allows seawater to flow through; the depth of layers of live bivalve molluscs should not impede the opening of shells during purification;

9. no crustaceans, fish or other marine species must be kept in a purification tank in which live bivalve molluscs are undergoing purification;

10. after completion of purification, the shells of live bivalve molluscs must be washed thoroughly by hosing with potable water or clean seawater; this may take place in the purification tank if necessary; the washing water must not be recirculated;

11. purification centres must have their own laboratories or secure the services of a laboratory equipped with the necessary facilities for checking the efficiency of purification by use of

microbiological specifications. Laboratory facilities outside the centres must be acceptable to the food authority;

12. purification centres must regularly keep a record of the following data—
  - results of microbiological tests on purification system water entering the purification tanks;
  - results of microbiological tests on unpurified live bivalve molluscs;
  - results of microbiological tests on purified live bivalve molluscs;
  - dates and quantities of live bivalve molluscs delivered to the purification centre and corresponding movement document numbers;
  - the times of filling and emptying of purification systems (purification times);
  - dispatch details of consignments after purification;

these records must be completed and accurate, legible and recorded in a permanent ledger book which must be available for inspection by the food authority or a person authorized by the Ministers;

13. purification centres must accept only those batches of live bivalve molluscs which are accompanied by a movement document or permanent transport authorization. Purification centres dispatching batches of live bivalve molluscs to dispatch centres must provide a movement document or permanent transport authorization;

14. every package containing purified live bivalve molluscs must be provided with a label certifying that all molluscs have been purified.

#### **Section IV**

##### **Requirements for dispatch centres**

1. In addition to the requirements under Sections I and II, the following conditions must be met—
  - (a) conditioning must not cause any contamination of the product, conditioning facilities must be used in accordance with procedures recognised by the Ministers, with special regard to the bacteriological and chemical quality of the seawater used in those facilities;
  - (b) equipment and containers in the conditioning facilities must not constitute a source of contamination;
  - (c) procedures for calibration of live shellfish must not result in additional contamination of the product or in any changes affecting the ability of the product to be transported and stored after wrapping;
  - (d) any washing or cleaning of live shellfish must be carried out using pressurised clean seawater or potable water; cleaning water may not be recycled.
2. Dispatch centres must accept only those batches of live shellfish which are accompanied by the movement document referred to in paragraph 6 of Chapter II, and coming from an approved production area, relaying area or purification centre.
3. Dispatch centres must have their own laboratories or secure the services of a laboratory equipped with the necessary facilities for checking *inter alia*, whether the shellfish comply with the microbiological standards of Chapter V. Laboratory facilities outside the centre must be acceptable to the food authority. However, these requirements do not apply to dispatch centres obtaining molluscs exclusively and directly from a purification centre where they have been examined after purification.
4. Dispatch centres must keep the following data at the disposal of the food authority—
  - results of microbiological tests on live bivalve molluscs from an approved production area or relaying area;

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- dates and quantities of live shellfish delivered to the dispatch centre and corresponding movement document numbers;
- dispatch details.

These data must be classified chronologically and preserved for a period to be laid down by the food authority, but not less than three months.

5. Dispatch centres situated aboard vessels shall be subject to the conditions laid down in paragraphs 1(b), (c) and (d) and in paragraphs 3 and 4. The conditions laid down in Section I and II shall apply *mutatis mutandis* to such dispatch centres although special conditions may be laid down in accordance with the procedure laid down in article 12 of the Live Bivalve Molluscs Directive.

## CHAPTER V

### REQUIREMENTS CONCERNING LIVE SHELLFISH

Live 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 100 grams 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 25 grams 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. the upper limits as regards the radionuclide contents must not be excessive;
6. 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 100 grams of mollusc flesh in accordance with the biological testing method—in association if necessary with a chemical method for detection of Saxitoxin. If the results of such tests are challenged, the reference method shall be the biological method;
7. 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;
8. in the absence of routine virus testing procedures and the establishment of virological standards, health checks must be based on faecal bacteria counts.

Any examination for checking compliance with the requirements of this Chapter 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.



## CHAPTER VI

### 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 or microbiological contaminants are present.

2. A food authority shall undertake periodic monitoring of live bivalve 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 of this Chapter 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 organised 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 by the food authority to check compliance with the requirements for the end product as laid down in Chapter V.

(2) A control system shall be established by the food authority 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 shellfish are handled and treated correctly;
- (d) on the correct application and functioning of purification or conditioning systems;

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- (e) on the ledger books referred to in paragraph 12 of Section III of Chapter IV;
  - (f) on the correct use of healthmarks.
- (2) The checks referred to in paragraph (1) above 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 food authority shall check on the storage and transport conditions for consignments of live shellfish.

## CHAPTER VII

### WRAPPING

- 1.—(1) Live 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 shellfish;
  - (b) not be capable of transmitting substances harmful to human health to the live shellfish;
  - (c) be strong enough to give adequate protection to the live shellfish.
2. Oysters must be wrapped with the concave shell downwards.
3. All wrappings of live shellfish 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 shellfish received and of the place of dispatch;
  - (b) live shellfish from different dispatch centres are not mixed when repackaged; and
  - (c) a healthmark is provided on the new packaging which is in accordance with Chapter X.

## CHAPTER VIII

### PRESERVATION AND STORAGE

1. In any storing rooms, live shellfish 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.
2. Re-immersion in or spraying with water of live shellfish must not take place after they have been wrapped and have left the dispatch centre except in the case of a retail sale at the dispatch centre.

## CHAPTER IX

### TRANSPORT FROM THE DISPATCH CENTRE

1. Except where paragraph 3 of Chapter VII applies, consignments of live 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 shellfish must have the following characteristics—

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- (a) their interior walls and any other parts which might come into contact with the live shellfish must be made of corrosion-resistant materials, and the walls must be smooth and easy to clean;
  - (b) they must be suitably equipped to provide efficient protection of the live shellfish against extremes of heat and cold, contamination with dirt or dust, and damage to the shells from vibration and abrasion;
  - (c) the live shellfish must not be transported with other products which might contaminate them.
3. Live shellfish must be transported and distributed using closed vehicles or containers which maintain the product at a temperature which does not adversely affect quality and viability.
4. The parcels containing live 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 shellfish, it must have been made from potable water or clean seawater.

## CHAPTER X

### MARKING OF CONSIGNMENTS

1. Without prejudice to the requirements of the Food Labelling Regulations 1996(1) and subject to paragraph 4, all parcels in a consignment of live 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 the healthmark shall be in the following form—

<b>HEALTHMARK LIVE SHELLFISH</b>	
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;
  - (b) affixed as a separate label to the wrapping material;
  - (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.

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- (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.
4. Where a person repackages any live shellfish in accordance with paragraph 3 of Chapter VII, the healthmark provided on the new wrapping shall be in the form set out in paragraph 1, except that it shall also contain—
- (a) if the live shellfish originate—
    - (i) in the European Economic Area or in a third country in respect of which the European Commission has adopted import conditions for live shellfish, the approval number of the original dispatch centre, or
    - (ii) in a third country in respect of which the European Commission has not adopted approved import conditions for live shellfish, the original dispatch details; and
  - (b) if the consignment was unwrapped—
    - (i) at a registered market, the registration number of the market where the consignment was unwrapped, or
    - (ii) elsewhere than at a registered market, the full name and address of the person repackaging the consignment.