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**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) No 854/2004**

(Text with EEA relevance)

(OJ L 338, 22.12.2005, p. 27)

Amended by:

		Official Journal		
		No	page	date
► <b><u>M1</u></b>	Commission Regulation (EC) No 1664/2006 of 6 November 2006	L 320	13	18.11.2006
► <b><u>M2</u></b>	Commission Regulation (EC) No 1244/2007 of 24 October 2007	L 281	12	25.10.2007
► <b><u>M3</u></b>	Commission Regulation (EC) No 1022/2008 of 17 October 2008	L 277	18	18.10.2008

**COMMISSION REGULATION (EC) No 2074/2005****of 5 December 2005**

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(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 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs <sup>(1)</sup>, and in particular Article 13(2) thereof,

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 <sup>(2)</sup>, and in particular Articles 9, 10 and 11 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 <sup>(3)</sup>, and in particular Articles 16, 17 and 18 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 <sup>(4)</sup>, and in particular Article 63 thereof,

Whereas:

- (1) Regulation (EC) No 853/2004 lays down specific requirements concerning hygiene rules for food of animal origin. It is necessary to lay down certain implementing measures for meat, live bivalve molluscs, fishery products, milk, eggs, frogs' legs and snails, and processed products thereof.
- (2) Regulation (EC) No 854/2004 lays down specific rules for the organisation of official controls on products of animal origin intended for human consumption. It is necessary to develop certain rules and further specify other requirements.
- (3) Regulation (EC) No 882/2004 establishes at Community level a harmonised framework of general rules for the organisation of official controls. It is necessary to develop certain rules and further specify other requirements.
- (4) Commission Decision 20XX/2005/EC <sup>(5)</sup> repeals certain Decisions implementing measures provided for in the Directives repealed by Directive 2004/41/EC of the European Parliament and of the Council of 21 April 2004 repealing certain Directives concerning food hygiene and health conditions for the production and placing on the market of certain products of animal origin

<sup>(1)</sup> OJ L 139, 30.4.2004, p. 1. Corrected by OJ L 226, 25.6.2004, p. 3.

<sup>(2)</sup> OJ L 139, 30.4.2004, p. 55. Corrected by OJ L 226, 25.6.2004, p. 22.

<sup>(3)</sup> OJ L 139, 30.4.2004, p. 206. Corrected by OJ L 226, 25.6.2004, p. 83.

<sup>(4)</sup> OJ L 165, 30.4.2004, p. 1. Corrected by OJ L 191, 28.5.2004, p. 1.

<sup>(5)</sup> Not yet published in the Official Journal.

**▼B**

intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC <sup>(1)</sup>. Certain parts of the relevant Decisions should therefore be retained in this Regulation.

- (5) Regulation (EC) No 852/2004 requires the food business operator to keep and retain records and on request to make relevant information in these records available to the competent authority and receiving food business operator.
- (6) Regulation (EC) No 853/2004 also requires the slaughterhouse operator to request, receive, check and act upon the food chain information for all animals, other than wild game, sent or intended to be sent to the slaughterhouse. In addition, he should make sure the food chain information provides all the details required under Regulation (EC) No 853/2004.
- (7) The food chain information assists the slaughterhouse operator to organise slaughter operations and assists the official veterinarian to determine the required inspection procedures. The food chain information should be analysed by the official veterinarian and used as an integral part of the inspection procedures.
- (8) Existing systems for information flow should be used as much as possible and adapted to comply with the requirements for the food chain information laid down in Regulation (EC) No 854/2004.
- (9) In order to improve animal management at holding level and in accordance with Regulation (EC) No 854/2004, the official veterinarian should record and, if necessary, communicate, to the food business operator of the holding of provenance and to any veterinarian attending the holding of provenance or any competent authority involved, any disease or condition observed at the slaughterhouse in respect of individual animals or the herd/flock and which may affect public or animal health or endanger animal welfare.
- (10) Regulations (EC) Nos 853/2004 and 854/2004 set out the requirements governing parasite checks during handling of fishery products on shore and on board vessels. It is up to food business operators to carry out their own checks at all stages in the production of fishery products in accordance with the rules in Chapter V(D) of Section VIII of Annex III to Regulation (EC) No 853/2004 so that fish which are obviously infested with parasites are not released for human consumption. The adoption of detailed rules relating to visual inspections calls for the concepts of visible parasites and visual inspection to be defined and the type and frequency of the observations to be determined.
- (11) The checks provided for in Regulation (EC) No 853/2004 to prevent fishery products which are unfit for human consumption from being placed on the market may comprise certain chemical checks, including checks of total volatile basic nitrogen (TVB-N). It is necessary to set levels of TVB-N that are not to be exceeded in the case of certain species categories and to specify the analysis methods to be used. The analysis methods that are scientifically recognised for checking TVB-N should continue to be used as a matter of routine, but a reference method should be specified for use where there is doubt regarding the results or in the event of dispute.
- (12) The limits for Paralytic Shellfish Poison (PSP), Amnesic Shellfish Poison (ASP) and lipophilic toxins are laid down in Regulation (EC) No 853/2004. Bioassays are the reference method for detecting certain toxins and preventing toxic shellfish from

