ISSN 1725-2555

Official Journal of the European Union

L 320

English edition

Legislation

Volume 49

18 November 2006

Contents

(1) Text with EEA relevance

(Continued overleaf)

EN

Acts whose titles are printed in light type are those relating to day-to-day management of agricultural matters, and are generally valid for a limited period.

The titles of all other acts are printed in bold type and preceded by an asterisk.

Contents *(continued)*

EN

([1]) Text with EEA relevance

I

(Acts whose publication is obligatory)

COMMISSION REGULATION (EC) No 1662/2006

of 6 November 2006

amending Regulation (EC) No 853/2004 of the European Parliament and of the Council laying down specific hygiene rules for food of animal origin

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard 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 [1], and in particular Article 10(1) thereof,

Whereas:

(1) When subject to the provisions of Annex III to Regulation (EC) No 853/2004, food business operators should ensure that each product of animal origin has an identification mark applied in compliance with the provisions laid down in Section I of Annex II to that Regulation. Unless expressly indicated and for control reasons, products of animal origin should not bear more than one identification mark.

(2) Section I of Annex III to Regulation (EC) No 853/2004 lays down rules on the production and placing on the market of meat from domestic ungulates. Exceptions to the complete skinning of the carcase and other parts of the body intended for human consumption are set out in point 8 of Chapter IV of that Section. Provision should be made to extend these exceptions to the muzzle and lips from bovine animals, provided they comply with the same conditions as those applying to heads of ovine and caprine animals.

(3) The tonsils serve as a filter of all noxious agents entering the oral cavity of animals and should be removed for hygienic and safety reasons during the process of slaughtering domestic ungulates. Since the removal was inadvertently omitted as mandatory for domestic swine, the requirement for removal of porcine tonsils should be re-inserted.

(4) Section VIII of Annex III to Regulation (EC) No 853/2004 sets out the requirements governing the production and placing on the market of fishery products intended for human consumption. Fish oil is included in the definition of fishery products. Specific requirements for production and placing on the market of fish oil for human consumption should, therefore, be laid down. Transitional arrangements should also be foreseen to give the possibility to establishments in third countries to adapt to the new situation.

(5) Colostrum is considered as a product of animal origin but is not covered by the definition of raw milk as referred to in Annex I to Regulation (EC) No 853/2004. Colostrum is produced in a similar way and can be considered as presenting a similar risk to human health as raw milk. It is therefore necessary to introduce specific hygiene rules for colostrum production.

(6) Section XV of Annex III to Regulation (EC) No 853/2004 sets out the requirements for the production of collagen. It specifies that collagen must be produced using a process that ensures that the raw material is subjected to a treatment involving washing, pH adjustment using acid or alkali followed by one or more rinses, filtration and extrusion or by an approved equivalent process. A different process resulting in a hydrolysed collagen that cannot be extruded was submitted for assessment to EFSA. EFSA adopted on 26 January 2005 an opinion on safety of collagen and a processing method for the production of collagen. It concluded that the production process proposed above ensures equivalent or higher health safety for collagen intended for human consumption compared to the safety achieved by applying the standards of Section XV. The conditions for the production of collagen should therefore be modified.

(7) Regulation (EC) No 853/2004 should be amended accordingly.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

[1] OJ L 139, 30.4.2004, p. 55, as corrected by OJ L 226, 25.6.2004, p. 22. Regulation as last amended by Commission Regulation (EC) No 2076/2005 (OJ L 338, 22.12.2005, p. 83).

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 853/2004 is amended as follows:

1. Annex II is amended in accordance with Annex I to this Regulation.

2. Annex III is amended in accordance with Annex II to this Regulation.

Article 2

This Regulation shall enter into force on the seventh day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 6 November 2006.

For the Commission

Markos KYPRIANOU

Member of the Commission

ANNEX I

Section I, Part A, point (2) of Annex II to Regulation (EC) No 853/2004 is replaced by the following:

'2. However, when a product's packaging and/or wrapping is removed or it is further processed in another establishment, a new mark must be applied to the product. In such cases, the new mark must indicate the approval number of the establishment where these operations take place.'

ANNEX II

Annex III to Regulation (EC) No 853/2004 is amended as follows:

1. In Section I, Chapter IV is amended as follows:

   (a) Point 8 is replaced by the following:

   '8. Carcases and other parts of the body intended for human consumption must be completely skinned, except in the case of porcine animals, the heads of ovine and caprine animals and calves, the muzzle and lips of bovine animals and the feet of bovine, ovine and caprine animals. Heads, including muzzle and lips, and feet must be handled in such a way as to avoid contamination.'

   (b) Point 16(a) is replaced by the following:

   '(a) the tonsils of bovine animals, porcine animals and solipeds must be removed hygienically;'.

2. In Section VIII, Chapter III, Part E is added as follows:

   'E. REQUIREMENTS FOR FISH OIL FOR HUMAN CONSUMPTION

   Food business operators must ensure that raw materials used in the preparation of fish oil for human consumption comply with the following requirements:

   1. they must derive from fishery products which have been found fit for human consumption;

   2. they must come from establishments, including vessels, approved in accordance with this Regulation;

   3. they must be transported and stored until processing in hygienic conditions.'

3. Section IX is replaced by the following:

   'SECTION IX: RAW MILK, COLOSTRUM, DAIRY PRODUCTS AND COLOSTRUM-BASED PRODUCTS

   For the purpose of this Section,

   1. "Colostrum" means the fluid secreted by the mammary glands of milk-producing animals up to three to five days post parturition that is rich in antibodies and minerals, and precedes the production of raw milk.

   2. "Colostrum-based products" means processed products resulting from the processing of colostrum or from the further processing of such processed products.

   CHAPTER I: RAW MILK AND COLOSTRUM — PRIMARY PRODUCTION

   Food business operators producing or, as appropriate, collecting raw milk and colostrum must ensure compliance with the requirements laid down in this Chapter.

   I. HEALTH REQUIREMENTS FOR RAW MILK AND COLOSTRUM PRODUCTION

   1. Raw milk and colostrum must come from animals:

   (a) that do not show any symptoms of infectious diseases communicable to humans through milk and colostrum;

   (b) that are in a good general state of health, present no sign of disease that might result in the contamination of milk and colostrum and, in particular, are not suffering from any infection of the genital tract with discharge, enteritis with diarrhoea and fever, or a recognisable inflammation of the udder;

   (c) that do not have any udder wound likely to affect the milk and colostrum;

   (d) to which no unauthorised substances or products have been administered and that have not undergone illegal treatment within the meaning of Directive 96/23/EC;

(e) in respect of which, where authorised products or substances have been administered, the withdrawal periods prescribed for these products or substances have been observed.

2. (a) In particular, as regards brucellosis, raw milk and colostrum must come from:

(i) cows or buffaloes belonging to a herd which, within the meaning of Directive 64/432/EEC ([1]), is free or officially free of brucellosis;

(ii) sheep or goats belonging to a holding officially free or free of brucellosis within the meaning of Directive 91/68/EEC ([2]); or

(iii) females of other species belonging, for species susceptible to brucellosis, to herds regularly checked for that disease under a control plan that the competent authority has approved.

(b) As regards tuberculosis, raw milk and colostrum must come from:

(i) cows or buffaloes belonging to a herd which, within the meaning of Directive 64/432/EEC, is officially free of tuberculosis; or

(ii) females of other species belonging, for species susceptible to tuberculosis, to herds regularly checked for this disease under a control plan that the competent authority has approved.

(c) If goats are kept together with cows, such goats must be inspected and tested for tuberculosis.

3. However, raw milk from animals that does not meet the requirements of point 2 may be used with the authorisation of the competent authority:

(a) in the case of cows or buffaloes that do not show a positive reaction to tests for tuberculosis or brucellosis, nor any symptoms of these diseases, after having undergone a heat treatment such as to show a negative reaction to the alkaline phosphatase test;

(b) in the case of sheep or goats that do not show a positive reaction to tests for brucellosis, or which have been vaccinated against brucellosis as part of an approved eradication programme, and which do not show any symptom of that disease, either:

(i) for the manufacture of cheese with a maturation period of at least two months; or

(ii) after having undergone heat treatment such as to show a negative reaction to the alkaline phosphatase test; and

(c) in the case of females of other species that do not show a positive reaction to tests for tuberculosis or brucellosis, nor any symptoms of these diseases, but belong to a herd where brucellosis or tuberculosis has been detected after the checks referred to in point 2(a)(iii) or 2(b)(ii), if treated to ensure its safety.

4. Raw milk and colostrum from any animal not complying with the appropriate requirements of points 1 to 3, and in particular, any animal showing individually a positive reaction to the prophylactic tests vis-à-vis tuberculosis or brucellosis as laid down in Directive 64/432/EEC and Directive 91/68/EEC, must not be used for human consumption.

([1]) Council Directive 64/432/EEC of 26 June 1964 on animal health problems affecting intra-Community trade in bovine animals and swine (OJ 121, 29.7.1964, p. 1977/64). Directive as last amended by Regulation (EC) No 21/2004 (OJ L 5, 9.1.2004, p. 8).

([2]) Council Directive 91/68/EEC of 28 January 1991 on animal health conditions governing intra-Community trade in ovine and caprine animals (OJ L 46, 19.2.1991, p. 19). Directive as last amended by Commission Decision 2005/932/EC.

5. The isolation of animals that are infected, or suspected of being infected, with any of the diseases referred to in point 1 or 2 must be effective to avoid any adverse effect on other animals' milk and colostrum.

II. HYGIENE ON MILK AND COLOSTRUM PRODUCTION HOLDINGS

A. **Requirements for premises and equipment**

1. Milking equipment and premises where milk and colostrum are stored, handled or cooled must be located and constructed so as to limit the risk of contamination of milk and colostrum.

2. Premises for the storage of milk and colostrum must be protected against vermin, have adequate separation from premises where animals are housed and, where necessary to meet the requirements laid down in Part B, have suitable refrigeration equipment.

3. Surfaces of equipment that are intended to come into contact with milk and colostrum (utensils, containers, tanks, etc. intended for milking, collection or transport) must be easy to clean and, where necessary, disinfect and must be maintained in a sound condition. This requires the use of smooth, washable and non-toxic materials.

4. After use, such surfaces must be cleaned and, where necessary, disinfected. After each journey, or after each series of journeys when the period of time between unloading and the following loading is very short, but in all cases at least once a day, containers and tanks used for the transport of milk and colostrum must be cleaned and disinfected in an appropriate manner before re-use.

B. **Hygiene during milking, collection and transport**

1. Milking must be carried out hygienically, ensuring in particular:

(a) that, before milking starts, the teats, udder and adjacent parts are clean;

(b) that milk and colostrum from each animal is checked for organoleptic or physico-chemical abnormalities by the milker or a method achieving similar results and that milk and colostrum presenting such abnormalities is not used for human consumption;

(c) that milk and colostrum from animals showing clinical signs of udder disease are not used for human consumption otherwise than in accordance with the instructions of a veterinarian;

(d) the identification of animals undergoing medical treatment likely to transfer residues to the milk and colostrum, and that milk and colostrum obtained from such animals before the end of the prescribed withdrawal period are not used for human consumption; and

(e) that teat dips or sprays are used only after authorisation or registration in accordance with the procedures laid down in Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market ([1]):

(f) that colostrum is milked separately and not mixed together with raw milk.

2. Immediately after milking, milk and colostrum must be held in a clean place designed and equipped to avoid contamination.

(a) Milk must be cooled immediately to not more than 8 °C in the case of daily collection, or not more than 6 °C if collection is not daily;

(b) Colostrum must be stored separately and immediately cooled to not more than 8 °C in the case of daily collection, or not more than 6 °C if collection is not daily, or frozen.

([1]) OJ L 123, 24.4.1998, p. 1. Directive as last amended by Commission Directive 2006/50/EC (OJ L 142, 30.5.2006, p. 6).

3. During transport the cold chain must be maintained and, on arrival at the establishment of destination, the temperature of the milk and the colostrum must not be more than 10 °C.

4. Food business operators need not comply with the temperature requirements laid down in points 2 and 3 if the milk meets the criteria provided for in Part III and either:

(a) the milk is processed within two hours of milking; or

(b) a higher temperature is necessary for technological reasons related to the manufacture of certain dairy products and the competent authority so authorises.

C. **Staff hygiene**

1. Persons performing milking and/or handling raw milk and colostrum must wear suitable clean clothes.

2. Persons performing milking must maintain a high degree of personal cleanliness. Suitable facilities must be available near the place of milking to enable persons performing milking and handling raw milk and colostrum to wash their hands and arms.

III. CRITERIA FOR RAW MILK AND COLOSTRUM

1. (a) The following criteria for raw milk apply pending the establishment of standards in the context of more specific legislation on the quality of milk and dairy products.

(b) National criteria for colostrum, as regards plate count, somatic cell count or antibiotic residues, apply pending the establishment of specific Community legislation.

2. A representative number of samples of raw milk and colostrum collected from milk production holdings taken by random sampling must be checked for compliance with points 3 and 4 in case of raw milk and with the existing national criteria referred to in point 1(b) in case of colostrum. The checks may be carried out by, or on behalf of:

(a) the food business operator producing the milk;

(b) the food business operator collecting or processing the milk;

(c) a group of food business operators; or

(d) in the context of a national or regional control scheme.

3. (a) Food business operators must initiate procedures to ensure that raw milk meets the following criteria:

(i) for raw cows' milk:

Plate count at 30 °C (per ml)	≤ 100 000 (*)
Somatic cell count (per ml)	≤ 400 000 (**)

(*) Rolling geometric average over a two-month period, with at least two samples per month.
(**) Rolling geometric average over a three-month period, with at least one sample per month, unless the competent authority specifies another methodology to take account of seasonal variations in production levels.

(ii) for raw milk from other species:

Plate count at 30 °C (per ml)	≤ 1 500 000 (*)

(*) Rolling geometric average over a two-month period, with at least two samples per month.

(b) However, if raw milk from species other than cows is intended for the manufacture of products made with raw milk by a process that does not involve any heat treatment, food business operators must take steps to ensure that the raw milk used meets the following criterion:

Plate count at 30 °C (per ml)	≤ 500 000 (*)

(*) Rolling geometric average over a two-month period, with at least two samples per month.

4. Without prejudice to Directive 96/23/EC, food business operators must initiate procedures to ensure that raw milk is not placed on the market if either:

(a) it contains antibiotic residues in a quantity that, in respect of any one of the substances referred to in Annexes I and III to Regulation (EEC) No 2377/90 ([1]), exceeds the levels authorised under that Regulation; or

(b) the combined total of residues of antibiotic substances exceeds any maximum permitted value.

5. When raw milk fails to comply with point 3 or 4, the food business operator must inform the competent authority and take measures to correct the situation.

CHAPTER II: REQUIREMENTS CONCERNING DAIRY AND COLOSTRUM-BASED PRODUCTS

I. TEMPERATURE REQUIREMENTS

1. Food business operators must ensure that, upon acceptance at a processing establishment,

(a) milk is quickly cooled to not more than 6 °C;

(b) colostrum is quickly cooled to not more than 6 °C or maintained frozen,

and kept at that temperature until processed.

