

Corrigendum to Regulation (EC) No 854/2004 of the European Parliament and of the Council of 29 April 2004

laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption

(Official Journal of the European Union L 139 of 30 April 2004)

Regulation (EC) No 854/2004 should read as follows:

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PARLIAMENT AND OF THE COUNCIL
of 29 April 2004
laying down specific rules for the organisation of official controls on
products of animal origin
intended for human consumption**

“Requirements and responsibilities of Competent Authorities”

- (b) Member States may also allow slaughterhouse staff to carry out specific sampling and testing tasks in accordance with Annex I, Section III, Chapter III, Part B.
7. Member States shall ensure that official veterinarians and official auxiliaries are qualified and undergo training in accordance with Annex I, Section III, Chapter IV.

Article 6

Live bivalve molluscs

Member States shall ensure that the production and placing on the market of live bivalve molluscs, live echinoderms, live tunicates and live marine gastropods undergo official controls as described in Annex II.

Article 7

Fishery products

Member States shall ensure that official controls with respect to fishery products take place in accordance with Annex III.

Article 8

Raw milk and dairy products

Member States shall ensure that official controls with respect to raw milk and dairy products take place in accordance with Annex IV.

Article 9

Action in the case of non-compliance

1. When the competent authority identifies non-compliance with the Regulations referred to in Article 4(2)(a) and (b), it shall take action to ensure that the food business operator remedies the situation. When deciding which action to take, the competent authority shall take account of the nature of the non-compliance and the food business operator's past record with regard to non-compliance.
2. Such action shall include, where appropriate, the following measures:
- the imposition of sanitation procedures or any other corrective action deemed necessary to ensure the safety of products of animal origin or compliance with the relevant legal requirements;
 - the restriction or prohibition of the placing on the market, import or export of products of animal origin;
 - monitoring or, if necessary, ordering the recall, withdrawal and/or destruction of products of animal origin;

- authorisation to use products of animal origin for purposes other than those for which they were originally intended;
 - the suspension of operations or closure of all or part of the food business concerned for an appropriate period of time;
 - the suspension or withdrawal of the establishment's approval;
 - in the case of consignments from third countries, seizure followed by destruction or re-dispatch;
 - any other measure that the competent authority deems appropriate.
3. The competent authority shall provide the food business operator concerned, or a representative, with:
- written notification of its decision concerning the action to be taken in accordance with paragraph 1, together with the reasons for the decision;
- and
- information on rights of appeal against such decisions and of the applicable procedure and time limits.

Where appropriate, the competent authority shall also notify the competent authority of the Member State of dispatch of its decision.

CHAPTER III

PROCEDURES CONCERNING IMPORTS

Article 10

General principles and conditions

To ensure the uniform application of the principles and conditions laid down in Article 11 of Regulation (EC) No 178/2002 the procedures laid down in this chapter shall apply.

Article 11

Lists of third countries and parts of third countries from which imports of specified products of animal origin are permitted

1. Products of animal origin shall be imported only from a third country or a part of third country that appears on a list drawn up and updated in accordance with the procedure referred to in Article 19(2).

In addition, fresh meat, minced meat, meat preparations, meat products and mechanically separated meat (MSM) may be imported into the Community only if they have been manufactured from meat obtained in slaughterhouses and cutting plants appearing on lists drawn up and updated in accordance with this Article or in approved Community establishments.

2. An establishment may be placed on such a list only if the competent authority of the third country of origin guarantees that:

(a) that establishment, together with any establishments handling raw material of animal origin used in the manufacture of the products of animal origin concerned, complies with relevant Community requirements, in particular those of Regulation (EC) No 853/2004, or with requirements that were determined to be equivalent to such requirements when deciding to add that third country to the relevant list in accordance with Article 11;

(b) an official inspection service in that third country supervises the establishments and makes available to the Commission, where necessary, all relevant information on establishments furnishing raw materials;

and

(c) it has real powers to stop the establishments from exporting to the Community in the event that the establishments fail to meet the requirements referred to under (a).

3. The competent authorities of third countries appearing on lists drawn up and updated in accordance with Article 11 shall guarantee that lists of the establishments referred to in paragraph 1 are drawn up, kept up-to-date and communicated to the Commission.