<sup>(1)</sup> OJ L 157, 30.4.2004, p. 33. Corrected by OJ L 195, 2.6.2004, p. 12.

**▼B**

being harvested. Maximum levels and methods of analysis should be harmonised and implemented by the Member States to protect human health. In addition to biological testing methods, alternative detection methods, such as chemical methods and *in vitro* assays, should be allowed if it is demonstrated that the performance of the chosen methods is at least as effective as the biological method and that their implementation provides an equivalent level of public health protection. The proposed maximum levels for lipophilic toxins are based on provisional data and should be reassessed once new scientific evidence becomes available. A lack of reference material and the sole use of non-bioassay tests currently means that the level of public health protection provided in respect of all toxins specified is not equivalent to that afforded by biological tests. Provision should be made for the replacement of biological tests as soon as possible.

- (13) Mechanically separated meat (MSM) produced using techniques that do not alter the structure of the bones used in the production of MSM should be treated as different from MSM produced using techniques that alter the structure of the bones.
- (14) MSM of the former type produced under specified conditions and of a specified composition should be permitted in meat preparations that are clearly not intended to be consumed without first undergoing heat treatment. These conditions are linked in particular to the calcium content of MSM, which should be specified in accordance with Article 11(2) of Regulation (EC) No 853/2004. An adjustment should be made to the specified maximum calcium content set in this Regulation once detailed information is available on variations occurring where different types of raw material are used.
- (15) Article 31(2)(f) of Regulation (EC) No 882/2004 provides for Member States to maintain up-to-date lists of approved establishments. A common framework should be laid down for the presentation of relevant information to other Member States and to the public.
- (16) Section XI of Annex III to Regulation (EC) No 853/2004 sets out the requirements governing the preparation of frogs' legs and snails intended for human consumption. Specific requirements, including model health certificates, should also be laid down for imports from third countries of frogs' legs and snails intended for human consumption.
- (17) Sections XIV and XV of Annex III to Regulation (EC) No 853/2004 lay down rules on the production and placing on the market of gelatine and collagen intended for human consumption. Specific requirements, including model health certificates, should also be laid down for imports from third countries of gelatine and collagen and raw materials for the production of gelatine and collagen intended for human consumption.
- (18) Flexibility is needed so foods with traditional characteristics can continue to be produced. Member States have already granted derogations for a wide range of such foods under the legislation in force before 1 January 2006. Food business operators should be able to continue without interruption to apply existing practices after that date. A procedure allowing Member States to exercise flexibility is provided for in Regulations (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/2004. However, in most cases where derogations have already been granted it is only a question of continuing established practices, so applying a full notification procedure, including a complete hazard analysis, may place an unnecessary and disproportionate burden on the Member States. Foods with traditional characteristics should therefore be defined and general conditions applicable to such

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foods should be laid down, by way of derogation from the structural requirements laid down in Regulation (EC) No 852/2004, with due regard to food health objectives.