2. However, food business operators may keep milk and colostrum at a higher temperature if:

(a) processing begins immediately after milking, or within four hours of acceptance at the processing establishment; or

(b) the competent authority authorises a higher temperature for technological reasons concerning the manufacture of certain dairy or colostrum-based products.

II. REQUIREMENTS FOR HEAT TREATMENT

1. When raw milk, colostrum, dairy or colostrum-based products undergo heat treatment, food business operators must ensure that this satisfies the requirements laid down in Chapter XI of Annex II to Regulation (EC) No 852/2004. In particular, they shall ensure, when using the following processes, that they comply with the specifications mentioned:

(a) Pasteurisation is achieved by a treatment involving:

(i) a high temperature for a short time (at least 72 °C for 15 seconds);

(ii) a low temperature for a long time (at least 63 °C for 30 minutes); or

([1]) Council Regulation (EEC) No 2377/90 of 26 June 1990 laying down a Community procedure for the establishment of maximum residue limits of veterinary medicinal products in foodstuffs of animal origin (OJ L 224, 18.8.1990, p. 1). Regulation as last amended by Commission Regulation (EC) No 1231/2006 (OJ L 225, 17.8.2006, p. 3).'

(iii) any other combination of time-temperature conditions to obtain an equivalent effect,

such that the products show, where applicable, a negative reaction to an alkaline phosphatase test immediately after such treatment.

(b) Ultra high temperature (UHT) treatment is achieved by a treatment:

(i) involving a continuous flow of heat at a high temperature for a short time (not less than 135 °C in combination with a suitable holding time) such that there are no viable microorganisms or spores capable of growing in the treated product when kept in an aseptic closed container at ambient temperature, and

(ii) sufficient to ensure that the products remain microbiologically stable after incubating for 15 days at 30 °C in closed containers or for seven days at 55 °C in closed containers or after any other method demonstrating that the appropriate heat treatment has been applied.

2. When considering whether to subject raw milk and colostrum to heat treatment, food business operators must:

(a) have regard to the procedures developed in accordance with the HACCP principles pursuant to Regulation (EC) No 852/2004; and

(b) comply with any requirements that the competent authority may impose in this regard when approving establishments or carrying out checks in accordance with Regulation (EC) No 854/2004.

III. CRITERIA FOR RAW COWS' MILK

1. Food business operators manufacturing dairy products must initiate procedures to ensure that, immediately before processing:

(a) raw cows' milk used to prepare dairy products has a plate count at 30 °C of less than 300 000 per ml; and

(b) processed cows' milk used to prepare dairy products has a plate count at 30 °C of less than 100 000 per ml.

2. When milk fails to meet the criteria laid down in paragraph 1, the food business operator must inform the competent authority and take measures to correct the situation.

CHAPTER III: WRAPPING AND PACKAGING

Sealing of consumer packages must be carried out immediately after filling in the establishment where the last heat treatment of liquid dairy products and colostrum-based products, takes place by means of sealing devices that prevent contamination. The sealing system must be designed in such a way that, after opening, the evidence of its opening remains clear and easy to check.

CHAPTER IV: LABELLING

1. In addition to the requirements of Directive 2000/13/EC, except in the cases envisaged in Article 13(4) and (5) of that Directive, labelling must clearly show:

(a) in the case of raw milk intended for direct human consumption, the words "raw milk";

(b) in the case of products made with raw milk, the manufacturing process for which does not include any heat treatment or any physical or chemical treatment, the words "made with raw milk";

(c) in case of colostrum, the word "colostrum";

(d) in case of products made with colostrum, the words "made with colostrum".

2. The requirements of paragraph 1 apply to products destined for retail trade. The term "labelling" includes any packaging, document, notice, label, ring or collar accompanying or referring to such products.

CHAPTER V: IDENTIFICATION MARKING

By way of derogation from the requirements of Annex II, Section I:

1. rather than indicating the approval number of the establishment, the identification mark may include a reference to where on the wrapping or packaging the approval number of the establishment is indicated;

2. in the case of the reusable bottles, the identification mark may indicate only the initials of the consigning country and the approval number of the establishment.

4. In Section XV, Chapter III, point 1 is replaced by the following:

'1. Collagen must be produced by a process that ensures that the raw material is subjected to a treatment involving washing, pH adjustment using acid or alkali followed by one or more rinses, filtration and extrusion or by an approved equivalent process. The extrusion step may be not carried out when manufacturing low molecular collagen from raw materials of non-ruminant origin.'

COMMISSION REGULATION (EC) No 1663/2006

of 6 November 2006

amending Regulation (EC) No 854/2004 of the European Parliament and of the Council laying down specific rules for the organisation of official controls on products of animal origin intended for human consumption

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard 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 [1], and in particular Article 17(1) thereof,

Whereas:

(1) According 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 [2], it is for the food business operator to remove tonsils after post mortem inspection.

(2) Regulation (EC) No 853/2004 lays down requirements for the production of colostrum. It should therefore be subject to official controls.

(3) Annex VI to Regulation (EC) No 854/2004 establishes general principles to be followed for certificates accompanying imports of products of animal origin from third countries. In particular, it requires certificates to be drawn up at least in the official language of the third country of dispatch and the Member State of entry. Due to many practical and operational problems already raised by this double requirement, it is more appropriate to limit these requirements to the basic principle of an obligation to draw up certificates at least in the official language or languages of the Member State of entry. However, due to its interest in certain situations, provision allowing the third country of dispatch to use its official language should be maintained as one possibility in supplement to the above principle. Annex VI should be amended accordingly.

(4) Regulation (EC) No 854/2004 should be amended accordingly.

(5) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Annexes I, IV and VI to Regulation (EC) No 854/2004 are amended in accordance with the Annex to this Regulation

Article 2

This Regulation shall enter into force on the seventh day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 6 November 2006.

For the Commission

Markos KYPRIANOU

Member of the Commission

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[1] OJ L 139, 30.4.2004, p. 206. Corrected by OJ L 226, 25.6.2004, p. 83. Regulation as last amended by Regulation (EC) No 2076/2005 (OJ L 338, 22.12.2005, p. 83).

[2] OJ L 139, 30.4.2004, p. 55. Corrected by OJ L 226, 25.6.2004, p. 22. Regulation as last amended by Regulation (EC) No 2076/2005

ANNEX

1. Annex I to Regulation (EC) No 854/2004 is amended as follows:

   (a) in Section IV, Chapter I:

      (i) Part A, Point 1, the words 'removal of the tonsils' are deleted;

      (ii) Part B, Point 1, the sentence 'The tonsils must be removed' is deleted;

   (b) in Section IV, Chapter III, Point 1, the sentence 'The tonsils must be removed' is deleted.

2. Annex IV to Regulation (EC) No 854/2004 is replaced by the following:

'ANNEX IV

RAW MILK, COLOSTRUM, DAIRY PRODUCTS AND COLOSTRUM BASED PRODUCTS

CHAPTER I: CONTROL OF MILK AND COLOSTRUM PRODUCTION HOLDINGS

1. Animals on milk and colostrum production holdings must be subject to official controls to verify that the health requirements for raw milk and colostrum production, and in particular the health status of the animals and the use of veterinary medicinal products, are being complied with.

   These controls may take place at the occasion of veterinary checks carried out pursuant to Community provisions on animal or public health or animal welfare and may be carried out by an approved veterinarian.

2. If there are grounds for suspecting that the animal health requirements are not being complied with, the general health status of the animals is to be checked.

3. Milk and colostrum production holdings are to undergo official controls to verify that hygiene requirements are being complied with. These official controls may involve inspections and/or the monitoring of controls that professional organisations carry out. If it is shown that the hygiene is inadequate, the competent authority is to verify that appropriate steps are taken to correct the situation.

CHAPTER II: CONTROL OF RAW MILK AND COLOSTRUM UPON COLLECTION

1. In the case of raw milk and colostrum, the competent authority is to monitor the checks carried out in accordance with Annex III, Section IX, Chapter I, Part III to Regulation (EC) No 853/2004:

2. If the food business operator has not corrected the situation within three months of first notifying the competent authority of non-compliance with the criteria with regard to plate count and/or somatic cell count, delivery of raw milk and colostrum from the production holding is to be suspended or — in accordance with a specific authorisation of, or general instructions from, the competent authority — subjected to requirements concerning its treatment and use necessary to protect public health. This suspension or these requirements are to remain in place until the food business operator has proved that the raw milk and colostrum again complies with the criteria.';

3. in Annex VI to Regulation (EC) No 854/2004 point 2 is replaced by the following:

   '2. Certificates must be drawn up at least in the official language or languages of the Member State of destination and those of the Member State in which the border inspection takes place, or be accompanied by a certified translation into that language or languages. However, a Member State may consent to the use of an official Community language other than its own.'

COMMISSION REGULATION (EC) No 1664/2006

of 6 November 2006

amending Regulation (EC) No 2074/2005 as regards implementing measures for certain products of animal origin intended for human consumption and repealing certain implementing measures

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard 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 [1], and in particular Articles 9 and11 thereof,

Having regard 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 [2], and in particular Article 16 thereof,

Having regard to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the compliance with feed and food law, animal health and animal welfare rules [3], and in particular Article 11(4) thereof,

Whereas:

(1) Commission Regulation (EC) No 2074/2005 [4] lays down implementing measures for Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004.

(2) Annex VI to Regulation (EC) No 2074/2005 lays down model health certificates for imports of certain products of animal origin intended for human consumption. These certificates have been developed to comply with the expert system Traces developed by the Commission to follow any movements of animals and products derived therefrom within the EU territory and from third countries. Particulars concerning the description of the commodities have recently been updated. The existing model health certificates should therefore be amended accordingly.

(3) Regulations (EC) No 852/2004 of the European Parliament and of the Council [5] and (EC) No 853/2004 lay down rules on the production of fishery products, live bivalve molluscs and honey intended for human consumption. Specific requirements, including model health certificates, should be laid down in Regulation (EC) No 2074/2005 for imports of these products from third countries. Existing Decisions setting the import certificates should consequently be repealed after a delay to give third countries the possibility to adapt their legislation.

(4) It is also appropriate to simplify the certification procedure for fishery products and live bivalve molluscs and, for consignments intended for human consumption, to incorporate the animal health certification requirements set out in Commission Decision 2003/804/EC of 14 November 2003 laying down animal health conditions and certification requirements for imports of molluscs their eggs and gametes for further growth, fattening, relaying or human consumption [6], and Commission Decision 2003/858/EC of 21 November 2003 laying down animal health conditions and certification requirements for imports of live fish, their eggs and gametes intended for farming, and live fish of aquaculture origin and products thereof intended for human consumption [7].

(5) In accordance with Article 11(4) of Regulation (EC) No 882/2004, methods for analysis and testing of milk and milk-based products should be established. In this context, the Community reference laboratory has compiled a list of updated reference methods, which was approved by national reference laboratories during their 2005 meeting. It is therefore necessary to provide in Regulation (EC) No 2074/2005 the last agreed list of reference methods of analysis and testing to be used to monitor compliance with the requirements laid down in Regulation (EC) No 853/2004. Commission decision 91/180/CEEof 14 February 1991 laying down certain methods of analysis and testing of raw milk and heat-treated milk [8] should consequently

[1] OJ L 139, 30.4.2004, p. 55, corrected by OJ L 226, 25.6.2004, p. 22. Regulation as last amended by Commission Regulation (EC) No 2076/2005 (OJ L 338, 22.12.2005, p. 83).

[2] OJ L 139, 30.4.2004, p. 206, corrected by OJ L 226, 25.6.2004, p. 83.

[3] OJ L 165, 30.4.2004, p. 1, as corrected by OJ L 191, 28.5.2004, p. 1. Regulation as last amended by Commission Regulation (EC) No 776/2006 (OJ L 136, 24.5.2006, p. 3).

[4] OJ L 338, 22.12.2005, p. 27.

[5] OJ L 139, 30.4.2004, p. 1, corrected by OJ L 226, 25.6.2004, p. 3.

[6] OJ L 302, 20.11.2003, p. 22. Decision as last amended by Decision 2005/409/EC (OJ L 139, 2.6.2005, p. 16).

[7] OJ L 324, 11.12.2003, p. 37. Decision as last amended by Decision 2006/680/EC (OJ L 279, 11.10.2006, p. 24).

[8] OJ L 93, 13.4.1991, p. 1.

be repealed. A delay should be granted to give the Member States the time to comply with the new methods.

(6) Regulation (EC) No 2074/2005 establishes the analytical methods for the detection of the paralytic shellfish poison (PSP) content of edible parts of molluscs (the whole body or any part edible separately). The so-called Lawrence method as published in AOAC Official Method 2005.06 (Paralytic Shellfish Poisoning Toxins in Shellfish) should be considered as an alternative method for the detection of PSP in bivalve molluscs. Its use should be reviewed in light of the analytical work currently carried out by the Community Reference Laboratory for marine biotoxins.

(7) Regulation (EC) No 2074/2005 should therefore be amended accordingly.

(8) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 2074/2005 is amended as follows:

(1) Article 6 is replaced by the following:

'*Article 6*

Model health certificates for imports of certain products of animal origin for the purpose of Regulation (EC) No 853/2004

The model health certificates, as referred to in Article 6(1)(d) of Regulation (EC) No 853/2004, to be used when importing products of animal origin listed in Annex VI to this Regulation are as set out in that Annex VI.'

(2) The following Article 6a is inserted:

'*Article 6a*

Testing methods for raw milk and heat-treated milk

The analytical methods set out in Annex VIa to this Regulation shall be used by the competent authorities, and, where appropriate, by food business operators, to check compliance with the limits laid down in Annex III, Section IX, Chapter I, Part III to Regulation (EC) No 853/2004 and to ensure appropriate application of a pasteurisation process to dairy products as referred to in Annex III, Section IX, Chapter II, Part II to that Regulation.'

(3) Annex III is amended in accordance with Annex I to this Regulation.

(4) Annex VI is amended in accordance with Annex II to this Regulation.

(5) Annex VIa is inserted in accordance with Annex III to this Regulation.

Article 2

The Decisions listed in Annex IV to this Regulation are repealed with effect from 1 May 2007.

Article 3

This Regulation shall enter into force on the seventh day following its publication in the *Official Journal of the European Union*.

Annex III to this Regulation shall apply at the latest six months after the entry into force of this Regulation.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 6 November 2006.

For the Commission

Markos KYPRIANOU

Member of the Commission

ANNEX I

Chapter I of Annex III to Regulation (EC) No 2074/2005 is replaced by the following:

'CHAPTER I

PARALYTIC SHELLFISH POISON (PSP) DETECTION METHOD

1. The paralytic shellfish poison (PSP) content of edible parts of molluscs (the whole body or any part edible separately) must be detected in accordance with the biological testing method or any other internationally recognised method. The so-called Lawrence method may also be used as an alternative method for the detection of those toxins as published in AOAC Official Method 2005.06 (Paralytic Shellfish Poisoning Toxins in Shellfish).

2. If the results are challenged, the reference method shall be the biological method.

3. Points 1 and 2 will be reviewed in light of the successful completion of the harmonisation of the implementing steps of the Lawrence method by the Community Reference Laboratory for marine biotoxins.'

