

**Corrigendum to Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29
April 2004**

laying down specific hygiene rules for food of animal origin
(Official Journal of the European Union L 139 of 30 April 2004)

Regulation (EC) No 853/2004 should read as follows:

**REGULATION (EC) No 853/2004 OF THE EUROPEAN
PARLIAMENT AND OF THE COUNCIL
of 29 April 2004
laying down specific hygiene rules for food of animal origin**

“Requirements and responsibilities of Food Business Operators”

8. A Member State may, of its own initiative and subject to the general provisions of the Treaty, maintain or establish national rules:

(a) prohibiting or restricting the placing on the market within its territory of raw milk or raw cream intended for direct human consumption;

or

(b) permitting the use, with the authorisation of the competent authority, of raw milk not meeting the criteria laid down in Annex III, Section IX, as regards plate count and somatic cell count of the manufacture of cheeses with an ageing or ripening period of at least 60 days, and dairy products obtained in connection with the manufacture of such cheeses, provided that this does not prejudice the achievement of the objectives of this Regulation.

Article 11

Specific decisions

Without prejudice to the generality of Article 9 and Article 10(1), implementing measures may be laid down, or amendments to Annex II or III adopted, in accordance with the procedure referred to in Article 12(2):

1. to lay down rules for the transport of meat while it is warm;

2. to specify, in respect of MSM, which calcium content is not significantly higher than that of minced meat;

3. to lay down other treatments that may be applied in a processing establishment to live bivalve molluscs from class B or C production areas that have not been submitted to purification or relaying;

4. to specify recognised testing methods for marine biotoxins;

5. to lay down additional health standards for live bivalve molluscs in cooperation with the relevant Community Reference Laboratory, including:

(a) limit values and analysis methods for other marine biotoxins;

(b) virus testing procedures and virological standards;

and

(c) sampling plans and the methods and analytical tolerances to be applied to check compliance with the health standards;

6. to lay down health standards or checks, where there is scientific evidence indicating that they are necessary to protect public health;

7. to extend Annex III, Section VII, Chapter IX, to live bivalve molluscs other than pectinidae;

8. to specify criteria for determining when epidemiological data indicate that a fishing ground does not present a health hazard with regard to the presence of parasites and, consequently, for determining when the competent authority may authorise food business operators not to freeze fishery products in accordance with Annex III, Section VIII, Chapter III, Part D;

9. to lay down freshness criteria and limits with regard to histamine and total volatile nitrogen for fisheries products;

10. to permit the use for the manufacture of certain dairy products of raw milk not meeting the criteria laid down in Annex III, Section IX, as regards its plate count and somatic cell count;

11. without prejudice to Directive 96/23/EC ⁽¹⁾, to fix a maximum permitted value for the combined total of residues of antibiotic substances in raw milk;

and

12. to approve equivalent processes for the production of gelatine or collagen.

Article 12

Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health.

2. Where reference is made to this paragraph, Articles 5 and 7 of Decision 1999/468/EC shall apply, having regard to the provisions of Article 8 thereof.

The period provided for in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its Rules of Procedure.

⁽¹⁾ Council Directive 96/23/EC of 29 April 1996 on measures to monitor certain substances and residues thereof in live animals and animal products (OJ L 125, 23.5.1996, p. 10). Directive as amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

- (d) eyes and eyelids;
 - (e) the external auditory meatus;
 - (f) horn tissue;
- and
- (g) in poultry, the head — except the comb and the ears, the wattles and caruncles — the oesophagus, the crop, the intestines and the genital organs.
2. All meat, including minced meat and meat preparations, used to produce meat product must meet the requirements for fresh meat. However, minced meat and meat preparations used to produce meat products need not satisfy other specific requirements of Section V.

SECTION VII: LIVE BIVALVE MOLLUSCS

1. This Section applies to live bivalve molluscs. With the exception of the provisions on purification, it also applies to live echinoderms, tunicates and marine gastropods.
2. Chapters I to VIII apply to animals harvested from production areas that the competent authority has classified in accordance with Regulation (EC) No 854/2004. Chapter IX applies to pectinidae harvested outside those areas.
3. Chapters V, VI, VIII and IX, and point 3 of Chapter VII, apply to retail.
4. The requirements of this Section supplement those laid down in Regulation (EC) No 852/2004:
 - (a) In the case of operations that take place before live bivalve molluscs arrive at a dispatch or purification centre, they supplement the requirements of Annex I to that Regulation.
 - (b) In the case of other operations, they supplement the requirements of Annex II to that Regulation.