- (19) Since Regulations (EC) Nos 853/2004 and 854/2004 were adopted before the accession on 1 May 2004, they did not refer to the new Member States. The ISO codes for those Member States and the abbreviations for the European Community in their languages should therefore be added to the relevant provisions of those Regulations.
- (20) 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 Chapter IV, point 8 of that Section. Provision should be made to extend these exceptions to feet from adult bovine animals, provided they comply with the same conditions as those applying to feet of calves.
- (21) Certain practices can mislead the consumer regarding the composition of certain products. In particular in order not to disappoint consumer expectations, the sale as fresh meat of poultrymeat treated with water retention agents should be banned.
- (22) The opinion of the European Food Safety Authority adopted on 30 August 2004 has demonstrated that fishery products belonging to the family of *Gempylidae*, in particular *Ruvettus pretiosus* and *Lepidocybium flavobrunneum*, may have adverse gastrointestinal effects if consumed under certain conditions. The fishery products belonging to this family should therefore be subjected to marketing conditions.
- (23) Section IX of Annex III to Regulation (EC) No 853/2004 lays down specific hygiene rules for raw milk and dairy products. According to Part II (B)(1)(e) of Chapter I, teat dips or other udder cleaning products may be used only if they have been approved by the competent authority. However, no detailed authorisation scheme is provided in this Part. It is therefore necessary, in order to ensure a harmonised approach by Member States, to clarify the procedures under which such authorisations should be given.
- (24) Regulation (EC) No 853/2004 requires food business operators to ensure that heat treatments used to process raw milk and dairy products should conform to an internationally recognised standard. However, owing to the specificity of certain heat treatments used in this sector and their impact on food safety and animal health, clearer guidance should be given to food business operators in this regard.
- (25) Regulation (EC) No 853/2004 introduces a new definition to cover products derived from eggs that, after removal of the shell, have not yet been processed. It is, therefore, necessary to clarify the rules applying to those products and amend Section X, Chapter II of Annex III to Regulation (EC) No 853/2004 accordingly.
- (26) Section XIV of Annex III to Regulation (EC) No 853/2004 lays down specific health rules for gelatine. These rules include requirements covering the type of raw materials that may be used to produce gelatine and the transport and storage of such materials. They also lay down specifications applicable to the manufacture of gelatine. However, the rules applying to labelling of gelatine should also be laid down.
- (27) Scientific progress has led to the establishment of ISO 16649-3 as an agreed reference method for analysis of *E. coli* in bivalve molluscs. This reference method is already established for live bivalve molluscs from areas A in accordance with Commission

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Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs<sup>(1)</sup>. Consequently, ISO 16649-3 should be specified as the reference MPN (most probable number) method for analysis of *E. coli* in bivalve molluscs originating in areas B and C too. The use of alternative methods should be allowed only where they are considered equivalent to the reference method.

- (28) Regulations (EC) Nos 853/2004 and 854/2004 should therefore be amended accordingly.
- (29) 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***Requirements concerning food chain information for the purpose of Regulations (EC) Nos 853/2004 and 854/2004**

Requirements concerning food chain information as referred to in Section III of Annex II to Regulation (EC) No 853/2004 and in Chapter II (A) of Section I of Annex I to Regulation (EC) No 854/2004 are set out in Annex I to this Regulation.

*Article 2***Requirements concerning fishery products for the purpose of Regulations (EC) Nos 853/2004 and 854/2004**

Requirements concerning fishery products as referred to in Article 11(9) of Regulation (EC) No 853/2004 and Article 18(14) and (15) of Regulation (EC) No 854/2004 are set out in Annex II to this Regulation.

*Article 3***Recognised testing methods for marine biotoxins for the purpose of Regulations (EC) Nos 853/2004 and 854/2004**

The recognised testing methods for detecting marine biotoxins as referred to in Article 11(4) of Regulation (EC) No 853/2004 and Article 18(13)(a) of Regulation (EC) No 854/2004 are as set out in Annex III to this Regulation.

*Article 4***Calcium content of mechanically separated meat for the purpose of Regulation (EC) No 853/2004**

The calcium content of mechanically separated meat as referred to in Article 11(2) of Regulation (EC) No 853/2004 is as set out in Annex IV to this Regulation.

<sup>(1)</sup> See page 1 of this Official Journal.