4. (a) The Commission shall provide the contact points that Member States have designated for this purpose with regular notifications concerning new or updated lists that it has received from the competent authorities of third countries concerned in accordance with paragraph 3.

(b) If no Member State objects to the new or updated list within 20 working days of the Commission's notification, imports shall be authorised from establishments appearing on the list 10 working days after the day on which the Commission makes it available to the public.

(c) The Commission shall, whenever at least one Member State makes written comments, or whenever it considers that the modification of a list is necessary in the light of relevant information such as Community inspection reports or a notification under the rapid alert system, inform all Member States and include the point on agenda of the next meeting of the relevant section of the Standing Committee on the Food Chain and Animal Health for decision, where appropriate, in accordance with the procedure referred to in Article 19(2).

5. The Commission shall arrange for up-to-date versions of all lists to be available to the public.

Article 13

Live bivalve molluscs, echinoderms, tunicates and marine gastropods

1. Notwithstanding Article 12(1)(b), live bivalve molluscs, echinoderms, tunicates and marine gastropods shall come from production areas in third countries that appear on lists drawn up and updated in accordance with Article 12.

2. The requirement of paragraph 1 shall not apply to pectinidae harvested outside classified production areas. However, official controls with respect to pectinidae shall take place in accordance with Annex II, Chapter III.

3. (a) Before the lists referred to in paragraph 1 are drawn up, particular account shall be taken of the guarantees that the competent authority of the third country can give concerning compliance with the requirements of this Regulation on the classification and control of production zones.

(b) An on-the-spot Community inspection visit shall take place before such lists are drawn up unless:

(i) the risk determined in accordance with Article 18(18) does not warrant it;

and

(ii) it is determined, when deciding to add a particular production area to a list in accordance with paragraph 1, that other information indicates that the competent authority provides the necessary guarantees.

4. The Commission shall arrange for up-to-date versions of all lists drawn up or updated in accordance with this Article to be available to the public.

Article 14

Documents

1. A document meeting the requirements set out in Annex VI shall accompany consignments of products of animal origin when they are imported into the Community.

2. The document shall certify that the products satisfy:

(a) the requirements laid down for such products according to Regulation (EC) No 852/2004 and Regulation (EC) No 853/2004 or provisions that are equivalent to those requirements;

and

(b) any special import conditions established in accordance with Article 18(19).

3. Member States may, without compromising achievement of the objectives of this Regulation, adopt, in accordance with paragraphs 4 to 7, national measures adapting the requirements laid down in Annex I.

4. The national measures referred to in paragraph 3 shall:

(a) have the aim of:

- (i) enabling the continued use of traditional methods at any of the stages of production, processing or distribution of food;
- (ii) accommodating the needs of food businesses with a low throughput or that are situated in regions that are subject to special geographic constraints;

or

- (iii) permitting pilot projects to take place in order to try out new approaches to hygiene controls on meat;

(b) concern in particular the following elements of Annex I:

- (i) food chain information;
- (ii) the presence of the competent authority in establishments.

5. Any Member State wishing to adopt national measures as referred to in paragraph 3 shall notify the Commission and other Member States. Each notification shall:

- (a) provide a detailed description of the requirements that that Member State considers need to be adapted and the nature of the adaptation sought;
 - (b) describe the establishments concerned;
 - (c) explain the reasons for the adaptation, including, where relevant, by providing a summary of the hazard analysis carried out and any measures to be taken to ensure that the adaptation will not compromise the objectives of this Regulation;
- and
- (d) give any other relevant information.

6. The other Member States shall have three months from the receipt of a notification referred to in paragraph 5 to send written comments to the Commission. The Commission may, and when it receives written comments from one or more Member States shall, consult Member States within the committee referred to in Article 19(1). The Commission may decide, in accordance with the procedure referred to in Article 19(2), whether the envisaged measures may be implemented subject, if necessary, to appropriate amendments. Where appropriate, the Commission may propose general measures in accordance with paragraphs 1 or 2 of this Article.

7. A Member State may adopt national measures adapting the requirements of Annex I only:

- (a) in compliance with a decision adopted in accordance with paragraph 6;
- (b) if, one month after the expiry of the period referred to in paragraph 6, the Commission has not informed Member States that it has received written comments or that it intends to propose the adoption of a decision in accordance with paragraph 6.