ANNEX II

Annex VI to Regulation (EC) No 2074/2005 is replaced by the following:

«*ANNEX VI*

MODEL HEALTH CERTIFICATES FOR IMPORTS OF CERTAIN PRODUCTS OF ANIMAL ORIGIN INTENDED FOR HUMAN CONSUMPTION

SECTION I

FROGS' LEGS AND SNAILS

Health certificates as referred to in Article 6(1)(d) of Regulation (EC) No 853/2004 for imports of frogs' legs and snails shall comply with the models laid down respectively in Part A and Part B of Appendix I to this Annex.

SECTION II

GELATINE

Without prejudice to other specific Community legislation, in particular to legislation on transmissible spongiform encephalopathies and hormones, health certificates as referred to in Article 6(1)(d) of Regulation (EC) No 853/2004 for imports of gelatine and raw materials for the production of gelatine shall comply with the models laid down respectively in Part A and Part B of Appendix II to this Annex.

SECTION III

COLLAGEN

Without prejudice to other specific Community legislation, in particular to legislation on transmissible spongiform encephalopathies and hormones, health certificates as referred to in Article 6(1)(d) of Regulation (EC) No 853/2004 for imports of collagen and raw materials for the production of collagen shall comply with the models laid down respectively in Part A and Part B of Appendix III to this Annex.

SECTION IV

FISHERY PRODUCTS

The health certificate as referred to in Article 6(1)(d) of Regulation (EC) No 853/2004 for imports of fishery products shall comply with the model laid down in Appendix IV to this Annex.

SECTION V

LIVE BIVALVE MOLLUSCS

The health certificate as referred to in Article 6(1)(d) of Regulation (EC) No 853/2004 for imports of live bivalve molluscs shall comply with the model laid down in Appendix V to this Annex.

SECTION VI

HONEY AND OTHER APICULTURE PRODUCTS

The health certificate as referred to in Article 6(1)(d) of Regulation (EC) No 853/2004 for imports of honey and other apiculture products shall comply with the model laid down in Appendix VI to this Annex.

Appendix I to Annex VI

PART A

MODEL HEALTH CERTIFICATE FOR IMPORTS OF CHILLED, FROZEN OR PREPARED FROGS' LEGS INTENDED FOR HUMAN CONSUMPTION

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor
Name
Address
Postal code
Tel No.

I.2. Certificate reference number | I.2.a.

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel No.

I.6.

I.7. Country of origin | ISO code | I.8.

I.9. Country of destination | ISO code | I.10.

I.11. Place of origin
Name | Approval number
Address

I.12.

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)
0208 20

I.20. Quantity

I.21. Temperature of product
Ambient ☐ Chilled ☐ Frozen ☐

I.22. Number of packages

I.23. Identification of container/Seal number

I.24. Type of packaging

I.25. Commodities certified for
Human consumption ☐

I.26.

I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Species (Scientific name)	Treatment type	Approval number of establishments: Manufacturing plant	Number of packages	Net weight

COUNTRY **Frogs' legs**

Part II: Certification

II. **Health attestation**	II.a. Certificate reference number	II.b.

I, the undersigned, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004 and (EC) No 853/2004 and certify that the frogs' legs described above were produced in accordance with those requirements, in particular that they:

— come from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004

and

— originate from frogs that have been bled, prepared and, where appropriate, chilled frozen or processed, packaged and stored in a hygienic manner in accordance with the requirements of Annex III, Section XI of Regulation (EC) No 853/2004

Notes

Part I:

— Box reference I.11: Place of origin: name and address of the dispatch establishment.
— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship). Separate information is to be provided in the event of unloading and reloading.
— Box reference I.23: Identification of container/seal number: only where applicable.
— Box reference I.28: Treatment type: chilled, frozen, processed.

Part II:

— The colour of the stamp and signature must be different to that of the other particulars in the certificate.

Official inspector

Name (in capitals): Qualification and title:
Date: Signature:
Stamp:

PART B

MODEL HEALTH CERTIFICATE FOR IMPORTS OF CHILLED, FROZEN, SHELLED, COOKED, PREPARED OR PRESERVED SNAILS INTENDED FOR HUMAN CONSUMPTION

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor
Name
Address
Postal code
Tel No.

I.2. Certificate reference number | I.2.a.

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel No.

I.6.

I.7. Country of origin | ISO code | I.8.

I.9. Country of destination | ISO code | I.10.

I.11. Place of origin
Name | Approval number
Address

I.12.

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20. Quantity

I.21. Temperature of product
Ambient ☐ Chilled ☐ Frozen ☐

I.22. Number of packages

I.23. Identification of container/Seal number

I.24. Type of packaging

I.25. Commodities certified for
Human consumption ☐

I.26.

I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Species (Scientific name)	Treatment type	Approval number of establishments: Manufacturing plant	Number of packages	Net weight

COUNTRY **Snails**

Part II: Certification

II. **Health attestation**	II.a. Certificate reference number	II.b.

I, the undersigned, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004 and (EC) No 853/2004 and certify that the snails described above were produced in accordance with those requirements, in particular that they:

— come from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004

and

— have been handled and, where appropriate, shelled, cooked, prepared, preserved, frozen, packaged and stored in a hygienic manner in accordance with the requirements of Annex III, Section XI of Regulation (EC) No 853/2004

Notes

Part I:

— Box reference I.11: Place of origin: name and address of the dispatch establishment.
— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship). Separate information is to be provided in case of unloading and reloading.
— Box reference I.19: Use the appropriate HS codes: 03.07.60, 16.05.
— Box reference I.23: Identification of container/seal number: only where applicable.
— Box reference I.28: Treatment type: chilled, frozen, shelled, cooked, prepared, preserved.

Part II:

— The colour of the stamp and signature must be different to that of the other particulars in the certificate.

Official inspector

Name (in capitals): Qualification and title:
Date: Signature:
Stamp:

Appendix II to Annex VI

PART A

MODEL HEALTH CERTIFICATE FOR IMPORTS OF GELATINE INTENDED FOR HUMAN CONSUMPTION

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor
Name
Address
Postal code
Tel No.

I.2. Certificate reference number | I.2.a.

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel No.

I.6.

I.7. Country of origin | ISO code | I.8.

I.9. Country of destination | ISO code | I.10.

I.11. Place of origin
Name | Approval number
Address

I.12.

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)
35.03

I.20. Quantity

I.21. Temperature of product
Ambient ☐ Chilled ☐ Frozen ☐

I.22. Number of packages

I.23. Identification of container/Seal number

I.24. Type of packaging

I.25. Commodities certified for
Human consumption ☐

I.26.

I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Species (Scientific name)	Treatment type	Approval number of establishments: Manufacturing plant	Number of packages	Net weight

COUNTRY **Gelatine intended for human consumption**

Part II: Certification

II. **Health attestation**	II.a. Certificate reference number	II.b.

I, the undersigned, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004 and (EC) No 853/2004 and certify that the gelatine described above was produced in accordance with those requirements, in particular that it:

— comes from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004,

— has been produced from raw material which met the requirements of Section XIV, Chapters I and II of Annex III to Regulation (EC) No 853/2004,

— has been manufactured in compliance with the conditions set out in Section XIV, Chapter III of Annex III to Regulation (EC) No 853/2004,

— satisfies the criteria of Section XIV, Chapter IV of Annex III to Regulation (EC) No 853/2004 and to Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs,

and (1)

— if from ruminant origin, does not contain and is not derived from:

either (1)

specified risk material as defined in Annex XI, section A, to Regulation (EC) No 999/2001 produced after 31 March 2001, or mechanically recovered meat obtained from bones of bovine, ovine or caprine animals produced after 31 March 2001. After 31 March 2001 the bovine, ovine and caprine animals, from which this product is derived, have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity.

or

bovine, ovine and caprine materials other than those derived from animals born, continuously reared and slaughtered in ……(2) (3).

Notes

Part I:

— Box reference I.11: Place of origin: name and address of the dispatch establishment.
— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship). Separate information is to be provided in case of unloading and reloading.
— Box reference I.23: Identification of container/seal number: only where applicable.
— Box reference I.28: Treatment type: date of manufacture (dd/mm/yyyy).

Part II:

(1) Delete as appropriate.
(2) Insert the name of the country.
(3) As listed in point 15(b) of Annex XI to Regulation (EC) No 999/2001 as amended.
— The colour of the stamp and signature must be different to that of the other particulars in the certificate.

Official veterinarian

Name (in capitals): Qualification and title:
Date: Signature:
Stamp:

PART B

MODEL HEALTH CERTIFICATE FOR IMPORTS OF RAW MATERIALS FOR THE PRODUCTION OF GELATINE INTENDED FOR HUMAN CONSUMPTION

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor
Name
Address
Postal code
Tel No.

I.2. Certificate reference number | I.2.a.

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel No.

I.6.

I.7. Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10.

I.11. Place of origin
Name | Approval number
Address

I.12.

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20. Quantity

I.21. Temperature of product
Ambient ☐ Chilled ☐ Frozen ☐

I.22. Number of packages

I.23. Identification of container/Seal number

I.24. Type of packaging

I.25. Commodities certified for
Human consumption ☐

I.26.

I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Species (Scientific name)	Nature of commodity	Approval number of establishments: Manufacturing plant	Number of packages	Net weight

COUNTRY **Raw materials for the production of gelatine intended for human consumption**

Part II: Certification

II. **Health attestation**	II.a. Certificate reference number	II.b.

I, the undersigned, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/2004 and certify that the raw material described above complies with those requirements, in particular that:

— bones, hides and skins of domestic and farmed ruminant animals, pig skins, poultry skin and tendons and sinews described above derive from animals which have been slaughtered in a slaughterhouse and whose carcases have been found fit for human consumption following ante- and post-mortem inspection (1)

and/or

— wild game hides and skins described above derive from killed animals whose carcases have been found fit for human consumption following post-mortem inspection (1)

and/or

— fish skin and bones described above come from plants manufacturing fish products for human consumption authorised for export (1)

and (1)

— if from ruminant origin, the raw material does not contain and is not derived from:

either (1)

specified risk material as defined in Annex XI, section A, to Regulation (EC) No 999/2001 produced after 31 March 2001, or mechanically recovered meat obtained from bones of bovine, ovine or caprine animals produced after 31 March 2001. After 31 March 2001 the bovine, ovine and caprine animals, from which this product is derived, have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity

or

bovine, ovine and caprine materials other than those derived from animals born, continuously reared and slaughtered in.....(2) (3).

Notes

Part I:

— Box reference I.8: Region of origin: if appropriate.
— Box reference I.11: Place of origin: name and address of the dispatch establishment.
— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship). Separate information is to be provided in case of unloading and reloading.
— Box reference I.19: Use the appropriate HS codes: 05.05, 05.06, 05.11.91, 05.11.99.
— Box reference I.23: Identification of container/seal number: only where applicable.
— Box reference I.28: Nature of commodity: (hides), (skins), (bones), (tendons) and (sinews);
Manufacturing plant: includes slaughterhouse, factory vessel, cutting plant, game handling establishment and processing plant.

Part II:

(1) Delete as appropriate.
(2) Insert the name of the country.
(3) As listed in point 15(b) of Annex XI to Regulation (EC) No 999/2001 as amended.
— The colour of the stamp and signature must be different to that of the other particulars in the certificate.

Official veterinarian

Name (in capitals): Qualification and title:
Date: Signature:
Stamp:

Appendix III to Annex VI

PART A

MODEL HEALTH CERTIFICATE FOR IMPORTS OF COLLAGEN INTENDED FOR HUMAN CONSUMPTION

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor
Name
Address
Postal code
Tel No.

I.2. Certificate reference number I.2.a.

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel No.

I.6.

I.7. Country of origin ISO code I.8.

I.9. Country of destination ISO code I.10.

I.11. Place of origin
Name Approval number
Address

I.12.

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)
35.04

I.20. Quantity

I.21. Temperature of product
Ambient ☐ Chilled ☐ Frozen ☐

I.22. Number of packages

I.23. Identification of container/Seal number

I.24. Type of packaging

I.25. Commodities certified for
Human consumption ☐

I.26.

I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Species (Scientific name)	Treatment type	Approval number of establishments: Manufacturing plant	Number of packages	Net weight

COUNTRY **Collagen intended for human consumption**

Part II: Certification

II. **Health attestation**	II.a. Certificate reference number	II.b.

I, the undersigned, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004 and (EC) No 853/2004 and certify that the collagen described above was produced in accordance with those requirements, in particular that it:

— comes from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004,

— has been produced from raw material which met the requirements of Section XV, Chapters I and II of Annex III to Regulation (EC) No 853/2004,

— has been manufactured in compliance with the conditions set out in Section XV, Chapter III of Annex III to Regulation (EC) No 853/2004,

and

— satisfies the criteria of Section XV, Chapter IV of Annex III to Regulation (EC) No 853/2004 and to Regulation (EC) No 2073/2005 on microbiological criteria for foodstufffs.

Notes

Part I:

— Box reference I.11: Place of origin: name and address of the dispatch establishment.
— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship). Separate information is to be provided in case of unloading and reloading.
— Box reference I.23: Identification of container/seal number: only where applicable.
— Box reference I.28: Treatment type: date of manufacture (dd/mm/yyyy).

Part II:

— The colour of the stamp and signature must be different to that of the other particulars in the certificate.

Official veterinarian

Name (in capitals): Qualification and title:
Date: Signature:
Stamp:

PART B

MODEL HEALTH CERTIFICATE FOR IMPORTS OF RAW MATERIALS FOR THE PRODUCTION OF COLLAGEN INTENDED FOR HUMAN CONSUMPTION

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor
Name
Address
Postal code
Tel No.

I.2. Certificate reference number | I.2.a.

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel No.

I.6.

I.7. Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10.

I.11. Place of origin
Name | Approval number
Address

I.12.

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20. Quantity

I.21. Temperature of product
Ambient ☐ Chilled ☐ Frozen ☐

I.22. Number of packages

I.23. Identification of container/Seal number

I.24. Type of packaging

I.25. Commodities certified for
Human consumption ☐

I.26.

I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Species (Scientific name)	Nature of commodity	Approval number of establishments: Manufacturing plant	Number of packages	Net weight

COUNTRY **Raw materials for the production of collagen intended for human consumption**

Part II: Certification

II. **Health attestation**	II.a. Certificate reference number	II.b.

I, the undersigned, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004 and 854/2004 and certify that the raw material described above complies with those requirements, in particular that:

— hides and skins of domestic and farmed ruminant animals/pig skins, bones and intestines/poultry skin and bones/tendons and sinews described above derive from animals which have been slaughtered in a slaughterhouse and whose carcases have been found fit for human consumption following ante- and post-mortem inspection (1),

and/or

— wild game hides and skins described above derive from killed animals whose carcases have been found fit for human consumption following post-mortem inspection (1),

and/or

— fish skin and bones described above derive from plants manufacturing fish products for human consumption authorised for export (1).

Notes

Part I:

— Box reference I.8: Region of origin: if appropriate.

— Box reference I.11: Place of origin: name and address of the dispatch establishment.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship). Separate information is to be provided in case of unloading and reloading.

— Box reference I.19: Use the appropriate HS codes: 05.04, 05.05, 05.06, 05.11.91, 05.11.99.

— Box reference I.23: Identification of container/seal number: only where applicable.

