
STATUTORY INSTRUMENTS

1992 No. 1508

FOOD
FOOD SAFETY

**The Food Safety (Live Bivalve Molluscs)
(Derogations) Regulations 1992**

<i>Made</i>	- - - -	<i>24th June 1992</i>
<i>Laid before Parliament</i>		<i>25th June 1992</i>
<i>Coming into force</i>	- -	<i>1st July 1992</i>

The Minister of Agriculture, Fisheries and Food and the Secretaries of State respectively concerned with health in England and food and health in Wales, acting jointly in relation to England and Wales, and the Secretary of State for Scotland in relation to Scotland, in the exercise of the powers conferred upon them by sections 6(4) and 17(1) of the Food Safety Act 1990⁽¹⁾ and all other powers enabling them in that behalf, after consultation in accordance with section 48(4) of that Act with such organisations as appeared to them to be representative of interests likely to be substantially affected, hereby make the following Regulations:—

Citation and commencement

1. These Regulations may be cited as the Food Safety (Live Bivalve Molluscs) (Derogations) Regulations 1992 and shall come into force on 1st July 1992.

Interpretation

2.—(1) In these Regulations—

“bivalve molluscs” means filter-feeding lamellibranch molluscs;

“the Commission Decision” means Commission Decision [92/92/EEC\(2\)](#), of 9th January 1992, laying down the requirements relating to equipment and structure of dispatch and purification centres for live bivalve molluscs, for which derogations may be granted pursuant to Articles 5 and 12 of the Council Directive;

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

(1) [1990 c. 16](#) Section 4(1) contains a definition of “the Ministers” which is relevant to the powers being exercised in the making of these Regulations.
(2) [OJNo. L 34/34, 11.2.92.](#)

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

“derogation” means the grant of a further period within which to comply fully with the conditions for the approval of dispatch centres and purification centres set out in Chapter IV of the Annex to the Council Directive, which conditions are set out in column (1) to the Schedule to these Regulations;

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

“food authority” means an authority specified in regulation 6 as an authority which is to enforce and execute these Regulations;

“purification centre” means an establishment with tanks fed by naturally clean seawater 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;

“relevant requirement” means, subject to paragraph (2), a condition set out in column (1) of the Schedule to these Regulations in respect of which there is an entry in column (2) of that Schedule which indicates that it is a condition in respect of which, in accordance with the Commission Decision, a derogation may be made.

(2) For the purposes of these Regulations where there is in relation to a relevant requirement a limitation mentioned in column (2) of the Schedule, that requirement is a relevant requirement only to the extent indicated by that limitation.

(3) In these Regulations—

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

(4) In the Schedule to these Regulations—

- (a) a reference to the Annex is a reference to the Annex to the Council Directive;
- (b) a reference to a numbered Chapter is a reference to the Chapter which bears that number in the Annex;
- (c) a reference in a Chapter to a numbered section or point is a reference to the section or point which bears that number in that Chapter.

Approval of dispatch and purification centres

3. On and after 1st January 1993 no person shall operate any dispatch centre or purification centre unless it has been approved by the Secretary of State, and no such centre shall be so approved unless—

- (a) the Secretary of State is satisfied that it meets the requirements of the Council Directive; or
- (b) the Secretary of State is satisfied that it meets those requirements save in so far as there is in force in respect of it a derogation granted under regulation 5.

(3) OJ No. L 268, 24.9.1991, p.1.

Method of applying for a derogation

4.—(1) The proprietor of a food business which consists of or includes the operation of a dispatch centre or purification centre which was operating either on the 31st December 1991 or on the last working day immediately before that date, may apply to the Secretary of State, before 1st July 1992, for a derogation.

- (2) An application for the purposes of paragraph (1) shall—
- (a) be made in writing;
 - (b) specify in respect of which centre and which of the relevant requirements a derogation is sought; and
 - (c) be accompanied by a plan of the work intended by the proprietor together with a timetable indicating the period within which the proprietor intends the dispatch or purification centre to comply with the relevant requirement the subject of the application for a derogation.

Method of determining an application for a derogation

5.—(1) After receiving an application for a derogation in respect of a centre which complies with the requirements of regulation 4 the Secretary of State shall send a copy of it to the food authority in whose area the centre is situated.

(2) A food authority which receives a copy of an application sent pursuant to paragraph (1) shall invite the representations of the applicant and, after having regard to any such representations, shall send to the Secretary of State, within 12 weeks of receipt of the copy, a written assessment of the need for the derogation and of the suitability of the plan of the work and the timetable.

(3) A food authority shall, at the same time as providing the written assessment to the Secretary of State, send a copy of it to the applicant, inviting him to send to the Secretary of State, within 4 weeks of the date on which the assessment was sent to the Secretary of State, his written observations on it.

(4) After considering the assessment of the food authority and any observations made pursuant to the invitation mentioned in paragraph (3), the Secretary of State shall either grant or refuse the application for a derogation in respect of all or any of the requirements in respect of which a derogation was sought.