**▼B***Article 5***Lists of establishments for the purpose of Regulation (EC) No 882/2004**

Requirements concerning the lists of establishments as referred to in Article 31(2)(f) of Regulation (EC) No 882/2004 are set out in Annex V to this Regulation.

**▼M1***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.

*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.

**▼M2***Article 6b***Requirements concerning official controls for the inspection of meat for the purpose of Regulation (EC) No 854/2004**

Requirements concerning official controls for the inspection of meat are laid down in Annex VIb.

**▼B***Article 7***Derogation from Regulation (EC) No 852/2004 for foods with traditional characteristics**

1. For the purposes of this Regulation, 'foods with traditional characteristics' means foods that, in the Member State in which they are traditionally manufactured, are:

- (a) recognised historically as traditional products, or
- (b) manufactured according to codified or registered technical references to the traditional process, or according to traditional production methods, or
- (c) protected as traditional food products by a Community, national, regional or local law.

2. Member States may grant establishments manufacturing foods with traditional characteristics individual or general derogations from the requirements set out in:

- (a) Chapter II(1) of Annex II to Regulation (EC) No 852/2004 as regards the premises where such products are exposed to an environment necessary for the part-development of their characteristics. Such premises may in particular comprise walls, ceilings and doors



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that are not smooth, impervious, non-absorbent or of corrosion-resistant material and natural geological walls, ceilings and floors;

- (b) Chapter II(1)(f) and Chapter V(1) of Annex II to Regulation (EC) No 852/2004 as regards the type of materials of which the instruments and the equipment used specifically for the preparation, packaging and wrapping of these products are made.

The cleaning and disinfecting measures for the premises referred in (a) and the frequency with which they are carried out shall be adapted to the activity in order to take account of their specific ambient flora.

The instruments and equipment referred to in (b) shall be maintained at all times in a satisfactory state of hygiene and be regularly cleaned and disinfected.

3. Member States granting the derogations provided for in paragraph 2 shall notify the Commission and the other Member States of this no later than 12 months after granting individual or general derogations. Each notification shall:

- (a) provide a short description of the requirements that have been adapted;
- (b) describe the foodstuffs and establishments concerned; and
- (c) give any other relevant information.

*Article 8***Amendments to Regulation (EC) No 853/2004**

Annexes II and III to Regulation (EC) No 853/2004 are amended in accordance with Annex VII to this Regulation.

*Article 9***Amendments to Regulation (EC) No 854/2004**

Annexes I, II and III to Regulation (EC) No 854/2004 are amended in accordance with Annex VIII to this Regulation.

*Article 10***Entry into force and applicability**

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

It shall apply from 1 January 2006, except for Chapters II and III of Annex V, which shall apply from 1 January 2007.

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



*ANNEX I***FOOD CHAIN INFORMATION**

## SECTION I

**OBLIGATIONS ON FOOD BUSINESS OPERATORS**

Food business operators raising animals dispatched for slaughter shall ensure that the food chain information referred to in to Regulation (EC) No 853/2004 is included as appropriate in the documentation relating to the animals dispatched in such a way as to be accessible to the slaughterhouse operator concerned.

## SECTION II

**OBLIGATIONS ON COMPETENT AUTHORITIES***CHAPTER I****PROVISION OF FOOD CHAIN INFORMATION***

1. The competent authority at the place of dispatch shall inform the dispatching food business operator of the minimum elements of food chain information to be supplied to the slaughterhouse in accordance with Section III of Annex II to Regulation (EC) No 853/2004.
2. The competent authority at the place of slaughter shall verify that:
  - (a) the food chain information is consistently and effectively communicated between the food business operator who raised or kept the animals before dispatch and the slaughterhouse operator;
  - (b) the food chain information is valid and reliable;
  - (c) feedback of relevant information to the holding, if applicable, is provided.
3. Where animals are dispatched for slaughter to another Member State, the competent authorities at the place of dispatch and the place of slaughter shall cooperate to ensure that the information provided by the dispatching food business operator is easily accessible to the slaughterhouse operator receiving it.