— Box reference I.28: Nature of commodity: (hides) (skins), (bones), (intestines), (tendons) and sinews);
Manufacturing plant: includes slaughterhouse, factory vessel, cutting plant, game handling establishment and processing plant.

Part II:

(1) Delete as appropriate.

— The colour of the stamp and signature must be different to that of the other particulars in the certificate.

Official veterinarian

Name (in capitals): Qualification and title:
Date: Signature:
Stamp:

Appendix IV to Annex VI

MODEL HEALTH CERTIFICATE FOR IMPORTS OF FISHERY PRODUCTS INTENDED FOR HUMAN CONSUMPTION

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor
Name
Address
Postal code
Tel No.

I.2. Certificate reference number | I.2.a.

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel No.

I.6.

I.7. Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10.

I.11. Place of origin
Name | Approval number
Address

I.12.

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)

I.20. Quantity

I.21. Temperature of product
Ambient ☐ Chilled ☐ Frozen ☐

I.22. Number of packages

I.23. Identification of container/Seal number

I.24. Type of packaging

I.25. Commodities certified for
Human consumption ☐

I.26.

I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Species (Scientific name)	Nature of commodity	Treatment type	Approval number of establishments: Manufacturing plant	Number of packages	Net weight

COUNTRY **Fishery products**

Part II: Certification

II. Health attestation	II.a. Certificate reference number	II.b.

II.1. Public health attestation

I, the undersigned, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/2004 and certify that the fishery products described above were produced in accordance with those requirements, in particular that they:

— come from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004,

— have been caught and handled on board vessels, landed, handled and where appropriate prepared, processed, frozen and thawed hygienically in compliance with the requirements laid down in Section VIII, Chapters I to IV of Annex III to Regulation (EC) No 853/2004,

— satisfy the health standards laid down in Section VIII, Chapter V of Annex III to Regulation (EC) No 853/2004 and the criteria laid down in Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs,

— have been packaged, stored and transported in compliance with Section VIII, Chapters VI to VIII of Annex III to Regulation (EC) No 853/2004,

— have been marked in accordance with Section I of Annex II to Regulation (EC) No 853/2004

— the guarantees covering live animals and products thereof, if from aquaculture origin, provided by the residue plans submitted in accordance with Directive 96/23/EC, and in particular Article 29 thereof, are fulfilled

and

— have satisfactorily undergone the official controls laid down in Annex III to Regulation (EC) No 854/2004.

II.2. (1) [Animal health attestation for products of aquaculture origin

I, the undersigned, declare that the fishery products described above originate from fish or crustaceans that were clinically healthy on the day of harvest, and have been transported under conditions that do not alter the animal health status of the products and certify, in particular that:

— (1)[(2) if from species susceptible (3) to ISA and/or EHN, they:

  — (1) [originate from a source (4) considered free from ISA and/or EHN in accordance with the relevant EU legislation or OIE Standard (5)],

  — (1) [have been slaughtered and eviscerated]].

— (1)[(6) if from species susceptible (3) to VHS and/or IHN, they:

  — (1) originate from a source (4) considered free from (1) VHS/(1) IHN in accordance with the relevant EU legislation or OIE Standard (5)],

  — (1) [have been slaughtered and eviscerated]]].

Notes

Part I:

— Box reference I.8: Region of origin: For products of aquaculture origin and if appropriate, indicate zones as listed in Commission Decisions 2002/308/EC and 2003/634/EC. For frozen or processed bivalve molluscs, indicate the production area.

— Box reference I.11: Place of origin: name and address of the dispatch establishment.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship). Separate information is to be provided in the event of unloading and reloading.

— Box reference I.19: Use the appropriate HS codes: 03.01, 03.02, 03.03, 03.04, 03.05, 03.06, 03.07, 05.11.91, 15.04, 15.18.00, 16.03, 16.04, 16.05.

— Box reference I.23: Identification of container/seal number: only where applicable.

— Box reference I.28: Nature of commodity: specify if aquaculture or wild origin.
Treatment type: live, chilled, frozen, processed.
Manufacturing plant: includes factory vessel, freezer vessel, cold store, processing plant.

Part II:

— Part II.2 is not relevant for consignments intended for retail, provided they comply with the rules applying to packaging and labelling laid down in Regulation (EC) No 853/2004.

([1]) Delete as appropriate.

([2]) This part of the animal health certificate is only relevant if the consignment comprises species referred to as susceptible to ISA and/or EHN. The requirement applies to exports to all Member States, whereby one of the two statements should be retained, unless the consignment is intended for further processing in an approved import centre.

([3]) Known susceptible species

Disease	**Susceptible host species**
EHN	Redfin perch *(Perca fluviatilis)*, rainbow trout *(Oncorhynchus mykiss)*
ISA	Atlantic salmon *(Salmo salar)*, rainbow trout *(Oncorhynchus mykiss)*, brown trout *(Salmo trutta)*,
VHS	Atlantic cod *(Gadus morhua)*, Atlantic herring *(Clupea harengus)*, brown trout *(Salmo trutta)*, chinook salmon *(Oncorhynchus tshawytscha)*, coho salmon *(O. kisutch)*, grayling *(Thymallus thymallus)*, haddock *(Melanogrammus aeglefinus)*, Pacific cod *(Gadus macrocephalus)*, Pacific herring *(Clupea harengus pallasi)*, pike *(Esox lucius)*, rainbow trout *(Oncorhynchus mykiss)*, rockling *(Rhinonemus cimbrius)*, sprat *(Sprattus sprattus)*, turbot *(Scophthalmus maximus)*, whitefish (*Coregonus* sp.)
IHN	Rainbow or steelhead trout (*Oncorhynchus mykiss*), the Pacific salmon species (chinook salmon (*O. tshawytscha*), sockeye salmon (*O. nerka*), chum salmon (*O. keta*), masou salmon (*O. masou*), pink salmon (*O. rhodurus*) and coho salmon (*O. kisutch*)), and Atlantic salmon (*Salmo salar*).

([4]) Source may be a country, zone, or an individual farm.

([5]) Freedom according to the provisions laid down in Annex B or C to Directive 91/67/EEC, and Commission Decisions 2001/183/EEC and 2003/466/EC. Freedom according to the most current edition of the OIE Code and Manual is also recognised.

([6]) This part of the animal health certificate is only relevant if the consignment comprises species referred to as susceptible to VHS and/or IHN. In order for the consignment to be authorised into a Member State or part thereof (boxes I.9 and I.10 of Part I of the certificate) declared free from VHS, and/or IHN, or undergoing a programme for such freedom, one of the two statements must be retained, unless the consignment is intended for further processing in an approved import centre.

A list of such Member States and zones are listed in Commission Decisions 2002/308/EC and 2003/634/EC.

— The colour of the stamp and signature must be different from that of the most particulars in the certificate.

Official inspector

Name (in capitals): Qualification and title:
Date: Signature:
Stamp:

Appendix V to Annex VI

PART A

MODEL HEALTH CERTIFICATE FOR IMPORTS OF LIVE BIVALVE MOLLUSCS INTENDED FOR HUMAN CONSUMPTION

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor
Name
Address
Postal code
Tel No.

I.2. Certificate reference number | I.2.a.

I.3. Central Competent Authority

I.4. Local Competent Authority

I.5. Consignee
Name
Address
Postal code
Tel No.

I.6.

I.7. Country of origin | ISO code | I.8. Region of origin | Code

I.9. Country of destination | ISO code | I.10.

I.11. Place of origin
Name | Approval number
Address

I.12.

I.13. Place of loading

I.14. Date of departure

I.15. Means of transport
Aeroplane ☐ Ship ☐ Railway wagon ☐
Road vehicle ☐ Other ☐
Identification:
Documentary references:

I.16. Entry BIP in EU

I.17.

I.18. Description of commodity

I.19. Commodity code (HS code)
03 07

I.20. Quantity

I.21.

I.22. Number of packages

I.23. Identification of container/Seal number

I.24. Type of packaging

I.25. Commodities certified for
Human consumption ☐

I.26.

I.27. For import or admission into EU ☐

I.28. Identification of the commodities

Species (Scientific name)	Nature of commodity	Approval number of establishments: Manufacturing plant	Number of packages	Net weight

COUNTRY **Live bivalve molluscs**

Part II: Certification

II. **Health attestation**	II.a. Certificate reference number	II.b.

II.1. Public health attestation

I, the undersigned, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/2004 and certify that the live bivalve molluscs described above were produced in accordance with those requirements, in particular that they:

— come from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004,

— have been harvested, where necessary relayed and transported in accordance with Section VII, Chapters I and II of Annex III to Regulation (EC) No 853/2004,

— were handled, where necessary purified, and packaged in compliance with Section VII, Chapters III and IV of Annex III to Regulation (EC) No 853/2004,

— satisfy the health standards laid down in Section VII, Chapter V of Annex III to Regulation (EC) No 853/2004 and the criteria laid down in Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs,

— have been packaged, stored and transported in compliance with Section VII, Chapters VI and VIII of Annex III to Regulation (EC) No 853/2004,

— have been marked and labelled in accordance with Section I of Annex II and Section VII, Chapter VII of Annex III to Regulation (EC) No 853/2004,

— in the case of *pectinidae* harvested outside classified production areas, comply with the specific requirements laid down in Section VII, Chapter IX of Annex III to Regulation (EC) No 853/2004

and

— have satisfactorily undergone the official controls laid down in Annex III to Regulation (EC) No 854/2004.

II.2. (1) **[Animal health attestation**

I, the undersigned, declare that the live molluscs described above originate from a source (2) where there are no unresolved abnormal mortality in the mollusc population, and certify, in particular that:

— (1)[(3) if from species susceptible (4) to infections with *Bonamia exitiosa, Mikrocytos roughleyi, Marteilia sydneyi, Mikrocytos mackini, Perkinsus marinus, P. olseni/atlanticus; Haplosporidium nelsoni, H. costale and/or Candidatus Xenohaliotis californiensis*, they:

  — (1) [originate from a source (2) considered free from bonamiosis (*Bonamia exitiosa* and *Mikrocytos roughleyi*); marteiliosis (Marteilia sydneyi); mikrocytosis (*Mikrocytos mackini*); *perkinsosis* (*Perkinsus marinus* and *P. olseni/atlanticus*); haplosporidiosis (*Haplosporidium nelsoni* and *H. costale*) and Withering syndrome (*Candidatus Xenohaliotis californiensis*) in accordance with the relevant EU legislation or OIE Standard (5)],

  — (1) [are dispatched as unprocessed or processed products]],

— (1)[(6) if from species susceptible (3) to infections with *Marteilia refringens* or *Bonamia ostrea*, they:

  — (1) [originate from a source (2) considered free from (1) *Marteilia refringens* / (1)*Bonamia ostrea* in accordance with the relevant EU legislation or OIE Standard (5)],

  — (1) [are dispatched as unprocessed or processed products]],]

Notes

Part I:

— Box reference I.8: Region of origin: indicate the production area.

— Box reference I.11: Place of origin: name and address of the dispatch establishment.

— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship). Separate information is to be provided in the event of unloading and reloading.

— Box reference I.23: Identification of container/seal number: only where applicable.

— Box reference I.28: Manufacturing plant: includes dispatch centre, purification centre.

Part II:

— Part II.2 is not relevant for consignments intended for retail, provided they comply with the rules applying to packaging and labelling laid down in Regulation (EC) No 853/2004.

([1]) Delete as appropriate

([2]) Source may be a country, zone, or an individual farm.

([3]) This requirement applies to exports to all Member States. However, it is only relevant if the consignment comprises species susceptible to bonamiosis (*Bonamia exitiosa and Mikrocytos roughleyi*); marteiliosis (*Marteilia sydneyi*); mikrocytosis (*Mikrocytos mackini*); perkinsosis (*Perkinsus marinus* and *P. olseni/atlanticus*); haplosporidiosis (*Haplosporidium nelsoni* and *H. costale*) and Withering syndrome (*Candidatus Xenohaliotis californiensis*), whereby one or the two statements must be retained.

([4]) Known susceptible species

Disease (Infection with)	**Susceptible host species**
Bonamia exitiosa	*Tiostrea chilensis and Ostrea angasi*
Bonamia ostrea	*Ostrea edulis*
Mikrocytos roughleyi	*Saccostrea (commercialis) glomerata*
Marteilia sydneyi	*Saccostrea (commercialis) glomerata*
Marteilia refringens	*Ostrea edulis*
Mikrocytos mackini	*Crassostrea gigas*; *C. virginica*; *Ostrea edulis*; *O. conchaphila*
Perkinsus marinus	*Crassostrea virginica* and *C. gigas*
Perkinsus olseni/atlanticus	*Haliotis ruber; H. cyclobates*; *H. scalaris; H. laevigata, Ruditapes philippinarum and R. decussatus*
Haplosporidium nelsoni	*Crassostrea virginica* and C. gigas
Haplosporidium costale	*Crassostrea virginica*
Xenohaliotis californiensis	black abalone *(Haliotis. cracherodii)*, red abalone *(H. rufescens)*, pink abalone *(H. corrugata)*, green abalone *(H. fulgens)* and white abalone *(H. sorenseni)*

([5]) Freedom according to the provisions laid down in Annex B or C to Directive 91/67/EEC, and Commission Decisions 2002/878/EEC. Freedom according to the current edition of the OIE Code and Manual is also recognised.

([6]) This part of the animal health certificate is only relevant if the consignment comprises species referred to as susceptible species to infections with *Marteilia refringens* and/or *Bonamia ostrea*. In order for the consignment to be authorised into a Member State or part thereof (boxes I.9 and I.10 of Part I of the certificate) declared free from *Marteilia refringens* and/or *Bonamia ostrea*, or undergoing a programme for such freedom, one of the two statements must be retained. List of such Member States and zones are laid down in Commission Decisions 2002/300/EC and 1994/722/EEC.

— The colour of the stamp and signature must be different to that of the other particulars in the certificate.

Official inspector

Name (in capitals): Qualification and title
Date: Signature:
Stamp:

PART B

ADDITIONAL MODEL HEALTH ATTESTATION FOR PROCESSED BIVALVE MOLLUSCS BELONGING TO THE SPECIES *ACANTHOCARDIA TUBERCULATUM*

The official inspector hereby certifies that the processed bivalve molluscs of the species *Acanthocardia tuberculatum*, certified in the health certificate reference No: .....

1. were harvested in production areas clearly identified, monitored and authorised by the competent authority for the purpose of Commission Decision 2006/766/EC ([1]), and where the PSP level in the edible parts of these molluscs is lower than 300 μg for 100g ;

2. were transported in containers or vehicles sealed by the competent authority, directly to the establishment:

   .....
   .....
   (name and official approval number of the establishment, especially authorised by the competent authority to carry out their treatment);

3. were accompanied during the transport to this establishment by a document issued by the competent authority which authorises the transport, attesting to the nature and quantity of the product, area of origin and establishment of destination;

4. were subjected to the heat treatment to the Annex to Decision 96/77/EC;

5. do not contain a PSP level detectable by the bioassay method, as demonstrated by the attached analytical report(s) of the test undertaken on each lot included in the consignment covered by this attestation.

The official inspector hereby certifies that the competent authority has verified that the 'own health' checks implemented in the establishment referred to in point 2 are specifically applied to the heat treatment referred to in point 4.