- (5) If an application for a derogation is granted the Secretary of State shall—
- (a) designate the premises and the relevant requirements in respect of which the derogation is granted;
 - (b) specify the period of the derogation, which shall not in any case expire after 31st December 1995;
 - (c) specify in the case of a derogation from the requirement in point 6 of Section II in the Schedule that the derogation shall apply only if and so long as any products intended for human consumption are not contaminated by waste or leakage from waste products; and
 - (d) specify in the case of a derogation from the requirement in point 7 of Section II in the Schedule that the derogation shall apply only if and so long as the products referred to in that point are sheltered from the sun and the elements and from any source of dirt or contamination.

(6) If an application is refused or is granted otherwise than in accordance with the application the Secretary of State shall give written notice to the applicant of the reasons for his decision.

(7) The Secretary of State shall in all cases give written notice of his decision to both the applicant and the food authority which provided the assessment.

Enforcement and execution

- 6.—(1) Subject to paragraph (2), these Regulations shall be enforced and executed—
- (a) as respects each London borough or district in England and Wales, by the Council of that borough or district;
 - (b) as respects the City of London (including the Temples), by the Common Council;
 - (c) as respects each islands area or district in Scotland, by the islands or district Council; and
 - (d) as respects the Isles of Scilly by the Council of the Isles of Scilly.
- (2) Where any functions are assigned—
- (a) by an order under section 2 or 7 of the Public Health (Control of Disease) Act 1984(4) to a port health authority; or
 - (b) by an order under section 172 of the Public Health (Scotland) Act 1897(5) to a port local authority;
- these Regulations shall be enforced by that authority within its area and not by the authority mentioned in paragraph (1).

In witness whereof the Official Seal of the Minister of Agriculture, Fisheries and Food is hereunto affixed on 24th June 1992.

L.S.

John Selwyn Gummer
Minister of Agriculture Fisheries and Food

Signed by authority of the Secretary of State for Health

24th June 1992

Cumberlege
Parliamentary Under Secretary of State
Department of Health

24th June 1992

David Hunt
Secretary of State for Wales

24th June 1992

Hector Monro
Parliamentary Under Secretary of State, Scottish
Office

(4) 1984 c. 22.
(5) 1897 c. 38.

SCHEDULE

Regulation 2

REQUIREMENTS OF CHAPTER IV OF THE ANNEX

<i>Column (1) Conditions for the approval of dispatch or purification centres</i>	<i>Column (2) Whether derogation possible and limitations</i>
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.	no
Centres must have at least:	yes, in so far as the construction of buildings or facilities is concerned
1. on premises where live bivalve molluscs 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;	yes
(c) adequate working space to allow for satisfactory performance of all operations;	yes
(d) durable walls which are easy to clean;	yes
(e) adequate natural or artificial lighting;	yes
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;	yes, in so far as the requirement relates to the number of changing rooms
3. adequate equipment for washing tools, containers and equipment;	no
4. facilities for the supply and, where appropriate, storage of exclusively potable water within the meaning of Council Directive 80/778/EEC of 15 July 1980 relating to the quality of water intended for human consumption ⁽⁶⁾ or facilities for the supply of clean sea water;	no
Facilities supplying non-potable water may be authorised. The water concerned may not come into direct contact with live bivalve molluscs or be used for cleaning or disinfecting containers, plant or equipment which come into contact	no

(6) OJ No. L229, 30.8.1980, p11. Directive last amended by the 1985 Act of Accession (OJ No. L302, 15.11.1985, p218).

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<i>Column (1) Conditions for the approval of dispatch or purification centres</i>	<i>Column (2) Whether derogation possible and limitations</i>
<p>with live bivalve molluscs. Pipes and outlets carrying non-potable water must be clearly distinguished from those carrying potable water;</p>	
<p>5. equipment and instruments or their surfaces which are intended to come into contact with live bivalve molluscs must be made of corrosion-resistant material which is easy to wash and clean repeatedly.</p>	<p>yes</p>
<p>Section II. General hygiene requirements</p>	
<p>A high degree of cleanliness and hygiene must be required of staff, premises, equipment and working conditions:</p>	<p>no</p>
<p>1. staff who treat or handle live bivalve molluscs must in particular wear clean working clothes and, where appropriate, gloves which are suitable for the work in which the person is engaged;</p>	<p>no</p>
<p>2. staff are obliged to refrain from personal behaviour, such as spitting, which could result in contamination of live bivalve molluscs; any person suffering from an illness which can be transmitted by live bivalve molluscs must be temporarily prohibited, until recovery, from working with or handling these products;</p>	<p>no</p>
<p>3. any rodents, insects or other vermin found must be destroyed and further infestation prevented. Domestic animals must not enter the facilities;</p>	<p>no</p>
<p>4. premises, equipment and instruments used for handling live bivalve molluscs 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;</p>	<p>no</p>
<p>5. premises, instruments and equipment must not be used for purposes other than the handling of live bivalve molluscs without authorisation by the competent authority;</p>	<p>no</p>
<p>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;</p>	<p>yes, in so far as a separate area for the storage of waste products is concerned</p>