*CHAPTER II****FEEDBACK TO HOLDING OF PROVENANCE***

1. The official veterinarian may use the model document laid down in Appendix I for the relevant inspection results that must be communicated to the holding where the animals were raised before slaughter in the same Member State in accordance with Chapter I of Section II of Annex I to Regulation (EC) No 854/2004.
2. The competent authority is responsible for communicating the relevant inspection results in cases where the animals are raised on a holding in another Member State and must use a version of the model document laid down in the Appendix in both the language of the dispatching country and the language of the recipient country.



*Appendix to Annex I*  
**MODEL DOCUMENT**

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**1. Identification details**

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1.1. holding of provenance (e.g. owner or manager)

name/number

full address

telephone number

1.2. identification numbers (attach separate list)

total number of animals (by species)

identification problems (if any)

1.3. herd/flock/cage identification (if applicable)

1.4. animal species

1.5. reference number of health certificate

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**2. *Ante-mortem* findings**

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2.1. welfare

number of animals affected

type/class/age

observations (e.g. tail-biting)

2.2. animals were delivered dirty

2.3. clinical findings (disease)

number of animals affected

type/class/age

observations

date of inspection

2.4. laboratory results <sup>(1)</sup>

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<sup>(1)</sup> Microbiological, chemical, serological, etc. (include results as attached).

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**3. Post-mortem findings**

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## 3.1. (macroscopic) findings

number of animals affected

type/class/age

organ or site of animal(s) affected

date of slaughter

3.2. disease (codes can be used <sup>(1)</sup>)

number of animals affected

type/class/age

organ or site of the animal(s) affected

partially or totally condemned carcase (give  
reason)

date of slaughter

3.3. laboratory results <sup>(2)</sup>

## 3.4. other results (e.g. parasites, foreign objects, etc)

3.5. welfare findings (e.g. broken legs)

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**4. Additional information**

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**5. Contact details**

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## 5.1. slaughterhouse (approval number)

name

full address

telephone number

5.2. electronic address if available

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**6. Official veterinarian (print name)**

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signature and stamp

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**7. Date**

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**8. Number of pages attached to this form:**

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<sup>(1)</sup> The competent authorities may introduce the following codes: Code A for OIE-listed diseases; codes B100 and B200 for welfare issues (Chapter II(C) of Section I of Annex I to Regulation (EC) No 854/2004) and C100 to C290 for decisions concerning meat (Chapter V(1)(a) to (u) of Section II of Annex I to Regulation (EC) No 854/2004). The coding system can, if necessary, include further subdivisions (e.g. C141 for a mild generalised disease, C142 for a more severe disease, etc.). If codes are used, they should be readily available to the food business operator with a suitable explanation of their meaning.

<sup>(2)</sup> Microbiological, chemical, serological, etc. (include results as attached).

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*ANNEX II*  
**FISHERY PRODUCTS**

SECTION I

**OBLIGATIONS ON FOOD BUSINESS OPERATORS**

This Section lays down detailed rules relating to visual inspections to detect parasites in fishery products.

*CHAPTER I*

**DEFINITIONS**

1. 'Visible parasite' means a parasite or a group of parasites which has a dimension, colour or texture which is clearly distinguishable from fish tissues.
2. 'Visual inspection' means non-destructive examination of fish or fishery products with or without optical means of magnifying and under good light conditions for human vision, including, if necessary, candling.
3. 'Candling' means, in respect of flat fish or fish fillets, holding up fish to a light in a darkened room to detect parasites.

*CHAPTER II*

**VISUAL INSPECTION**

1. Visual inspection shall be performed on a representative number of samples. The persons in charge of establishments on land and qualified persons on board factory vessels shall determine the scale and frequency of the inspections by reference to the type of fishery products, their geographical origin and their use. During production, visual inspection of eviscerated fish must be carried out by qualified persons on the abdominal cavity and livers and roes intended for human consumption. Depending on the system of gutting used, the visual inspection must be carried out:
  - (a) in the case of manual evisceration, in a continuous manner by the handler at the time of evisceration and washing;
  - (b) in the case of mechanical evisceration, by sampling carried out on a representative number of samples being not less than 10 fish per batch.
2. The visual inspection of fish fillets or fish slices must be carried out by qualified persons during trimming and after filleting or slicing. Where an individual examination is not possible because of the size of the fillets or the filleting operations, a sampling plan must be drawn up and kept available for the competent authority in accordance with Chapter II(4) of Section VIII of Annex III to Regulation (EC) No 853/2004. Where candling of fillets is necessary from a technical viewpoint, it must be included in the sampling plan.