The undersigned official inspector hereby declares that he/she is aware of the provisions of Decision 96/77/EC and that the attached analytical report(s) correspond(s) to the test carried out in the products after processing.

Official inspector	
Name (in capitals):	Qualification and title:
Date:	Signature:
Stamp:	

([1]) See page 53 of this Official Journal.

Appendix VI to Annex VI

MODEL HEALTH CERTIFICATE FOR IMPORTS OF HONEY AND OTHER APICULTURE PRODUCTS INTENDED FOR HUMAN CONSUMPTION

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor Name Address Postal code Tel No.		I.2. Certificate reference number	I.2.a.
		I.3. Central Competent Authority	
		I.4. Local Competent Authority	
I.5. Consignee Name Address Postal code Tel No.		I.6.	
I.7. Country of origin	ISO code I.8.	I.9. Country of destination	ISO code I.10.
I.11. Place of origin Name Address		I.12.	
I.13. Place of loading		I.14. Date of departure	
I.15. Means of transport Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification: Documentary references:		I.16. Entry BIP in EU I.17.	
I.18. Description of commodity		I.19. Commodity code (HS code)	
		I.20. Quantity	
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐		I.22. Number of packages	
I.23. Identification of container/Seal number		I.24. Type of packaging	
I.25. Commodities certified for Human consumption ☐			
I.26.		I.27. For import or admission into EU ☐	

I.28. Identification of the commodities

Species (Scientific name)	Treatment type	Approval number of establishments: Manufacturing plant	Number of packages	Net weight

COUNTRY **Honey and apiculture products**

Part II: Certification

II. **Health attestation**	II.a. Certificate reference number	II.b.

I, the undersigned, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004 and (EC) No 853/2004 and certify that honey and apiculture products described above were produced in accordance with those requirements, in particular that they:

— come from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004,

— have been handled and, where appropriate, prepared, packaged and stored in a hygienic manner in accordance with the requirements of Annex II to Regulation (EC) No 852/2004

and

— the guarantees covering live animals and products thereof provided by the residue plans submitted in accordance with Directive 96/23/EC, and in particular Article 29 thereof, are fulfilled.

Notes

Part I:

— Box reference I.11: Place of origin: name and address of the dispatch establishment.
— Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship). Separate information is to be provided in case of unloading and reloading.
— Box reference I.19: Use the appropriate HS codes: 04.09, 04.10.
— Box reference I.23: Identification of container/seal number: only where applicable.

Part II:

— The colour of the stamp and signature must be different to that of the other particulars in the certificate.

Official inspector

Name (in capitals): Qualification and title:
Date: Signature:
Stamp:

ANNEX III

The following Annex VIa on testing methods for raw milk and heat-treated milk is added to Regulation (EC) No 2074/2005:

'ANNEX VIa

TESTING METHODS FOR RAW MILK AND HEAT-TREATED MILK

CHAPTER I

DETERMINATION OF PLATE COUNT AND SOMATIC CELL COUNT

1. When checking against the criteria laid down in Annex III, Section IX, Chapter I, Part III to Regulation (EC) No 853/2004, the following standards must be applied as reference methods:

   (a) EN/ISO 4833 for the plate count at 30 °C;

   (b) ISO 13366-1 for the somatic cell count.

2. The use of alternative analytical methods is acceptable:

   (a) For the plate count at 30 °C, when the methods are validated against the reference method mentioned in point 1(a) in accordance with the protocol set out in EN/ISO standard 16140 or other similar internationally accepted protocols.

   In particular the conversion relationship between an alternative method and the reference method mentioned in point 1(a) is established according to ISO standard 21187.

   (b) For the somatic cell count, when the methods are validated against the reference method mentioned in point 1(b) in accordance with the protocol set out in ISO 8196 and when operated in accordance with ISO standard 13366-2 or other similar internationally accepted protocols.

CHAPTER II

DETERMINATION OF ALKALINE PHOSPHATASE ACTIVITY

1. When determining alkaline phosphatase activity, ISO standard 11816-1 must be applied as reference method.

2. The alkaline phosphatase activity is expressed as milliunits of enzyme activity per litre (mU/l). A unit of alkaline phosphatase activity is the amount of alkaline phosphatase enzyme that catalyses the transformation of 1 micromole of substrate per minute.

3. An alkaline phosphatase test is considered to give a negative result if the measured activity in cow's milk is not higher than 350 mU/l.

4. The use of alternative analytical methods is acceptable when the methods are validated against the reference method mentioned in point 1 in accordance with internationally accepted protocols.'

ANNEX IV

1. Commission Decision 91/180/EEC of 14 February 1991 laying down certain methods of analysis and testing of raw milk and heat-treated milk ([1]).

2. Commission Decision 2000/20/EC of 10 December 1999 establishing health certificates for the importation from third countries of gelatine intended for human consumption and of raw materials destined for the production of gelatine intended for human consumption ([2]).

3. Decisions laying down import conditions for fishery products.

   (1) Commission Decision 93/436/EEC of 30 June 1993 laying down special conditions governing imports of fishery products orginating in Chile ([3]).

   (2) Commission Decision 93/437/EEC of 30 June 1993 laying down special conditions governing imports of fishery products originating in Argentina ([4]).

   (3) Commission Decision 93/494/EEC of 23 July 1993 laying down special conditions governing imports of fishery products originating in the Faeroe Islands ([5]).

   (4) Commission Decision 93/495/EEC of 26 July 1993 laying down special conditions governing imports of fishery products originating in Canada ([6]).

   (5) Commission Decision 94/198/EC of 7 April 1994 laying down special conditions governing the import of fishery and aquaculture products originating in Brazil ([7]).

   (6) Commission Decision 94/200/EC of 7 April 1994 laying down special conditions governing the import of fishery and aquaculture products originating in Ecuador ([8]).

   (7) Commission Decision 94/269/EC of 8 April 1994 laying down special conditions governing imports of fishery and aquaculture products originating in Colombia ([9]).

   (8) Commission Decision 94/323/EC of 19 May 1994 laying down special conditions governing imports of fishery products originating in Singapore ([10]).

   (9) Commission Decision 94/324/EC of 19 May 1994 laying down special conditions governing imports of fishery and aquaculture products originating in Indonesia ([11]).

   (10) Commission Decision 94/325/EC of 19 May 1994 laying down special conditions governing imports of fishery and aquaculture products originating in Thailand ([12]).

   (11) Commission Decision 94/448/EC of 20 June 1994 laying down special conditions governing imports of fishery and aquaculture products originating in New Zealand ([13]).

   (12) Commission Decision 94/766/EC of 21 November 1994 laying down special conditions governing the import of fishery and aquaculture products originating in Taiwan ([14]).

   (13) Commission Decision 95/30/EC of 10 February 1995 laying down special conditions governing imports of fishery and aquaculture products originating in Morocco ([15]).

([1]) OJ L 93, 13.4.1991, p. 1.
([2]) OJ L 6, 11.1.2000, p. 60.
([3]) OJ L 202, 12.8.1993, p. 31.
([4]) OJ L 202, 12.8.1993, p. 42.
([5]) OJ L 232, 15.9.1993, p. 37.
([6]) OJ L 232, 15.9.1993, 43.
([7]) OJ L 93, 12.4.1994, p. 26.
([8]) OJ L 93, 12.4.1994, p. 34.
([9]) OJ L 115, 6.5.1994, p. 38.
([10]) OJ L 145, 10.6.1994, p. 19.
([11]) OJ L 145, 10.6.1994, p. 23.
([12]) OJ L 145, 10.6.1994, p. 30.
([13]) OJ L 184, 20.7.1994, p. 16.
([14]) OJ L 305, 30.11.1994, p. 31.
([15]) OJ L 42, 24.2.1995, p. 32, as corrected by OJ L 48, 3.3.1995.

(14) Commission Decision 95/90/EC of 17 March 1995 laying down special conditions governing the import of fishery and aquaculture products originating in Albania ([1]).

(15) Commission Decision 95/173/EC of 7 March 1995 laying down special conditions governing imports of fishery and aquaculture products originating in Peru ([2]).

(16) Commission Decision 95/190/EC of 17 May 1995 laying down special conditions governing the import of fishery and aquaculture products originating in the Philippines ([3]).

(17) Commission Decision 95/454/EC of 23 October 1995 laying down special conditions governing imports of fishery and aquaculture products originating in the Republic of Korea ([4]).

(18) Commission Decision 95/538/EC of 6 December 1995 laying down special conditions governing the import of fishery and aquaculture products originating in Japan ([5]).

(19) Commission Decision 96/355/EC of 30 May 1996 laying down special conditions governing the import of fishery and aquaculture products originating in Senegal ([6]).

(20) Commission Decision 96/356/EC of 30 May 1996 laying down special conditions governing the import of fishery and aquaculture products originating in Gambia ([7]).

(21) Commission Decision 96/425/EC of 28 June 1996 laying down special conditions governing the import of fishery and aquaculture products originating in Mauritania ([8]).

(22) Commission Decision 96/606/EC of 11 October 1996 laying down special conditions governing the import of fishery and aquaculture products originating in Uruguay ([9]).

(23) Commission Decision 96/607/EC of 11 October 1996 laying down special conditions governing the import of fishery and aquaculture products originating in South Africa ([10]).

(24) Commission Decision 96/608/EC of 11 October 1996 laying down special conditions governing the import of fishery and aquaculture products originating in Malaysia ([11]).

(25) Commission Decision 96/609/EC of 14 October 1996 laying down special conditions governing the import of fishery and aquaculture products originating in the Ivory Coast ([12]).

(26) Commission Decision 97/102/EC of 16 January 1997 laying down special conditions governing the import of fishery and aquaculture products originating in Russia ([13]).

(27) Commission Decision 97/426/EC of 25 June 1997 laying down special conditions governing the import of fishery and aquaculture products originating in Australia ([14]).

(28) Commission Decision 97/757/EC of 6 November 1997 laying down special conditions governing imports of fishery and aquaculture products originating in Madagascar ([15]).

(29) Commission Decision 97/876/EC of 23 December 1997 laying down special conditions governing imports of fishery and aquaculture products originating in India ([16]).

(30) Commission Decision 98/147/EC of 13 February 1998 laying down special conditions governing imports of fishery and aquaculture products originating in Bangladesh ([17]).

([1]) OJ L 70, 30.3.1995, p. 27.
([2]) OJ L 116, 23.5.1995, p. 41.
([3]) OJ L 123, 3.06.1995, p. 20.
([4]) OJ L 264, 7.11.1995, p. 37.
([5]) OJ L 304, 16.12.1995, p. 52.
([6]) OJ L 137, 8.6.1996, p. 24.
([7]) OJ L 137, 8.6.1996, p. 31.
([8]) OJ L 175, 13.7.1996, p. 27.
([9]) OJ L 269, 22.10.1996, p. 18.
([10]) OJ L 269, 22.10.1996, p. 23.
([11]) OJ L 269, 22.10.1996, p. 32.
([12]) OJ L 269, 22.10.1996, p. 37.
([13]) OJ L 35, 5.2.1997, p. 23.
([14]) OJ L 183, 11.7.1997, p. 21.
([15]) OJ L 307, 12.11.1997, p. 33.
([16]) OJ L 356, 31.12.1997, p. 57.
([17]) OJ L 46, 17.2.1998, p. 13.

(31) Commission Decision 98/420/EC of 30 June 1998 laying down special conditions governing imports of fishery and aquaculture products originating in Nigeria ([1]).

(32) Commission Decision 98/421/EC of 30 June 1998 laying down special conditions governing imports of fishery and aquaculture products originating in Ghana ([2]).

(33) Commission Decision 98/422/EC of 30 June 1998 laying down special conditions governing imports of fishery and aquaculture products originating in Tanzania ([3]).

(34) Commission Decision 98/423/EC of 30 June 1998 laying down special conditions governing imports of fishery and aquaculture products originating in Falkland Islands ([4]).

(35) Commission Decision 98/424/EC of 30 June 1998 laying down special conditions governing imports of fishery and aquaculture products originating in Maldives ([5]).

(36) Commission Decision 98/568/EC of 6 October 1998 laying down special conditions governing imports of fishery and aquaculture products originating in Guatemala ([6]).

(37) Commission Decision 98/570/EC of 7 October 1998 laying down special conditions governing imports of fishery and aquaculture products originating in Tunisia ([7]).

(38) Commission Decision 98/572/EC of 12 October 1998 laying down special conditions governing imports of fishery and aquaculture products originating in Cuba ([8]).

(39) Commission Decision 98/695/EC of 24 November 1998 laying down special conditions governing imports of fishery and aquaculture products originating in Mexico ([9]).

(40) Commission Decision 1999/245/EC of 26 March 1999 laying down special conditions governing imports of fishery and aquaculture products originating in the Seychelles ([10]).

(41) Commission Decision 1999/276/EC of 23 April 1999 laying down special conditions governing imports of fishery and aquaculture products originating in Mauritius ([11]).

(42) Commission Decision 1999/526/EC of 14 July 1999 laying down special conditions governing imports of fishery and aquaculture products originating in Panama ([12]).

(43) Commission Decision 1999/527/EC of 14 July 1999 laying down special conditions governing imports of fishery and aquaculture products originating in Oman ([13]).

(44) Commission Decision 1999/528/EC of 14 July 1999 laying down special conditions governing imports of fishery and aquaculture products originating in Yemen ([14]).

(45) Commission Decision 1999/813/EC of 16 November 1999 laying down special conditions governing imports of fishery products originating in the Socialist Republic of Vietnam ([15]).

(46) Commission Decision 2000/83/EC of 21 December 1999 laying down special conditions governing imports of fishery and aquaculture products originating in Pakistan ([16]).

(47) Commission Decision 2000/86/EC of 21 December 1999 laying down special conditions governing imports of fishery products originating in China and repealing Decision 97/368/EC ([17]).

([1]) OJ L 190, 4.7.1998, p. 59.
([2]) OJ L 190, 4.7.1998, p. 66.
([3]) OJ L 190, 4.7.1998, p. 71.
([4]) OJ L 190, 4.7.1998, p. 76.
([5]) OJ L 190, 4.7.1998, p. 81.
([6]) OJ L 277, 14.10.1998, p. 26, as corrected by OJ L 325, 3.12.1998.
([7]) OJ L 277, 14.10.1998, p. 36.
([8]) OJ L 277, 14.10.1998, p. 44.
([9]) OJ L 33, 8.12.1998, p. 9.
([10]) OJ L 91, 7.4.1999, p. 40.
([11]) OJ L 108, 27.4.1999, p. 52.
([12]) OJ L 203, 3.8.1999, p. 58.
([13]) OJ L 203, 3.8.1999, p. 63.
([14]) OJ L 203, 3.8.1999, p. 68.
([15]) OJ L 315, 9.12.1999, p. 39.
([16]) OJ L 26, 2.2.2000, p. 13.
([17]) OJ L 26, 2.2.2000, p. 26.

(48) Commission Decision 2000/672/EC of 20 October 2000 laying down special conditions governing imports of fishery products originating in Venezuela ([1]).

(49) Commission Decision 2000/673/EC of 20 October 2000 laying down special conditions governing imports of fishery products originating in Namibia ([2]).