8. When a Member State adopts national measures implementing a pilot project to try out new approaches to hygiene controls on meat in accordance with paragraphs 3 to 7, the Member State shall communicate the results to the Commission as soon as they are available. The Commission shall then consider proposing general measures in accordance with paragraph 1.

Article 18

Specific decisions

Without prejudice to the generality of Article 16 and Article 17(1), implementing measures may be laid down, or amendments to Annexes I, II, III, IV, V or VI adopted, in accordance with the procedure referred to in Article 19(2), to specify:

- 1. tests to assess the performance of food business operators and their staff;
- 2. the method of communicating inspection results;
- 3. criteria to determine when, on the basis of a risk analysis, the official veterinarian need not be present in slaughterhouses and game handling establishments throughout ante-mortem and post-mortem inspection;
- 4. rules concerning the content of tests for official veterinarians and official auxiliaries;
- 5. microbiological criteria for process control in relation to hygiene in establishments;
- 6. alternative procedures, serological or other laboratory tests that provide guarantees at least equivalent to specific post-mortem inspection procedures described in Annex I, Section IV, and may therefore replace them, if the competent authority so decides;
- 7. circumstances in which certain of the specific post-mortem inspection procedures described in Annex I, Section IV, are not necessary, having regard to the holding, region or country of origin and to the principles of risk analysis;
- 8. rules for laboratory testing;

9. the cold treatment to be applied to meat in relation to cysticercosis and trichinosis;
10. conditions under which holdings and regions can be certified as officially free of cysticercus or trichinae;
11. methods to be applied when examining for the conditions referred to in Annex I, Section IV, Chapter IX;
12. for fattening pigs, criteria for controlled housing conditions and integrated production systems;
13. criteria for the classification of production and relaying areas for live bivalve molluscs in cooperation with the relevant Community Reference Laboratory, including:
 - (a) limit values and analysis methods for 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 criteria;
14. organoleptic criteria for the evaluation of the freshness of fishery products;
15. analytical limits, methods of analysis and sampling plans for the official controls on fishery products required under Annex III, including with regard to parasites and environmental contaminants;
16. the method by which the Commission will make lists of third countries and establishments in third countries available to the public pursuant to Articles 11, 12, 13 and 15;
17. models for documents and criteria for the use of electronic documents;
18. criteria for determining the risk that particular products of animal origin imported into the Community present;
19. special import conditions for particular products of animal origin, taking account of the associated risks, information that relevant third countries have provided and, where necessary, the results of Community controls carried out in such third countries. These special import conditions may be

established for a single product of animal origin or for group of products. They may apply to a single third country, to regions of a third country, or to a group of third countries;

and

20. the conditions governing imports of products of animal origin from a third country or a region of a third country pursuant to the implementation of an equivalence agreement, or to a satisfactory audit, recognising that measures applied in that third country or region offer guarantees equivalent to those applied in the Community, if the third country supplies objective proof in this respect.

Article 19

Committee procedure

1. The Commission shall be assisted by the Standing Committee on the Food Chain and Animal Health instituted by Article 58 of Regulation (EC) No 178/2002.
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 laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.

3. The Committee shall adopt its Rules of Procedure.

Article 20

Consultation of the European Food Safety Authority

The Commission shall consult the European Food Safety Authority on matters falling within the scope of this Regulation whenever necessary and, in particular:

1. before proposing to modify the specific requirements concerning post-mortem inspection procedures laid down in Section IV of Annex I;
2. before proposing to modify the rules of Annex I, Section IV, Chapter IX, on meat from animals in which post-mortem inspection has revealed lesions indicating infection with brucellosis or tuberculosis;

and

3. before proposing implementing measures on the matters referred to in Article 18(5) to (15).

Article 21

Report to the European Parliament and to the Council

1. The Commission shall, not later than 20 May 2009, submit a report to the European Parliament and the Council reviewing the experience gained from the application of this Regulation.

ANNEX II

LIVE BIVALVE MOLLUSCS

CHAPTER I: SCOPE

This Annex applies to live bivalve molluscs and, by analogy, to live echinoderms, live tunicates and live marine gastropods.