<i>Column (1) Conditions for the approval of dispatch or purification centres</i>	<i>Column (2) Whether derogation possible and limitations</i>
<p>7. the finished products must be stored under cover and must be kept away from the areas where animals other than live bivalve molluscs such as crustaceans, are handled.</p>	yes
Section III. Requirements for purification centres	
<p>In addition to the requirements under Sections I and II, the following conditions must be met:</p>	yes, in so far as it relates to water storage containers and the slope of the base of purification tanks
<p>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 pressurized water. The base of the purification tanks must be sufficiently sloped and be equipped with drainage sufficient for the volume of work;</p>	
<p>2. live bivalve molluscs must be washed free of mud with pressurized clean sea water 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;</p>	no
<p>3. the purification tanks must be supplied with a sufficient flow of sea water per hour and per tonne of live bivalve molluscs treated;</p>	no
<p>4. clean sea water or sea water cleaned by treatment must be used for purifying live bivalve molluscs; the distance between the sea water intake point and the waste water outlets must be sufficient to avoid contamination; if treatment of the sea water is necessary, the process shall be authorised once its effectiveness has been verified by the competent authority; potable water used to prepare sea water from its major constituent chemicals must comply with the requirements laid down in Directive 80/778/EEC;</p>	no
<p>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;</p>	no

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<i>Column (1) Conditions for the approval of dispatch or purification centres</i>	<i>Column (2) Whether derogation possible and limitations</i>
<p>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 of 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;</p>	no
<p>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;</p>	no
<p>8. containers used to hold live bivalve molluscs in purification systems must have a construction which allows sea water to flow through; the depth of layers of live bivalve molluscs should not impede the opening of shells during purification;</p>	no
<p>9. no crustaceans, fish or other marine species must be kept in a purification tank in which live bivalve molluscs are undergoing purification;</p>	no
<p>10. after completion of purification, the shells of live bivalve molluscs must be washed thoroughly by hosing with potable water or clean sea water; this may take place in the purification tank if necessary; the washing water must not be recirculated;</p>	no
<p>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 recognised by the competent authority;</p>	no

<i>Column (1) Conditions for the approval of dispatch or purification centres</i>	<i>Column (2) Whether derogation possible and limitations</i>
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12. purification centres must regularly keep a no 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 registration document numbers;
- the times of filling and emptying of purification systems (purification times);
- dispatch details of consignments after purification;

These records must be complete and accurate, legible and recorded in a permanent ledger book which must be available for inspection by the competent authority;

13. purification centres must accept only no those batches of live molluscs which are accompanied by the registration document referred to in Chapter II;

Purification centres dispatching batches of no live bivalve molluscs to dispatch centres must provide the registration document referred to in Chapter II, section 6.

14. every package containing purified live no 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 no 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 competent authorities, with special regard to the bacteriological and chemical quality of the sea water used in those facilities;

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(b) equipment and containers in the conditioning facilities must not constitute a source of contamination;	no
(c) procedures for calibration of live bivalve molluscs 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;	no
(d) any washing or cleaning of live bivalve molluscs must be carried out using pressurised clean sea water or potable water; cleaning water may not be recycled.	no
2. Dispatch centres must accept only those batches of live bivalve molluscs which are accompanied by the registration document referred to in Chapter II, section 6 and coming from an approved production area, relaying area or purification centre.	no
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 molluscs comply with the microbiological standards of Chapter V. Laboratory facilities outside the centre must be recognised by the competent authority.	no
However, these requirements do not apply to dispatch centres obtaining their molluscs exclusively and directly from a purification centre where they have been examined after purification.	no
4. Dispatch centres must keep the following data at the disposal of the competent authority:	
— results of microbiological tests on live bivalve molluscs from an approved production area or relaying area;	no
— dates and quantities of live bivalve molluscs delivered to the dispatch centre and corresponding registration document numbers;	
— dispatch details.	
These data must be classified chronologically and preserved for a period to be laid down by the competent authority, but not less than three months.	

<i>Column (1) Conditions for the approval of dispatch or purification centres</i>	<i>Column (2) Whether derogation possible and limitations</i>
<p>5. Dispatch centres situated aboard vessels shall be subject to the conditions laid down in point 1(b), (c) and (d) and in points 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 Council Directive.</p>	

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations relate to the implementation of Council Directive [91/492/EEC](#) of 15th July 1991, laying down health conditions for the production and placing on the market of live bivalve molluscs (“the Directive”). The Directive is to be implemented by 1st January 1993.

One of the requirements of the Directive is that dispatch centres and purification centres are to be approved, only if they meet the requirements of the Directive. Amongst those requirements are requirements relating to equipment and structures, set out in Chapter IV of the Annex to the Directive.

The Directive provides for member States to grant a derogation in respect of certain of the requirements relating to equipment and structures (set out in Commission Decision [92/92/EEC](#)), provided that an application for the derogation is made before 1st July 1992 (see regulation 3). All of the requirements relating to equipment and structures are set out in Column (1) of the Schedule to these Regulations. Those which are capable of being the subject of a derogation are indicated appropriately in Column (2) of that Schedule.

These Regulations set out the procedure to be followed on an application for a derogation (see regulation 4) and for how such an application is determined (see regulation 5). They do not implement the main substantive provisions of the Directive.