(50) Commission Decision 2000/675/EC of 20 October 2000 laying down special conditions governing imports of fishery products originating in the Islamic Republic of Iran ([3]).

(51) Commission Decision 2001/36/EC of 22 December 2000 laying down special conditions governing imports of fishery products originating in Jamaica ([4])

(52) Commission Decision 2001/632/EC of 16 August 2001 laying down special conditions governing imports of fishery products originating in Nicaragua ([5]).

(53) Commission Decision 2001/633/EC of 16 August 2001 laying down special conditions governing imports of fishery products originating in Uganda ([6]).

(54) Commission Decision 2001/634/EC of 16 August 2001 laying down special conditions governing imports of fishery products originating or proceeding from Guinea ([7]).

(55) Commission Decision 2002/25/EC of 11 January 2002 laying down special conditions governing imports of fishery products originating in the Republic of Croatia ([8]).

(56) Commission Decision 2002/26/EC of 11 January 2002 laying down special conditions governing imports of fishery products originating in the Republic of Gabon ([9]).

(57) Commission Decision 2002/27/EC of 11 January 2002 laying down special conditions governing imports of fishery products originating in the Republic of Turkey ([10]).

(58) Commission Decision 2002/472/EC of 20 June 2002 laying down specific conditions for imports of fishery products from the Republic of Bulgaria ([11]).

(59) Commission decision 2002/854/EC of 29 October 2002 laying down specific conditions for imports of fishery products from Costa Rica ([12]).

(60) Commission decision 2002/855/EC of 29 October 2002 laying down specific conditions for imports of fishery products from New Caledonia ([13]).

(61) Commission decision 2002/856/EC of 29 October 2002 laying down specific conditions for imports of fishery products from Greenland ([14]).

(62) Commission decision 2002/857/EC of 29 October 2002 laying down specific conditions for imports of fishery products from Suriname ([15]).

(63) Commission decision 2002/858/EC of 29 October 2002 laying down specific conditions for imports of fishery products from Mozambique ([16]).

(64) Commission decision 2002/859/EC of 29 October 2002 laying down specific conditions for imports of fishery products from Papua New Guinea ([17]).

([1]) OJ L 280, 4.11.2000, p. 46.
([2]) OJ L 280, 4.11.2000, p. 52.
([3]) OJ L 280, 4.11.2000, p. 63.
([4]) OJ L 10, 13.1.2001, p. 59.
([5]) OJ L 221, 17.8.2001, p. 40.
([6]) OJ L 221, 17.8.2001, p. 45.
([7]) OJ L 221, 17.8.2001, p. 50.
([8]) OJ L 11, 15.1.2002, p. 25.
([9]) OJ L 11, 15.1.2002, p. 31.
([10]) OJ L 11, 15.1.2002, p. 36.
([11]) OJ L 163, 21.6.2002, p. 24.
([12]) OJ L 301, 5.11.2002, p. 1.
([13]) OJ L 301, 5.11.2002, p. 6.
([14]) OJ L 301, 5.11.2002, p. 11.
([15]) OJ L 301, 5.11.2002, p. 19.
([16]) OJ L 301, 5.11.2002, p. 24.
([17]) OJ L 301, 5.11.2002, p. 33.

(65) Commission decision 2002/860/EC of 29 October 2002 laying down specific conditions for imports of fishery products from Switzerland ([1]).

(66) Commission decision 2002/861/EC of 29 October 2002 laying down specific conditions for imports of fishery products from Honduras ([2])

(67) Commission decision 2002/862/EC of 29 October 2002 laying down specific conditions for imports of fishery products from Kazakhstan ([3]).

(68) Commission Decision 2003/302/EC of 25 April 2003 laying down specific conditions for imports of fishery products from Sri Lanka ([4]).

(69) Commission Decision 2003/608/EC of 18 August 2003 laying down special conditions governing imports of fishery products from Mayotte ([5]).

(70) Commission Decision 2003/609/EC of 18 August 2003 laying down special conditions governing imports of fishery products from Saint Pierre et Miquelon ([6]).

(71) Commission Decision 2003/759/EC of 15 October 2003 laying down special conditions governing imports of fishery products from Belize ([7]).

(72) Commission Decision 2003/760/EC of 15 October 2003 laying down special conditions governing imports of fishery products from French Polynesia ([8]).

(73) Commission Decision 2003/761/EC of 15 October 2003 laying down special conditions governing imports of fishery products from the United Arab Emirates ([9]).

(74) Commission Decision 2003/762/EC of 15 October 2003 laying down special conditions governing imports of fishery products from the Netherlands Antilles ([10]).

(75) Commission Decision 2003/763/EC of 15 October 2003 laying down special conditions governing imports of fishery products from Cape Verde ([11]).

(76) Commission Decision 2004/37/EC of 23 December 2003 laying down special conditions governing imports of fishery products from Serbia and Montenegro ([12]).

(77) Commission Decision 2004/38/EC of 23 December 2003 laying down special conditions governing imports of fishery products from Egypt ([13]).

(78) Commission Decision 2004/39/EC of 23 December 2003 laying down special conditions governing imports of fishery products from Kenya, and repealing Decision 2000/759/EC ([14]).

(79) Commission Decision 2004/40/EC of 23 December 2003 laying down special conditions governing imports of fishery products from Guyana ([15]).

(80) Commission Decision 2004/360/EC of 13 April 2004 laying down special conditions for imports of fishery products from Zimbabwe ([16]).

(81) Commission Decision 2004/361/EC of 13 April 2004 laying down special conditions for imports of fishery products from Romania ([17]).

([1]) OJ L 301, 5.11.2002, p. 38.
([2]) OJ L 301, 5.11.2002, p. 43.
([3]) OJ L 301, 5.11.2002, p. 48.
([4]) OJ L 110, 3.5.2003, p. 6.
([5]) OJ L 210, 20.8.2003, p. 25.
([6]) OJ L 210, 20.8.2003, p. 30.
([7]) OJ L 273, 24.10.2003, p. 18.
([8]) OJ L 273, 24.10.2003, p. 23.
([9]) OJ L 273, 24.10.2003, p. 28.
([10]) OJ L 273, 24.10.2003, p. 33.
([11]) OJ L 273, 24.10.2003, p. 38.
([12]) OJ L 8, 14.1.2004, p. 12.
([13]) OJ L 8, 14.1.2004, p. 17.
([14]) OJ L 8, 14.1.2004, p. 22.
([15]) OJ L 8, 14.1.2004, p. 27.
([16]) OJ L 113, 20.4.2004, p. 48.
([17]) OJ L 113, 20.4.2004, p. 54.

(82) Commission Decision 2005/72/EC of 28 January 2005 laying down special conditions for imports of fishery products from Antigua and Barbuda ([1]).

(83) Commission Decision 2005/73/EC of 28 January 2005 laying down special conditions for imports of fishery products from Hong Kong ([2]).

(84) Commission Decision 2005/74/EC of 28 January 2005 laying down special conditions for imports of fishery products from El Salvador ([3]).

(85) Commission Decision 2005/218/EC of 11 March 2005 laying down special conditions for imports of fishery products from Saudi Arabia ([4]).

(86) Commission Decision 2005/498/EC of 12 July 2005 laying down special conditions for imports of fishery products from Algeria ([5]).

(87) Commission Decision 2005/499/EC of 12 July 2005 laying down special conditions for imports of fishery products from the Bahamas ([6]).

(88) Commission Decision 2005/500/EC of 12 July 2005 laying down special conditions for imports of fishery products from Grenada ([7]).

4. Decisions laying down import conditions for bivalve molluscs, echinoderms, tunicates and marine gastropods:

(1) Commission Decision 93/387/EEC of 7 June 1993 laying down special conditions for the import of live bivalve molluscs, echinoderms, tunicates and marine gastropods originating in Morocco ([8]).

(2) Commission Decision 94/777/EC of 30 November 1994 laying down special conditions for the import of live bivalve molluscs, echinoderms, tunicates and marine gastropods originating in Turkey ([9]).

(3) Commission Decision 95/453/EC of 23 October 1995 laying down special conditions for the import of live bivalve molluscs, echinoderms, tunicates and marine gastropods originating in the Republic of Korea ([10]).

(4) Commission Decision 96/675/EC of 25 November 1996 laying down special conditions for the import of live bivalve molluscs, echinoderms, tunicates and marine gastropods originating in Chile ([11]).

(5) Commission Decision 97/427/EC of 25 June 1997 laying down special conditions for the import of live bivalve molluscs, echinoderms, tunicates and marine gastropods originating in Australia ([12]).

(6) Commission Decision 97/562/EC of 28 July 1997 laying down special conditions for the import of bivalve molluscs, echinoderms, tunicates and marine gastropods originating in Thailand ([13]).

(7) Commission Decision 98/569/EC of 6 October 1998 laying down special conditions governing imports of live bivalve molluscs, echinoderms, tunicates and marine gastropods originating in Tunisia ([14]).

([1]) OJ L 28, 1.2.2005, p. 45.
([2]) OJ L 28, 1.2.2005, p. 54.
([3]) OJ L 28, 1.2.2005, p. 59.
([4]) OJ L 69, 16.3.2005, p. 50.
([5]) OJ L 183, 14.7.2005, p. 92.
([6]) OJ L 183, 14.7.2005, p. 99.
([7]) OJ L 183, 14.7.2005, p. 104.
([8]) OJ L 166, 8.7.1993, p. 40. Decision as last amended by Decision 96/31/EC.
([9]) OJ L 312, 6.12.1994, p. 35.
([10]) OJ L 264, 7.11.1995, p. 35. Decision as last amended by Decision 2001/676/EC
([11]) OJ L 313, 3.12.1996, p. 38.
([12]) OJ L 183, 11.7.1997, p. 38.
([13]) OJ L 232, 23.8.1997, p. 9.
([14]) OJ L 277, 14.10.1998, p. 31. Decision as last amended by Decision 2002/819/EC.

(8) Commission Decision 2000/333/EC of 25 April 2000 laying down special conditions for the import of bivalve molluscs, echinoderms, tunicates and marine gastropods originating in the Socialist Republic of Vietnam ([1]).

(9) Commission Decision 2001/37/EC of 22 December 2000 laying down special conditions for the import of marine gastropods originating in Jamaica ([2]).

(10) Commission Decision 2002/19/EC of 11 January 2002 laying down special conditions for the import of bivalve molluscs, echinoderms, tunicates and marine gastropods originating in Uruguay ([3]).

(11) Commission Decision 2002/470/EC of 20 June 2002 laying down special conditions for the import of processed or frozen bivalve molluscs, echinoderms, tunicates and marine gastropods from Japan ([4]).

(12) Commission Decision 2004/30/EC of 23 December 2003 laying down specific conditions for the import of processed and frozen bivalve molluscs, echinoderms, tunicates and marine gastropods from Peru and repealing Decisions 2001/338/EC and 95/174/EC ([5]).

([1]) OJ L 114, 13.5.2000, p. 42.
([2]) OJ L 10, 13.1.2001, p. 64.
([3]) OJ L 10, 12.1.2002, p. 73.
([4]) OJ L 163, 21.6.2002, p. 19.
([5]) OJ L 6, 10.1.2004, p. 53.

COMMISSION REGULATION (EC) No 1665/2006

of 6 November 2006

amending Regulation (EC) No 2075/2005 laying down specific rules on official controls for *Trichinella* in meat

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard 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 [1], and in particular Article 16 thereof,

Whereas:

(1) Regulation (EC) No 854/2004 lays down specific rules for the organisation of official controls on products of animal origin intended for human consumption, in particular as regards health marking.

(2) Commission Regulation (EC) No 2075/2005 of 5 December 2005 laying down specific rules on official controls for *Trichinella* in meat [2] generally does not allow meat of domestic swine to leave slaughterhouses before the results of examination for *Trichinella* infestation have been communicated to the official veterinarian. However, Regulation (EC) No 2075/2005 permits under certain strict conditions to apply the health mark and release the meat for transport before the results are known. Under such circumstances it is essential that the competent authority verifies that full traceability of the released meat is in place at all times.

(3) Regulation (EC) No 2075/2005 should, therefore, be amended accordingly

(4) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS REGULATION:

Article 1

Article 4(3) of Regulation (EC) No 2075/2005 is replaced by the following:

'3. Where a procedure is in place in the slaughterhouse to ensure that no part of carcases examined leaves the premises until the result of the *Trichinella* examination is found to be negative and the procedure is formally approved by the competent authority or where the derogation provided for in Article 2(2)(b) applies, the health mark provided for in Article 5 (2) of Regulation (EC) No 854/2004 may be applied before the results of the *Trichinella* examination are available.'

Article 2

This Regulation shall enter into force on the seventh day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 6 November 2006.

For the Commission

Markos KYPRIANOU

Member of the Commission

[1] OJ L 139, 30.4.2004, p. 206. Corrected by OJ L 226, 25.6.2004, p. 83. Regulation as last amended by Regulation (EC) No 2076/2005 (OJ L 338, 22.12.2005, p. 83).

[2] OJ L 338, 22.12.2005, p. 60.

COMMISSION REGULATION (EC) No 1666/2006

of 6 November 2006

amending Regulation (EC) No 2076/2005 laying down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council

(Text with EEA relevance)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard 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 ([1]), and in particular Article 9 thereof,

Having regard 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 ([2]), and in particular Article 16 thereof,

Whereas:

(1) Commission Regulation (EC) No 2076/2005 ([3]) lays down transitional arrangements for the implementation of Regulations (EC) No 853/2004, (EC) No 854/2004 and (EC) No 882/2004 of the European Parliament and of the Council ([4]). It is necessary to amend certain provisions.

(2) Commission Decision 2006/766/EC ([5]) draws up a list of third countries which satisfy the conditions referred to in Article 11(4) of Regulation (EC) No 854/2004 and which are therefore able to guarantee that bivalve molluscs, tunicates, echinoderms and marine gastropods and fishery products exported to the Community meet the sanitary conditions laid down in Community legislation to protect the health of consumers.

(3) Commission Decisions 97/20/EC ([6]) and 97/296/EC ([7]) allowed certain third countries which had not yet undergone a Community control to export live bivalve molluscs and fishery products into the Community under certain conditions. Those Decisions are repealed by Commission Decision 2006/765/EC ([8]). This possibility is not foreseen by Regulation (EC) No 854/2004. In order to avoid any disruption of the traditional pattern of trade, that possibility should be maintained on a transitional basis.

(4) The conditions to be applied to imports of live bivalve molluscs, tunicates, echinoderms and marine gastropods and fishery products from these third countries or territories should be at least equivalent to those governing the production and placing on the market of Community products.

(5) Without prejudice to the general principle laid down in Chapter II(A)(4) of Annex II to Regulation (EC) No 854/2004 whereby live bivalve molluscs from classified B areas must not exceed the limits of 4 600 *E.coli* per 100 g of flesh and intravalvular liquid, tolerance in 10 % of samples should be allowed for live bivalve molluscs originating from those areas. Since the tolerance in 10 % of samples does not represent a risk for public health and with a view to allowing competent authorities to adapt progressively to the scope of the relevant provisions in Regulation (EC) No 854/2004 regarding the classification of B areas, a transitional period should be granted for the classification of those areas.

(6) Regulation (EC) No 2076/2005 should be amended accordingly.