CHAPTER II: OFFICIAL CONTROLS CONCERNING LIVE BIVALVE MOLLUSCS FROM CLASSIFIED PRODUCTION AREAS

A. CLASSIFICATION OF PRODUCTION AND RELAYING AREAS

1. The competent authority must fix the location and boundaries of production and relaying areas that it classifies. It may, where appropriate, do so in cooperation with the food business operator.
2. The competent authority must classify production areas from which it authorises the harvesting of live bivalve molluscs as being of one of three categories according to the level of faecal contamination. It may, where appropriate, do so in cooperation with the food business operator.
3. The competent authority may classify as being of Class A areas from which live bivalve molluscs may be collected for direct human consumption. Live bivalve molluscs taken from these areas must meet the health standards for live bivalve molluscs laid down in Annex III, Section VII, Chapter V, of Regulation (EC) No 853/2004.
4. The competent authority may classify as being of Class B areas from which live bivalve molluscs may be collected, but placed on the market for human consumption only after treatment in a purification centre or after relaying so as to meet the health standards referred to in paragraph 3. Live bivalve molluscs from these areas must not exceed the limits of a five-tube, three dilution Most Probable Number (MPN) test of 4 600 *E.coli* per 100 g of flesh and intravalvular liquid.
5. The competent authority may classify as being of Class C areas from which live bivalve molluscs may be collected but placed on the market only after relaying over a long period so as to meet the health standards referred to in paragraph 3. Live bivalve molluscs from these areas must not exceed the limits of a five-tube, three dilution MPN test of 46 000 *E.coli* per 100 g of flesh and intravalvular liquid.
6. If the competent authority decides in principle to classify a production or relaying area, it must:
 - (a) make an inventory of the sources of pollution of human or animal origin likely to be a source of contamination for the production area;
 - (b) examine the quantities of organic pollutants which are released during the different periods of the year, according to the seasonal variations of both human and animal populations in the catchment area, rainfall readings, waste-water treatment, etc.;
 - (c) determine the characteristics of the circulation of pollutants by virtue of current patterns, bathymetry and the tidal cycle in the production area;and
 - (d) establish a sampling programme of bivalve molluscs in the production area which is based on the examination of established data, and with a number of samples, a geographical distribution of the sampling points and a sampling frequency which must ensure that the results of the analysis are as representative as possible for the area considered.

B. MONITORING OF CLASSIFIED RELAYING AND PRODUCTION AREAS

1. Classified relaying and production areas must be periodically monitored to check:
 - (a) that there is no malpractice with regard to the origin, provenance and destination of live bivalve molluscs;

- (b) the microbiological quality of live bivalve molluscs in relation to the production and relaying areas;
 - (c) for the presence of toxin-producing plankton in production and relaying waters and biotoxins in live bivalve molluscs;
- and
- (d) for the presence of chemical contaminants in live bivalve molluscs.
2. To implement paragraph 1(b), (c) and (d), sampling plans must be drawn up providing for such checks to take place at regular intervals, or on a case-by-case basis if harvesting periods are irregular. The geographical distribution of the sampling points and the sampling frequency must ensure that the results of the analysis are as representative as possible for the area considered.
 3. Sampling plans to check the microbiological quality of live bivalve molluscs must take particular account of:
 - (a) the likely variation in faecal contamination,

and

 - (b) the parameters referred to in paragraph 6 of Part A.
 4. Sampling plans to check for the presence of toxin-producing plankton in production and relaying waters and for biotoxins in live bivalve molluscs must take particular account of possible variations in the presence of plankton containing marine biotoxins. Sampling must comprise:
 - (a) periodic sampling to detect changes in the composition of plankton containing toxins and their geographical distribution. Results suggesting an accumulation of toxins in mollusc flesh must be followed by intensive sampling;
 - (b) periodic toxicity tests using those molluscs from the affected area most susceptible to contamination.
 5. The sampling frequency for toxin analysis in the molluscs is, as a general rule, to be weekly during the periods at which harvesting is allowed. This frequency may be reduced in specific areas, or for specific types of molluscs, if a risk assessment on toxins or phytoplankton occurrence suggests a very low risk of toxic episodes. It is to be increased where such an assessment suggests that weekly sampling would not be sufficient. The risk assessment is to be periodically reviewed in order to assess the risk of toxins occurring in the live bivalve molluscs from these areas.
 6. When knowledge of toxin accumulation rates is available for a group of species growing in the same area, a species with the highest rate may be used as an indicator species. This will allow the exploitation of all species in the group if toxin levels in the indicator species are below the regulatory limits. When toxin levels in the indicator species are above the regulatory limits, harvesting of the other species is only to be allowed if further analysis on the other species shows toxin levels below the limits.
 7. With regard to the monitoring of plankton, the samples are to be representative of the water column and to provide information on the presence of toxic species as well as on population trends. If any changes in toxic populations that may lead to toxin accumulation are detected, the sampling frequency of molluscs is to be increased or precautionary closures of the areas are to be established until results of toxin analysis are obtained.
 8. Sampling plans to check for the presence of chemical contaminants must enable the detection of any overshooting of the levels laid down in Commission Regulation (EC) No 466/2001 ⁽¹⁾.