CHAPTER I: GENERAL REQUIREMENTS FOR THE PLACING ON THE MARKET OF LIVE BIVALVE MOLLUSCS

1. Live bivalve molluscs may not be placed on the market for retail sale otherwise than via a dispatch centre, where an identification mark must be applied in accordance with Chapter VII.
2. Food business operators may accept batches of live bivalve molluscs only if the documentary requirements set out in points 3 to 7 have been complied with.
3. Whenever a food business operator moves a batch of live bivalve molluscs between establishments, up to and including the arrival of the batch at a dispatch centre or processing establishment, a registration document must accompany the batch.
4. The registration document must be in at least one official language of the Member State in which the receiving establishment is located and contain at least the information specified below.
 - (a) In the case of a batch of live bivalve molluscs sent from a production area, the registration document must contain at least the following information:
 - (i) the gatherer's identity and address;
 - (ii) the date of harvesting;
 - (iii) the location of the production area described in as precise detail as is practicable or by a code number;
 - (iv) the health status of the production area;

- (v) the shellfish species and quantity;
 - and
 - (vi) the destination of the batch.
- (b) In the case of a batch of live bivalve molluscs sent from a relaying area, the registration document must contain at least the information referred to in (a) and the following information:
- (i) the location of the relaying area;
 - and
 - (ii) the duration of relaying.
- (c) In the case of a batch of live bivalve molluscs sent from a purification centre, the registration document must contain at least the information referred to in (a) and the following information:
- (i) the address of the purification centre;
 - (ii) the duration of purification;
 - and
 - (iii) the dates on which the batch entered and left the purification centre.
5. Food business operators sending batches of live bivalve molluscs must complete the relevant sections of the registration document so that they are easy to read and cannot be altered. Food business operators receiving batches must date-stamp the document on receipt of the batch or record the date of receipt in another manner.
6. Food business operators must keep a copy of the registration document relating to each batch sent and received for at least twelve months after its dispatch or receipt (or such longer period as the competent authority may specify).
7. However, if:
- (a) the staff gathering live bivalve molluscs also operate the dispatch centre, purification centre, relaying area or processing establishment receiving the live bivalve molluscs;
 - and
 - (b) a single competent authority supervises all the establishments concerned,
- registration documents are not necessary if that competent authority so permits.

CHAPTER II: HYGIENE REQUIREMENTS FOR THE PRODUCTION AND HARVESTING OF LIVE BIVALVE MOLLUSCS

A. REQUIREMENTS FOR PRODUCTION AREAS

1. Gatherers may only harvest live bivalve molluscs from production areas with fixed locations and boundaries that the competent authority has classified — where appropriate, in cooperation with food business operators — as being of class A, B or C in accordance with Regulation (EC) No 854/2004.
2. Food business operators may place live bivalve molluscs collected from class A production areas on the market for direct human consumption only if they meet the requirements of Chapter V.

3. Food business operators may place live bivalve molluscs collected from class B production areas on the market for human consumption only after treatment in a purification centre or after relaying.
4. Food business operators may place live bivalve molluscs collected from class C production areas on the market for human consumption only after relaying over a long period in accordance with Part C of this Chapter.
5. After purification or relaying, live bivalve molluscs from class B or C production areas must meet all of the requirements of Chapter V. However, live bivalve molluscs from such areas that have not been submitted for purification or relaying may be sent to a processing establishment, where they must undergo treatment to eliminate pathogenic micro-organisms (where appropriate, after removal of sand, mud or slime in the same or another establishment). The permitted treatment methods are:
 - (a) sterilisation in hermetically sealed containers;

and
 - (b) heat treatments involving:
 - (i) immersion in boiling water for the period required to raise the internal temperature of the mollusc flesh to not less than 90 °C and maintenance of this minimum temperature for a period of not less than 90 seconds;
 - (ii) cooking for three to five minutes in an enclosed space where the temperature is between 120 and 160 °C and the pressure is between 2 and 5 kg/cm², followed by shelling and freezing of the flesh to a core temperature of – 20 °C;

and
 - (iii) steaming under pressure in an enclosed space satisfying the requirements relating to cooking time and the internal temperature of the mollusc flesh mentioned under (i). A validated methodology must be used. Procedures based on the HACCP principles must be in place to verify the uniform distribution of heat.
6. Food business operators must not produce live bivalve molluscs in, or harvest them from, areas that the competent authority has not classified, or which are unsuitable for health reasons. Food business operators must take account of any relevant information concerning areas' suitability for production and harvesting, including information obtained from own-checks and the competent authority. They must use this information, particularly information on environmental and weather conditions, to determine the appropriate treatment to apply to harvested batches.

B. REQUIREMENTS FOR HARVESTING AND HANDLING FOLLOWING HARVESTING

Food business operators harvesting live bivalve molluscs, or handling them immediately after harvesting, must ensure compliance with the following requirements.