(7) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

([1]) OJ L 139, 30.4.2004, p. 55. Corrected by OJ L 226, 25.6.2004, p. 22. Regulation as last amended by Commission Regulation (EC) No 2076/2005 (OJ L 338, 22.12.2005, p. 83).

([2]) OJ L 139, 30.4.2004, p. 206. Corrected by OJ L 226, 25.6.2004, p. 83. Regulation as last amended by Commission Regulation (EC) No 2076/2005.

([3]) OJ L 338, 22.12.2005, p. 83.

([4]) OJ L 165, 30.4.2004, p. 1. Corrected by OJ L 191, 28.5.2004, p. 1. Regulation as amended by Commission Regulation (EC) No 776/2006 (OJ L 136, 24.5.2006, p. 3).

([5]) See page 53 of this Official Journal.

([6]) OJ L 6, 10.1.1997, p. 46. Decision as last amended by Decision 2002/469/EC (OJ L 163, 21.6.2002, p. 16).

([7]) OJ L 122, 14.5.1997, p. 21. Decision as last amended by Decision 2006/200/EC (OJ L 71, 10.3.2002, p. 50).

([8]) See page 50 of this Official Journal.

HAS ADOPTED THIS REGULATION:

Article 1

Regulation (EC) No 2076/2005 is amended as follows:

1. in Article 7, the following paragraphs 3 and 4 are added:

'3. By way of derogation from Annex III, Section VIII, Chapter III, Part E to Regulation 853/2004, food business operators may continue until 31 October 2007 to import fish oil from establishments in third countries that were approved for that purpose before the entry into force of Commission Regulation (EC) No 1664/2006 (*).

4. By way of derogation from Annex VI to Regulation (EC) 2074/2005 the products referred in that Annex for which the relevant import certificates have been issued in accordance with the harmonised Community rules in force before 1 January 2006 where applicable, and with the national rules implemented by the Member States before that date in other cases, may be imported into the Community until 1 May 2007.

(*) OJ L 320, 18.11.2006, p. 13.'

2. in Article 17 the following paragraph 2 is added:

'2. By way of derogation from Article 11(1) of Regulation (EC) No 854/2004, the Member States may authorise the import of bivalve molluscs and fishery products from the countries listed respectively in Annex I and Annex II to this Regulation, provided that:

(a) the competent authority of the third country or territory has provided to the Member State concerned the guarantees that the products in question have been obtained in conditions at least equivalent to those governing the production and placing on the market of Community products and

(b) the competent authority of the third country or territory takes appropriate measures in order to ensure that these imported products are accompanied by the model health certificates laid down in Commission Decisions 95/328/EC (*) and 96/333/EC (**) and marketed only on the domestic market of the importing Member State or Member States allowing the same import.

(*) OJ L 191, 12.8.1995, p. 32.
(**) OJ L 127, 25.5.1996, p. 33.'

3. The following Article 17*a* is inserted:

'Article 17a

Classification of production and relaying areas for live bivalve molluscs

By way of derogation from Chapter II (A) (4) of Annex II to Regulation (EC) No 854/2004, the competent authority may continue to classify as being of Class B areas for which the relevant limits of 4 600 *E. coli* par 100 g are not exceeded in 90 % of samples.';

4. Annex I and Annex II are added in accordance with the Annex to this Regulation.

Article 2

This Regulation shall enter into force on the seventh day following its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels, 6 November 2006.

For the Commission

Markos KYPRIANOU

Member of the Commission

ANNEX

'ANNEX I

List of third countries and territories from which imports of bivalve molluscs, echinoderms, tunicates and marine gasteropods in whatever form for human consumption may be permitted

CA — CANADA

GL — GREENLAND

US — UNITED STATES OF AMERICA

ANNEX II

List of third countries and territories from which imports of fishery products in whatever form for human consumption may be permitted

AO — ANGOLA

AZ — AZERBAIJAN [1]

BJ — BENIN

CG — REPUBLIC OF CONGO [2]

CM — CAMEROON

ER — ERITREA

FJ — FIJI

IL — ISRAEL

MM — MYANMAR

SB — SOLOMON ISLANDS

SH — ST HELENA

TG — TOGO

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[1] Authorised only for imports of caviar.

[2] Authorised only for imports of fishery products caught, frozen and packed in their final packaging at sea.'

II

(Acts whose publication is not obligatory)

COMMISSION

COMMISSION DECISION

of 6 November 2006

repealing certain implementing acts concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption

(notified under document number C(2006) 5175)

(Text with EEA relevance)

(2006/765/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard 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 [1], and in particular Article 9 thereof,

Having regard 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 [2], and in particular Article 16 thereof,

Whereas:

(1) The animal and public health rules governing the production and placing on the market of products of animal origin are laid down in Regulations (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs [3], (EC) No 853/2004 and (EC) No 854/2004.

(2) Directive 2004/41/EC of the European Parliament and of the Council [4] repealed certain directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin intended for human consumption and specified that the implementing measures adopted on the basis of these texts would remain in force pending their replacement. For reasons of legal certainty it is necessary formally to repeal the implementing measures, which have been replaced by the following acts:

— Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs [5],

— Commission Regulation (EC) No 2074/2005 of 5 December 2005 laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) 854/2004 [6],

— Commission Regulation (EC) No 2075/2005 of 5 December 2005 laying down specific rules on official controls for *Trichinella* in meat [7].

[1] OJ L 139, 30.4.2004, p. 55; corrected by OJ L 226, 25.6.2004, p. 22. Regulation as last amended by Commission Regulation (EC) No 2076/2005 (OJ L 338, 22.12.2005, p. 83).

[2] OJ L 139, 30.4.2004, p. 206; corrected by OJ L 226, 25.6.2004, p. 83. Regulation as last amended by Regulation (EC) No 2076/2005.

[3] OJ L 139, 30.4.2004, p. 1; corrected by OJ L 226, 25.6.2004, p. 3.

[4] OJ L 157, 30.4.2004, p. 33; corrected by OJ L 195, 2.6.2004, p. 12.

[5] OJ L 338, 22.12.2005, p. 1.

[6] OJ L 338, 22.12.2005, p. 27.

[7] OJ L 338, 22.12.2005, p. 60.

(3) The abovementioned Regulations have applied since 11 January 2006.

(4) Council Decision 94/371/EC of 20 June 1994 laying down specific public health conditions for the putting on the market of certain types of eggs ([1]) was adopted by the Council following the unfavourable opinion of the veterinary committee. The Commission, however, retains its implementing powers.

(5) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

The following directives and decisions are repealed with effect from 11 January 2006:

1. Commission Directive 83/201/EEC of 12 April 1983 establishing exceptions from Council Directive 77/99/EEC for certain products which contain other foodstuffs and only a small percentage of meat or meat product ([2]).

2. Commission Decision 84/371/EEC of 3 July 1984 establishing the characteristics of the special mark for fresh meat referred to in Article 5(a) of Directive 64/433/EEC ([3]).

3. Commission Decision 87/260/EEC of 28 April 1987 granting a derogation to the Netherlands and fixing the equivalent health conditions to be respected in relation to cutting of fresh meat ([4]).

4. Commission Decision 87/266/EEC of 8 May 1987 recognizing that the staff medical check-up scheme submitted by the Netherlands offers equivalent guarantees ([5]).

5. Commission Decision 87/562/EEC of 24 November 1987 granting derogation to the Federal Republic of Germany and fixing the equivalent health conditions to be respected in relation to cutting of fresh meat ([6]).

6. Commission Decision 88/235/EEC of 7 March 1988 granting derogation to Denmark and fixing the equivalent health conditions to be respected in relation to cutting of fresh meat ([7]).

7. Commission Decision 88/363/EEC of 13 June 1988 granting derogation to the United Kingdom and fixing the equivalent health conditions to be respected in relation to cutting of fresh meat ([8]).

8. Commission Decision 90/30/EEC of 10 January 1990 granting derogation to Spain and fixing the equivalent health conditions to be respected in relation to cutting of fresh meat ([9]).

9. Commission Decision 90/31/EEC of 10 January 1990 granting derogation to France and fixing the equivalent health conditions to be respected to cutting of fresh meat ([10]).

10. Commission Decision 90/469/EEC of 5 September 1990 granting derogation to Italy and fixing the equivalent health conditions to be respected in relation to cutting of fresh meat ([11]).

11. Commission Decision 90/514/EEC of 25 September 1990 recognizing that the staff medical check-up scheme submitted by Denmark offers equivalent guarantees ([12]).

12. Commission Decision 92/92/EEC of 9 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 ([13]).

13. Commission Decision 93/140/EEC of 19 January 1993 laying down the detailed rules relating to the visual inspection for the purpose of detecting parasites in fishery products ([14]).

14. Commission Decision 94/14/EC of 21 December 1993 setting up the list of establishments in the Community for which are granted temporary and limited derogation from specific Community health rules on the production and marketing of fresh meat ([15]).

15. Commission Decision 94/92/EC of 17 February 1994 concerning the financial aid from the Community for the operations of the Community Reference Laboratory for marine biotoxins (Laboratorio del Ministerio de Sanidad y Consumo, Vigo, Spain) ([16]).

([1]) OJ L 168, 2.7.1994, p. 34.
([2]) OJ L 112, 28.4.1983, p. 28.
([3]) OJ L 196, 26.7.1984, p. 46.
([4]) OJ L 123, 12.5.1987, p. 8.
([5]) OJ L 126, 15.5.1987, p. 20.
([6]) OJ L 341, 3.12.1987, p. 35.
([7]) OJ L 105, 26.4.1988, p. 20.
([8]) OJ L 177, 8.7.1988, p. 57.
([9]) OJ L 16, 20.1.1990, p. 35.
([10]) OJ L 16, 20.1.1990, p. 37.
([11]) OJ L 255, 19.9.1990, p. 16.
([12]) OJ L 286, 18.10.1990, p. 29.
([13]) OJ L 34, 11.2.1992, p. 34.
([14]) OJ L 56, 9.3.1993, p. 42.
([15]) OJ L 14, 17.1.1994, p. 1.
([16]) OJ L 46, 18.2.1994, p. 63.

16. Commission Decision 94/356/EC of 20 May 1994 laying down detailed rules for the application of Council Directive 91/493/EEC, as regards own health checks on fishery products ([1]).

17. Council Decision 94/371/EC of 20 June 1994 laying down specific public health conditions for the putting on the market of certain types of eggs ([2]).

18. Commission Decision 94/383/EC of 3 June 1994 on the criteria to be applied to establishments manufacturing meat products without having an industrial structure or an industrial production capacity ([3]).

19. Commission Decision 94/837/EC of 16 December 1994 laying down special conditions for the approval of the re-wrapping centres referred to in Council Directive 77/99/EEC and rules for the marketing of the products therefrom ([4]).

20. Commission Decision 95/149/EC of 8 March 1995 fixing the total volatile basic nitrogen (TVB-N) limit values for certain categories of fishery products and specifying the analysis methods to be used ([5]).

21. Commission Decision 95/165/EC of 4 May 1995 establishing uniform criteria for the grant of derogations to certain establishments manufacturing milk-based products ([6]).

22. Commission Decision 96/536/EC of 29 July 1996 establishing the list of milk-based products in respect of which Member States are authorised to grant individual or general derogations pursuant to Article 8(2) of Directive 92/46/EEC and the nature of the derogations applicable to the manufacture of such products ([7]).

23. Commission Decision 96/658/EC of 13 November 1996 laying down the special conditions for the approval of establishments situated in wholesale markets ([8]).

24. Commission Decision 98/470/EC of 9 July 1998 implementing Council Directive 89/662/EEC as regards information on veterinary checks ([9]).

25. Commission Decision 2001/471/EC of 8 June 2001 laying down rules for the regular checks on the general hygiene carried out by the operators in establishments according to Directive 64/433/EEC on health conditions for the production and marketing of fresh meat and Directive 71/118/EEC on health problems affecting the production and placing on the market of fresh poultry meat ([10]).

26. Commission Decision 2002/225/EC of 15 March 2002 laying down detailed rules for the implementation of Council Directive 91/492/EEC as regards the maximum levels and the methods of analysis of certain marine biotoxins in bivalve molluscs, echinoderms, tunicates and marine gastropods ([11]).

27. Commission Decision 2002/477/EC of 20 June 2002 laying down public health requirements for fresh meat and fresh poultrymeat imported from third countries, and amending Decision 94/984/EC ([12]).

28. Commission Decision 2003/380/EC of 22 May 2003 granting to Sweden a derogation from Council Directive 64/433/EEC and fixing the equivalent health conditions to be respected in relation to cutting of fresh meat ([13]).

29. Commission Decision 2003/774/EC of 30 October 2003 approving certain treatments to inhibit the development of pathogenic micro-organisms in bivalve molluscs and marine gastropods ([14]).

Article 2

This Decision is addressed to the Member States.

Done at Brussels, 6 November 2006.

For the Commission

Markos KYPRIANOU

Member of the Commission

([1]) OJ L 156, 23.6.1994, p. 50.
([2]) OJ L 168, 2.7.1994, p. 34.
([3]) OJ L 174, 8.7.1994, p. 33.
([4]) OJ L 352, 31.12.1994, p. 15.
([5]) OJ L 97, 29.4.1995, p. 84.
([6]) OJ L 108, 13.5.1995, p. 84.
([7]) OJ L 230, 11.9.1996, p. 12.
([8]) OJ L 302, 26.11.1996, p. 22.
([9]) OJ L 208, 24.7.1998, p. 54.
([10]) OJ L 165, 21.6.2001, p. 48.
([11]) OJ L 75, 16.3.2002, p. 62.
([12]) OJ L 164, 22.6.2002, p. 39.
([13]) OJ L 131, 28.5.2003, p. 18.
([14]) OJ L 283, 31.10.2003, p. 78.

COMMISSION DECISION

of 6 November 2006

establishing the lists of third countries and territories from which imports of bivalve molluscs, echinoderms, tunicates, marine gastropods and fishery products are permitted

(notified under document number C(2006) 5171)

(Text with EEA relevance)

(2006/766/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard 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 [1], and in particular Article 11(1) thereof,

Whereas:

(1) The special conditions for the import of bivalve molluscs, tunicates, echinoderms and marine gastropods and of fishery products from third countries have been laid down in Regulation (EC) No 854/2004.

(2) Commission Decision 97/20/EC [2] established the list of third countries fulfilling the equivalence conditions for the production and placing on the market of bivalve molluscs, echinoderms, tunicates and marine gastropods and Commission Decision 97/296/EC [3] drew up the list of third countries from which the import of fishery products is authorised for human consumption.

(3) Lists should be drawn up containing the third countries and territories which satisfy the criteria referred to in Article 11 (4) of Regulation (EC) No 854/2004 and which are therefore able to guarantee that bivalve molluscs, tunicates, echinoderms and marine gastropods and fishery products exported to the Community meet the sanitary conditions laid down to protect the health of consumers. Nevertheless, imports of adductor muscles of *pectinidae* other than aquaculture animals, completely separated from the viscera and gonads, should also be permitted from third countries not appearing on such a list.

(4) The competent authorities of Australia, New Zealand and Uruguay have provided appropriate guarantees that the conditions applicable to live bivalve molluscs, echinoderms, tunicates and marine gastropods are equivalent to those provided for in the relevant Community legislation.