C. DECISIONS AFTER MONITORING

1. Where the results of sampling show that the health standards for molluscs are exceeded, or that there may be otherwise a risk to human health, the competent authority must close the production area concerned, preventing the

⁽¹⁾ OJ L 77, 16.3.2001, p. 1. Regulation as last amended by Regulation (EC) No 655/2004 (OJ L 104, 8.4.2004, p. 48).

harvesting of live bivalve molluscs. However, the competent authority may reclassify a production area as being of Class B or C if it meets the relevant criteria set out in Part A and presents no other risk to human health.

2. The competent authority may re-open a closed production area only if the health standards for molluscs once again comply with Community legislation. If the competent authority closes a production because of the presence of plankton or excessive levels of toxins in molluscs, at least two consecutive results below the regulatory limit separated at least 48 hours are necessary to re-open it. The competent authority may take account of information on phytoplankton trends when taking this decision. When there are robust data on the dynamic of the toxicity for a given area, and provided that recent data on decreasing trends of toxicity are available, the competent authority may decide to re-open the area with results below the regulatory limit obtained from one single sampling.

D. ADDITIONAL MONITORING REQUIREMENTS

1. The competent authority is to monitor classified production areas from which it has forbidden the harvesting of bivalve molluscs or subjected harvesting to special conditions, to ensure that products harmful to human health are not placed on the market.
2. In addition to the monitoring of relaying and production zones referred to in paragraph 1 of Part B, a control system must be set up comprising laboratory tests to verify food business operators' compliance with the requirements for the end product at all stages of production, processing and distribution. This control system is, in particular, to verify that the levels of marine biotoxins and contaminants do not exceed safety limits and that the microbiological quality of the molluscs does not constitute a hazard to human health.

E. RECORDING AND EXCHANGE OF INFORMATION

The competent authority must:

- (a) establish and keep up to date a list of approved production and relaying areas, with details of their location and boundaries, as well as the class in which the area is classified, from which live bivalve molluscs may be taken in accordance with the requirements of this Annex. This list must be communicated to interested parties affected by this Annex, such as producers, gatherers and operators of purification centres and dispatch centres;
 - (b) immediately inform the interested parties affected by this Annex, such as producers, gatherers and operators of purification centres and dispatch centres, about any change of the location, boundaries or class of a production area, or its closure, be it temporary or final;
- and
- (c) act promptly where the controls prescribed in this Annex indicate that a production area must be closed or reclassified or can be re-opened.

F. FOOD BUSINESS OPERATORS' OWN CHECKS

To decide on the classification, opening or closure of production areas, the competent authority may take into account the results of controls that food business operators or organisations representing food business operators have carried out. In that event, the competent authority must have designated the laboratory carrying out the analysis and, if necessary, sampling and analysis must have taken place in accordance with a protocol that the competent authority and the food business operators or organisation concerned have agreed.

CHAPTER III: OFFICIAL CONTROLS CONCERNING PECTINIDAE HARVESTED OUTSIDE CLASSIFIED PRODUCTION AREAS

Official controls on pectinidae harvested outside classified production areas are to be carried out in fish auctions, dispatch centres and processing establishments. Such official controls are to verify compliance with the health standards for live bivalve molluscs laid down in Annex III, Section VII, Chapter V, to Regulation (EC) No 853/2004 as well as compliance with other requirements of Annex III, Section VII, Chapter IX to that Regulation.