1. Harvesting techniques and further handling must not cause additional contamination or excessive damage to the shells or tissues of the live bivalve molluscs or result in changes significantly affecting their suitability for treatment by purification, processing or relaying. Food business operators must in particular:
 - (a) adequately protect live bivalve molluscs from crushing, abrasion or vibration;
 - (b) not expose live bivalve molluscs to extreme temperatures;
 - (c) not re-immerses live bivalve molluscs in water that could cause additional contamination;

and
 - (d) if carrying out conditioning in natural sites, use only areas that the competent authority has classified as being of class A.

2. Means of transport must permit adequate drainage, be equipped to ensure the best survival conditions possible and provide efficient protection against contamination.

C. REQUIREMENTS FOR RELAYING LIVE BIVALVE MOLLUSCS

Food business operators relaying live bivalve molluscs must ensure compliance with the following requirements.

1. Food business operators may use only those areas that the competent authority has approved for relaying live bivalve molluscs. Buoys, poles or other fixed means must clearly identify the boundaries of the sites. There must be a minimum distance between relaying areas, and also between relaying areas and production areas, so as to minimise any risk of the spread of contamination.
2. Conditions for relaying must ensure optimal conditions for purification. In particular, food business operators must:
 - (a) use techniques for handling live bivalve molluscs intended for relaying that permit the resumption of filter-feeding activity after immersion in natural waters;
 - (b) not relay live bivalve molluscs at a density that prevents purification;
 - (c) immerse live bivalve molluscs in seawater at the relaying area for an appropriate period, fixed depending on the water temperature, which period must be of at least two months' duration unless the competent authority agrees to a shorter period on the basis of the food business operator's risk analysis;and
 - (d) ensure sufficient separation of sites within a relaying area 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.
3. Food business operators managing relaying areas must keep permanent records of the source of live bivalve molluscs, relaying periods, relaying areas used and the subsequent destination of the batch after relaying, for inspection by the competent authority.

CHAPTER III: STRUCTURAL REQUIREMENTS FOR DISPATCH AND PURIFICATION CENTRES

1. The location of premises on land must not be subject to flooding by ordinary high tides or run-off from surrounding areas.
2. Tanks and water storage containers must meet the following requirements:
 - (a) Internal surfaces must be smooth, durable, impermeable and easy to clean.
 - (b) They must be constructed so as to allow complete draining of water.
 - (c) Any water intake must be situated in a position that avoids contamination of the water supply.
3. In addition, in purification centres, purification tanks must be suitable for the volume and type of products to be purified.

CHAPTER IV: HYGIENE REQUIREMENTS FOR PURIFICATION AND DISPATCH CENTRES

A. REQUIREMENTS FOR PURIFICATION CENTRES

Food business operators purifying live bivalve molluscs must ensure compliance with the following requirements.

1. Before purification commences, live bivalve molluscs must be washed free of mud and accumulated debris using clean water.

2. Operation of the purification system must allow live bivalve molluscs rapidly to resume and to maintain filter-feeding activity, to eliminate sewage contamination, not to become re-contaminated and to be able to remain alive in a suitable condition after purification for wrapping, storage and transport before being placed on the market.
3. 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 achieve compliance with allow the health standards of Chapter V and microbiological criteria adopted in accordance with Regulation (EC) No 852/2004.
4. Should a purification tank contain several batches of live bivalve molluscs, they must be of the same species and the length of the treatment must be based on the time required by the batch needing the longest period of purification.
5. Containers used to hold live bivalve molluscs in purification systems must have a construction that allows clean seawater to flow through. The depth of layers of live bivalve molluscs must not impede the opening of shells during purification.
6. No crustaceans, fish or other marine species may be kept in a purification tank in which live bivalve molluscs are undergoing purification.
7. Every package containing purified live bivalve molluscs sent to a dispatch centre must be provided with a label certifying that all molluscs have been purified.

B. REQUIREMENTS FOR DISPATCH CENTRES

Food business operators operating dispatch centres must ensure compliance with the following requirements.

1. Handling of live bivalve molluscs, particularly conditioning, calibration, wrapping and packing, must not cause contamination of the product or affect the viability of the molluscs.
2. Before dispatch, the shells of live bivalve molluscs must be washed thoroughly with clean water.
3. Live bivalve molluscs must come from:
 - (a) a class A production area;
 - (b) a relaying area;
 - (c) a purification centre;or
 - (d) another dispatch centre.
4. The requirements laid down in points 1 and 2 also apply to dispatch centres situated on board vessels. Molluscs handled in such centres must come from a class A production area or a relaying area.

CHAPTER V: HEALTH STANDARDS FOR LIVE BIVALVE MOLLUSCS

In addition to ensuring compliance with microbiological criteria adopted in accordance with Regulation (EC) No 852/2004, food business operators must ensure that live bivalve molluscs placed on the market for human consumption meet the standards laid down in this Chapter.