(5) The competent authorities of Armenia, Belarus and Ukraine have provided appropriate guarantees that the conditions applicable to fishery products are equivalent to those provided for in the relevant Community legislation.

(6) Decisions 97/20/EC and 97/296/EC should therefore be repealed and replaced by a new Decision.

(7) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Imports of bivalve molluscs, tunicates, echinoderms and marine gastropods

1. The list of third countries from which bivalve molluscs, tunicates, echinoderms and marine gastropods may be imported, as referred to in Article 11(1) of Regulation (EC) No 854/2004, is established in Annex I to this Decision.

2. Notwithstanding Article 11(1) of Regulation (EC) No 854/2004 , Paragraph 1 shall not apply to the adductor muscles of *pectinidae* other than aquaculture animals, completely separated from the viscera and gonads, that may be imported also from third countries not appearing on the list referred to in paragraph 1.

Article 2

Imports of fishery products

The list of third countries and territories from which fishery products may be imported, as referred to in Article 11(1) of Regulation (EC) No 854/2004, is established in Annex II to this Decision.

[1] OJ L 139, 30.4.2004, p. 206; corrected by OJ L 226, 25.6.2004, p. 83. Regulation as last amended by Commission Regulation (EC) No 2076/2005 (OJ L 338, 22.12.2005, p. 83).

[2] OJ L 6, 10.1.1997, p. 46. Decision as last amended by Decision 2002/469/EC (OJ L 163, 21.6.2002, p. 16).

[3] OJ L 122, 14.5.1997, p. 21. Decision as last amended by Decision 2006/200/EC (OJ L 71, 10.3.2006, p. 50).

Article 3

Repeal

Decisions 97/20/EC and 97/296/EC are repealed.

References to the repealed Decisions shall be construed as references to this Decision.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 6 November 2006.

For the Commission

Markos KYPRIANOU

Member of the Commission

ANNEX I

List of third countries from which imports of bivalve molluscs, echinoderms, tunicates and marine gastropods in any form for human consumption are permitted

(Countries and territories referred to in Article 11 of Regulation (EC) No 854/2004)

AU — AUSTRALIA

CL — CHILE ([1])

JM — JAMAICA ([2])

JP — JAPAN ([1])

KR — SOUTH KOREA ([1])

MA — MOROCCO

NZ — NEW ZEALAND

PE — PERU ([1])

TH — THAILAND ([1])

TN — TUNISIA

TR — TURKEY

UY — URUGUAY

VN — VIETNAM ([1])

([1]) Only frozen or processed bivalve molluscs, echinoderms, tunicates and marine gastropods.

([2]) Only marine gastropods.

ANNEX II

List of third countries and territories from which imports of fishery products in any form for human consumption are permitted

(Countries and territories referred to in Article 11 of Regulation (EC) No 854/2004)

AE — UNITED ARAB EMIRATES

AG — ANTIGUA AND BARBUDA (1)

AL — ALBANIA

AM — ARMENIA (2)

AN — NETHERLANDS ANTILLES

AR — ARGENTINA

AU — AUSTRALIA

BD — BANGLADESH

BG — BULGARIA (3)

BR — BRAZIL

BS — THE BAHAMAS

BY — BELARUS

BZ — BELIZE

CA — CANADA

CH — SWITZERLAND

CI — IVORY COAST

CL — CHILE

CN — CHINA

CO — COLOMBIA

CR — COSTA RICA

CU — CUBA

CV — CAPE VERDE

DZ — ALGERIA

EC — ECUADOR

EG — EGYPT

FK — FALKLAND ISLANDS

GA — GABON

GD — GRENADA

GH — GHANA

GL — GREENLAND

GM — GAMBIA

GN — GUINEA CONAKRY (4) (5)

GT — GUATEMALA

GY — GUYANA

HK — HONG KONG

HN — HONDURAS

HR — CROATIA

ID — INDONESIA

IN — INDIA

IR — IRAN

JM — JAMAICA

JP — JAPAN

KE — KENYA

KR — SOUTH KOREA

KZ — KAZAKHSTAN

LK — SRI LANKA

MA — MOROCCO (6)

MG — MADAGASCAR

MR — MAURITANIA

MU — MAURITIUS

MV — MALDIVES

MX — MEXICO

MY — MALAYSIA

MZ — MOZAMBIQUE

(1) Only live crustaceans.

(2) Only for live non farmed crayfish.

(3) Only applicable until this Acceding State becomes a Member State of the Community.

(4) Only fish that has not undergone any preparation or processing operation other than heading, gutting, chilling or freezing.

(5) The reduced frequency of physical checks, provided for by Commission Decision 94/360/EC (OJ L 158, 25.6.1994, p. 41), shall not be applied.

(6) Processed bivalve molluscs belonging to the species *Acanthocardia tuberculatum* must be accompanied by: (a) an additional health attestation in accordance with the model set out in Part B of Appendix V of Annex VI to Commission Regulation (EC) No 2074/2005 (OJ L 338, 22.12.2005, p. 27); and (b) the analytical results of the test demonstrating that the molluscs do not contain a paralytic shellfish poison (PSP) level detectable by the bioassay method.

NA — NAMIBIA

NC — NEW CALEDONIA

NG — NIGERIA

NI — NICARAGUA

NZ — NEW ZEALAND

OM — OMAN

PA — PANAMA

PE — PERU

PG — PAPUA NEW GUINEA

PH — PHILIPPINES

PF — FRENCH POLYNESIA

PM — ST PIERRE & MIQUELON

PK — PAKISTAN

RO — ROMANIA [1]

RU — RUSSIA

SA — SAUDI ARABIA

SC — SEYCHELLES

SG — SINGAPORE

SN — SENEGAL

SR — SURINAME

SV — EL SALVADOR

TH — THAILAND

TN — TUNISIA

TR — TURKEY

TW — TAIWAN

TZ — TANZANIA

UA — UKRAINE

UG — UGANDA

US — UNITED STATES OF AMERICA

UY — URUGUAY

VE — VENEZUELA

VN — VIETNAM

XM — MONTENEGRO [2]

XS — SERBIA [2] [3]

YE — YEMEN

YT — MAYOTTE

ZA — SOUTH AFRICA

ZW — ZIMBABWE

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(1) Only applicable until this Acceding State becomes a Member State of the Community.

(2) Only whole fresh fish from wild seawater catches.

(3) Not including Kosovo as defined by the United Nations Security Council Resolution 1244 of 10 June 1999.

COMMISSION DECISION

of 6 November 2006

amending Commission Decisions 2003/804/EC and 2003/858/EC, as regards certification requirements for live molluscs and live fish of aquaculture origin and products thereof intended for human consumption

(notified under document number C(2006) 5167)

(Text with EEA relevance)

(2006/767/EC)

THE COMMISSION OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Community,

Having regard to Council Directive 91/67/EEC of 28 January 1991 concerning the animal health conditions governing the placing on the market of aquaculture animals and products [1], and in particular Article 19(1), 20(1) and 21(2) thereof,

Whereas:

(1) Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs [2] lays down the general rules for food business operators on the hygiene of foodstuffs.

(2) Regulation (EC) No 853/2004 of the European Parliament and of the Council of 29 April 2004 laying down specific requirements concerning hygiene rules for food of animal origin [3] lays down specific requirements concerning hygiene rules for food of animal origin.

(3) 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 [4], lays down specific rules for the organisation of official controls on products of animal origin intended for human consumption.

(4) Commission Regulation (EC) No 2074/2005 [5] lays down implementing measures for certain products under Regulation (EC) No 853/2004 and for the organisation of official controls under Regulation (EC) No 854/2004 and Regulation (EC) No 882/2004 of the European Parliament and of the Council [6], derogating from Regulation (EC) No 852/2004 and amending Regulations (EC) No 853/2004 and (EC) No 854/2004.

(5) Council Directive 95/70/EC [7] introduces minimum Community measures for the control of certain diseases affecting bivalve molluscs.

(6) Directive 91/67/EEC provides for the animal health conditions governing the placing on the market of aquaculture animals and products.

(7) Commission Decision 2003/804/EC of 14 November 2003 laying down animal health conditions and certification requirements for imports of molluscs their eggs and gametes for further growth, fattening, relaying or human consumption [8], and Commission Decision 2003/858/EC of 21 November 2003 laying down animal health conditions and certification requirements for imports of live fish, their eggs and gametes intended for farming, and live fish of aquaculture origin and products thereof intended for human consumption [9] lay down the certification requirements for live molluscs and live fish of aquaculture origin and products thereof intended for human consumption.

(8) In order to simplify the certification procedure for these products, animal health certification requirements laid down in those Decisions have been incorporated into the health certificates drawn up in accordance with Regulation (EC) No 853/2004 for consignments intended for human consumption.

(9) Decisions 2003/804/EC and 2003/858/EC should therefore be amended accordingly, also taking into account Council Directive COM(2005) 362 on animal health requirements for aquaculture animals and products thereof, and on the prevention and control of certain diseases in aquatic animals [10].

[1] OJ L 46, 19.2.1991, p. 1. Directive as last amended by Regulation (EC) No 806/2003 (OJ L 122, 16.5.2003, p. 1).

[2] OJ L 139, 30.4.2004, p. 1; corrected by OJ L 226, 25.6.2004, p. 3.

[3] OJ L 139, 30.4.2004, p. 55; corrected by OJ L 226, 25.6.2004, p. 22. Regulation as last amended by Commission Regulation (EC) No 2076/2005 (OJ L 338, 22.12.2005, p. 83).

[4] OJ L 139, 30.4.2004, p. 206; corrected by OJ L 226, 25.6.2004, p. 83. Regulation as last amended by Regulation (EC) No 2076/2005.

[5] OJ L 338, 22.12.2005, p. 27.

[6] OJ L 191, 28.5.2004, p. 1. Regulation as amended by Commission Regulation (EC) No 776/2006 (OJ L 136, 24.5.2006, p. 3).

[7] OJ L 332, 30.12.1995, p. 33. Directive as last amended by the 2003 Act of Accession.

[8] OJ L 302, 20.11.2003, p. 22. Decision as last amended by Decision 2005/409/EC (OJ L 139, 2.6.2005, p. 16).

[9] OJ L 324, 11.12.2003, p. 37. Decision as last amended by Decision 2005/742/EC (OJ L 279, 22.10.2005, p. 71).

[10] Not yet published in the Official Journal.

(10) The measures provided for in this Decision are in accordance with the opinion of the Standing Committee on the Food Chain and Animal Health,

HAS ADOPTED THIS DECISION:

Article 1

Amendments to Decision 2003/804/EC

Decision 2003/804/EC is amended as follows:

1. Article 4 is replaced by the following:

'*Article 4*

Conditions for the importation of live molluscs for human consumption

1. Member States shall authorise the importation into their territory live molluscs intended for human consumption, only if:

(a) the third country of dispatch appears on the list established by Commission Decision 2006/766/EC (*);

(b) the consignment is accompanied by a joint public and animal health certificate drawn up in conformity with the model laid down in Commission Regulation (EC) No 2074/2005;

(c) the consignment comply with the provisions for packaging and labelling provided for in Regulation (EC) No 853/2004.

2. If molluscs are to be relayed or re-immersed in Community waters, the consignment must also comply with the provisions laid down in Article 3(1).

(*) OJ L 320, 18.11.2006, p. 53.'

2. Article 5 is replaced by the following:

'*Article 5*

Additional conditions for the importation of certain live molluscs for human consumption

1. Consignments of mollusc species susceptible to one or more of the diseases referred to in Annex D to Directive 95/70/EC must, in addition to the requirements set out in Article 4:

(a) come from a source without any unresolved abnormal mortality and recognised free from diseases in question in accordance with Community legislation or the relevant OIE (World Organisation for Animal Health) Standard by the competent authority of the third country of origin; or

(b) be imported as processed or unprocessed products as defined in Article 2(1) of Regulation (EC) No 852/2004; or

(c) be sent directly to an approved import centre where the molluscs are further processed without prejudice to Annex III Section VII of Regulation (EC) No 853/2004 and Article 6 of Regulation (EC) No 854/2004.

2. Consignments of mollusc species susceptible to infection with *Bonamia ostrea* and/or *Marteilia refringens,* imported into Member States or zones being declared free, or under programme for achieving such status in accordance with Articles 5 or 10 of Directive 91/67/EEC, must comply with the following, in addition to the requirements set out in Article 4:

(a) the source must be recognised free from the relevant disease in accordance with Community legislation or the relevant OIE Standard by the competent authority of the third country of origin; or

(b) the consignment must be imported as processed or unprocessed products as defined in Article 2(1) of Regulation (EC) No 852/2004; or

(c) the consignment must be sent directly to an approved import centre where the molluscs are further processed without prejudice to Annex III Section VII of Regulation (EC) No 853/2004 and Article 6 of Regulation (EC) No 854/2004;

3. This Article shall not apply if the molluscs are packed and labelled to be presented for sale to the final consumer in accordance with Regulation (EC) No 853/2004.';

3. In Part A of Annex V, point 2 is replaced by the following:

'2. Viable molluscs may only leave approved import centres if they are packaged and labelled to be presented for sale to the final consumer in accordance with Regulation (EC) No 853/2004.'

Article 2

Amendments to Decision 2003/858/EC

Decision 2003/858/EC is amended as follows:

1. Article 5(1) is replaced by the following:

'*Article 5*

Conditions for the importation of fish products of aquaculture origin for human consumption

1. Member States shall authorise the importation into their territory of fish products of aquaculture origin intended for human consumption, only if:

(a) the third country of dispatch appears on the list established by Commission Decision 2006/766/EC (*);

(b) the consignment is accompanied by a joint public and animal health certificate drawn up in conformity with the model laid down in Commission Regulation (EC) No 2074/2005;

(c) the consignment comply with the provisions for packaging and labelling provided for in Regulation (EC) No 853/2004.

(*) OJ L 320, 18.11.2006, p. 53'

2. Article 6 is replaced by the following

'Article 6

Additional conditions for the importation of certain fish products of aquaculture origin for human consumption

1. Consignments of fish species susceptible to ISA and/or EHN must, in addition to the requirements set out in Article 5, also comply with the following:

(a) the source must be recognised free from diseases in question in accordance with Community legislation or the relevant OIE (World Organisation for Animal Health) Standard by the competent authority of the third country of origin, or

(b) the fish must be eviscerated before dispatch, or

(c) the consignment must be sent directly to an approved import centre where the fish are further processed.

2. Consignments of fish species susceptible to VHS and/or IHN, imported into Member States or zones being declared free or under programme for achieving such status in accordance with Articles 5 or 10 of Directive 91/67/EEC, must comply with the following, in addition to the requirements set out in Article 5:

(a) the source must be recognised free from the relevant disease in accordance with Community legislation or the relevant OIE Standard by the competent authority of the third country of origin, or

(b) the fish must be eviscerated before dispatch, or

(c) the consignment must be sent directly to an approved import centre where the fish are further processed.'

3. Annexes IV and V are deleted.

Article 3

This Decision shall apply on the seventh day following its publication in the *Official Journal of the European Union*.

Article 4

This Decision is addressed to the Member States.

Done at Brussels, 6 November 2006.

For the Commission
Markos KYPRIANOU
Member of the Commission