SECTION II

**OBLIGATIONS ON THE COMPETENT AUTHORITIES**

*CHAPTER I*

**TOTAL VOLATILE BASIC NITROGEN (TVB-N) LIMIT VALUES FOR  
CERTAIN CATEGORIES OF FISHERY PRODUCTS AND ANALYSIS  
METHODS TO BE USED**

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1. Unprocessed fishery products shall be regarded as unfit for human consumption where organoleptic assessment has raised doubts as to their freshness and chemical checks reveal that the following TVB-N limits are exceeded:
  - (a) 25 mg of nitrogen/100 g of flesh for the species referred to in point 1 of Chapter II;

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- (b) 30 mg of nitrogen/100 g of flesh for the species referred to in point 2 of Chapter II;
- (c) 35 mg of nitrogen/100 g of flesh for the species referred to in point 3 of Chapter II;
- (d) 60 mg of nitrogen/100 g of whole fishery products used directly for the preparation of fish oil for human consumption as referred to in the second sub-paragraph of Part B(1) of Chapter IV of Section VIII of Annex III to Regulation (EC) No 853/2004; however, where the raw material complies with points (a), (b) and (c) of Part B(1) of that Chapter, Member States may set limits at a higher level for certain species pending the establishment of specific Community legislation.

The reference method to be used for checking the TVB-N limits involves distilling an extract deproteinised by perchloric acid as set out in Chapter III.

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2. Distillation as referred to in point 1 must be performed using apparatus which complies with the diagram in Chapter IV.
3. The routine methods which may be used to check the TVB-N limit are as follows:
  - microdiffusion method described by Conway and Byrne (1933),
  - direct distillation method described by Antonacopoulos (1968),
  - distillation of an extract deproteinised by trichloroacetic acid (Codex Alimentarius Committee on Fish and Fishery Products (1968)).
4. The sample must consist of about 100 g of flesh, taken from at least three different points and mixed together by grinding.

Member States shall recommend that official laboratories use, as a matter of routine, the reference method referred to above. Where the results are dubious or in the event of dispute regarding the results of analysis performed by one of the routine methods, only the reference method may be used to check the results.

*CHAPTER II****SPECIES CATEGORIES FOR WHICH TVB-N LIMIT VALUES ARE FIXED***

1. *Sebastes* spp., *Helicolenus dactylopterus*, *Sebastichthys capensis*.
2. Species belonging to the *Pleuronectidae* family (with the exception of halibut: *Hippoglossus* spp.).
3. *Salmo salar*, species belonging to the *Merlucciidae* family, species belonging to the *Gadidae* family.

*CHAPTER III****DETERMINATION OF THE CONCENTRATION OF TVB-N IN FISH AND FISHERY PRODUCTS*****Reference procedure**

1. *Purpose and area of application*

This method describes a reference procedure for identifying the nitrogen concentration of TVB-N in fish and fishery products. This procedure is applicable at TVB-N concentrations of 5 mg/100 g to at least 100 mg/100 g.

2. *Definition*

‘TVB-N concentration’ means the nitrogen content of volatile nitrogenous bases as determined by the procedure described.

The concentration shall be expressed in mg/100 g.

3. *Brief description*

The volatile nitrogenous bases are extracted from a sample using a solution of 0,6 mol perchloric acid. After alkalisation the extract undergoes steam distillation and the volatile base components are absorbed by an acid

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receiver. The TVB-N concentration is determined by titration of the absorbed bases.