1. They must have organoleptic 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 not contain marine biotoxins in total quantities (measured in the whole body or any part edible separately) that exceed the following limits:
 - (a) for paralytic shellfish poison (PSP), 800 micrograms per kilogram;
 - (b) for amnesic shellfish poison (ASP), 20 milligrams of domoic acid per kilogram;
 - (c) for okadaic acid, dinophysistoxins and pectenotoxins together, 160 micrograms of okadaic acid equivalents per kilogram;
 - (d) for yessotoxins, 1 milligram of yessotoxin equivalent per kilogram;and
 - (e) for azaspiracids, 160 micrograms of azaspiracid equivalents per kilogram.

CHAPTER VI: WRAPPING AND PACKAGING OF LIVE BIVALVE MOLLUSCS

1. Oysters must be wrapped or packaged with the concave shell downwards.
2. Individual consumer-size packages of live bivalve molluscs must be closed and remain closed after leaving the dispatch centre and until presented for sale to the final consumer.

CHAPTER VII: IDENTIFICATION MARKING AND LABELLING

1. The label, including the identification mark, must be waterproof.
2. In addition to the general requirements for identification marks contained in Annex II, Section I, the following information must be present on the label:
 - (a) the species of bivalve mollusc (common name and scientific name);and
 - (b) the date of packaging, comprising at least the day and the month.

By way of derogation from Directive 2000/13/EC, the date of minimum durability may be replaced by the entry 'these animals must be alive when sold'.

3. The retailer must keep the label attached to the packaging of live bivalve molluscs that are not in individual consumer-size packages for at least 60 days after splitting up the contents.

CHAPTER VIII: OTHER REQUIREMENTS

1. Food business operators storing and transporting live bivalve molluscs must ensure that they are kept at a temperature that does not adversely affect food safety or their viability.
2. Live bivalve molluscs must not be re-immersed in, or sprayed with, water after they have been packaged for retail sale and left the dispatch centre.

CHAPTER IX: SPECIFIC REQUIREMENTS FOR PECTINIDAE HARVESTED OUTSIDE CLASSIFIED PRODUCTION AREAS

Food business operators harvesting pectinidae outside classified production areas or handling such pectinidae must comply with the following requirements.

1. Pectinidae may not be placed on the market unless they are harvested and handled in accordance with Chapter II, Part B, and meet the standards laid down in Chapter V, as proved by a system of own-checks.

2. In addition, where data from official monitoring programmes enable the competent authority to classify fishing grounds — where appropriate, in cooperation with food business operators — the provisions of Chapter II, Part A, apply by analogy to pectinidae.
3. Pectinidae may not be placed on the market for human consumption otherwise than via a fish auction, a dispatch centre or a processing establishment. When they handle pectinidae, food business operators operating such establishments must inform the competent authority and, as regards dispatch centres, comply with the relevant requirements of Chapters III and IV.
4. Food business operators handling pectinidae must comply:
 - (a) with the documentary requirements of Chapter I, points 3 to 7, where applicable. In this case, the registration document must clearly indicate the location of the area where the pectinidae were harvested;
 - or
 - (b) as regards packaged pectinidae, and wrapped pectinidae if the wrapping provides protection equivalent to that of packaging, with the requirements of Chapter VII concerning identification marking and labelling.

SECTION VIII: FISHERY PRODUCTS

1. This Section does not apply to bivalve molluscs, echinoderms, tunicates and marine gastropods when placed on the market live. With the exception of Chapters I and II, it applies to such animals when not placed on the market live, in which case they must have been obtained in accordance with Section VII.
2. Chapter III, Parts A, C and D, Chapter IV and Chapter V apply to retail.
3. The requirements of this Section supplement those laid down in Regulation (EC) No 852/2004:
 - (a) In the case of establishments, including vessels, engaged in primary production and associated operations they supplement the requirements of Annex I to that Regulation.
 - (b) In the case of other establishments, including vessels, they supplement the requirements of Annex II to that Regulation.
4. In relation to fishery products:
 - (a) primary production covers the farming, fishing and collection of live fishery products with a view to their being placed on the market;
 - and
 - (b) associated operations cover any of the following operations, if carried out on board fishing vessels: slaughter, bleeding, heading, gutting, removing fins, refrigeration and wrapping; they also include:
 1. the transport and storage of fishery products the nature of which has not been substantially altered, including live fishery products, within fish farms on land;
 - and
 2. the transport of fishery products the nature of which has not been substantially altered, including live fishery products, from the place of production to the first establishment of destination.

CHAPTER I: REQUIREMENTS FOR VESSELS

Food business operators must ensure that:

1. vessels used to harvest fishery products from their natural environment, or to handle or process them after harvesting, comply with the structural and equipment requirements laid down in Part I;
- and
2. operations carried out on board vessels take place in accordance with the rules laid down in Part II.