4. *Chemicals*

Unless otherwise indicated, reagent-grade chemicals should be used. The water used must be either distilled or demineralised and of at least the same purity. Unless otherwise indicated, 'solution' means an aqueous solution as follows:

- (a) perchloric acid solution = 6 g/100 ml;
- (b) sodium hydroxide solution = 20 g/100 ml;
- (c) hydrochloric acid standard solution 0,05 mol/l ((0,05 N),

*Note:* When using an automatic distillation apparatus, titration should take place with a hydrochloric acid standard solution of 0,01 mol/l ((0,01 N);

- (d) boric acid solution = 3 g/100 ml;
- (e) silicone anti-foaming agent;
- (f) phenolphthalein solution = 1 g/100 ml 95 % ethanol;
- (g) indicator solution (Tashiro Mixed Indicator) 2 g methyl-red and 1 g methylene-blue are dissolved in 1 000 ml 95 % ethanol.

5. *Instruments and accessories*

- (a) A meat grinder to produce a sufficiently homogenous fish mince.
- (b) High-speed blender with a speed of between 8 000 and 45 000 revolutions/min.
- (c) Fluted filter, diameter 150 mm, quick-filtering.
- (d) Burette, 5 ml, graduated to 0,01 ml.
- (e) Apparatus for steam distillation. The apparatus must be able to regulate various amounts of steam and produce a constant amount of steam over a given period of time. It must ensure that during the addition of alkalisating substances the resulting free bases cannot escape.

6. *Execution*

Warning: When working with perchloric acid, which is strongly corrosive, necessary caution and preventive measures should be taken. The samples should, if at all possible, be prepared as soon as possible after their arrival, in accordance with the following instructions:

(a) *Preparing the sample*

The sample to be analysed should be ground carefully using a meat grinder as described in point 5(a). Exactly 10 g  $\pm$ 0,1 g of the ground sample is weighed out into a suitable container. This is mixed with 90,0 ml perchloric acid solution as specified in point 4(a), homogenised for two minutes with a blender as described in point 5(b), and then filtered.

The extract thereby obtained can be kept for at least seven days at a temperature of between approximately 2 °C and 6 °C;

(b) *Steam distillation*

50,0 ml of the extract obtained in accordance with point (a) is put into an apparatus for steam distillation as described in point 5(e). For a later check on the extract's alkalisation, several drops of phenolphthalein as specified in point 4(f) are added. After adding a few drops of silicone anti-foaming agent, 6,5 ml of sodium hydroxide solution as specified in point 4(b) is added to the extract and steam distillation begins immediately.

The steam distillation is regulated so that around 100 ml of distillate is produced in 10 minutes. The distillation outflow tube is submerged in a receiver with 100 ml boric acid solution as specified in point 4(d), to which three to five drops of the indicator solution as described in point 4(g) have been added. After exactly 10 minutes, distillation is ended. The distillation outflow tube is removed from the receiver and washed out with water. The volatile bases contained in the receiver solution are

**▼B**

determined by titration with standard hydrochloric solution as specified in point 4(c).

The pH of the end point should be 5,0±0,1.

**(c) Titration**

Duplicate analyses are required. The applied method is correct if the difference between the duplicates is not greater than 2 mg/100 g.

**(d) Blank**

A blind test is carried out as described in point (b). Instead of the extract, 50,0 ml perchloric acid solution as specified in point 4(a) is used.

**7. Calculation of TVB-N**

By titration of the receiver solution with hydrochloric acid as in point 4(c), the TVB-N concentration is calculated using the following equation:

$$\text{TVB - N (expressed in mg/100 g sample)} = \frac{(V_1 - V_0) \times 0,14 \times 2 \times 100}{M}$$

$V_1$  = Volume of 0,01 mol hydrochloric acid solution in ml for sample

$V_0$  = Volume of 0,01 mol hydrochloric acid solution in ml for blank

$M$  = Weight of sample in g.

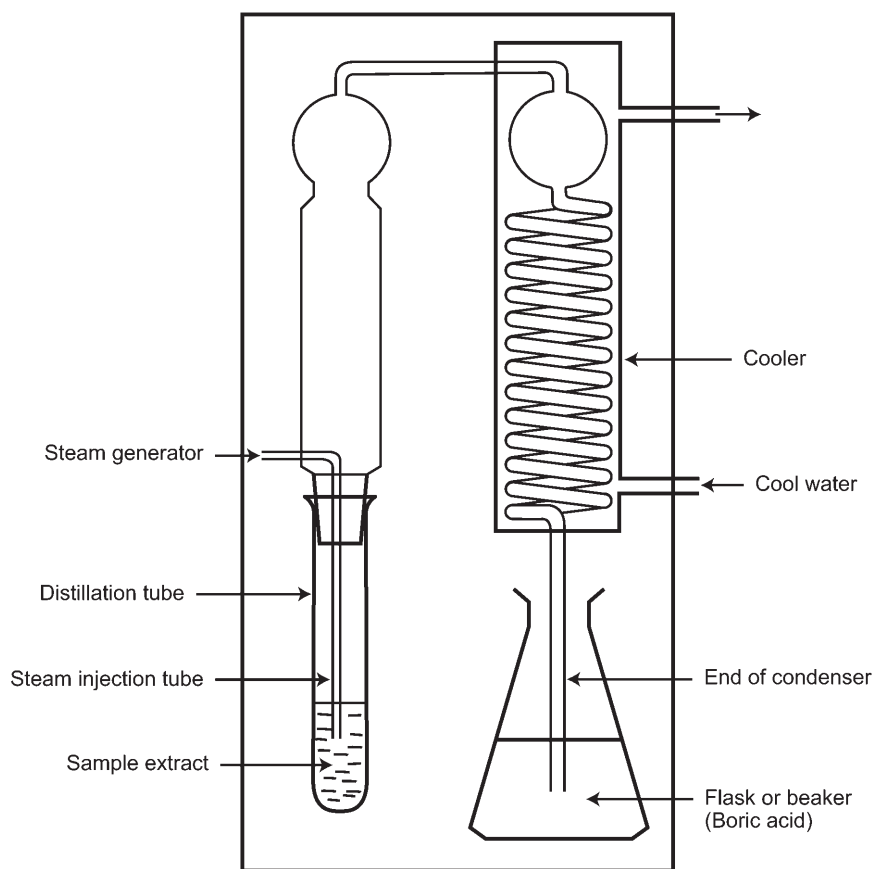
**Remarks**

1. Duplicate analyses are required. The applied method is correct if the difference between duplicates is not greater than 2 mg/100 g.
2. Check the equipment by distilling solutions of  $\text{NH}_4\text{Cl}$  equivalent to 50 mg TVB-N/100 g.
3. Standard deviation of reproducibility  $S_r = 1,20$  mg/100 g. Standard deviation of comparability  $S_R = 2,50$ mg/100 g.



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CHAPTER IV  
TVB-N STEAM DISTILLATION APPARATUS



**▼B***ANNEX III***RECOGNISED TESTING METHODS FOR DETECTING MARINE BIOTOXINS**

The following analytical methods shall be used by the competent authorities to check compliance with the limits laid down in Chapter V(2) of Section VII of Annex III to Regulation (EC) No 853/2004 and, where appropriate, by food business operators.

In accordance with Article 7(2) and (3) of Council Directive 86/609/EEC <sup>(1)</sup>, elements of replacement, refinement and reduction must be taken into account when biological methods are used.

**▼M1**

## 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.

**▼M2**

## CHAPTER II

**AMNESIC SHELLFISH POISON (ASP) DETECTION METHOD**

The total content of amnesic shellfish poison (ASP) of edible parts of molluscs (the entire body or any part edible separately) must be detected using the high-performance liquid chromatography (HPLC) method or any other internationally recognised method.

However, for screening purposes, the 2006.02 ASP ELISA method as published in the AOAC Journal of June 2006 may also be used to detect the total content of ASP of edible parts of molluscs.

If the results are challenged, the reference method shall be the HPLC method.

**▼B**

## CHAPTER III

**LIPHILIC TOXIN DETECTION METHODS****A. Biological methods**

1. A series of mouse bioassay procedures, differing in the test portion (hepatopancreas or whole body) and in the solvents used for extraction and purification, may be used for detecting marine toxins as referred to in Chapter V(2)(c), (d) and (e) of Section VII of Annex III, to Regulation (EC) No 853/2004. Sensitivity and selectivity depend on the choice of solvents used for extraction and purification and this should be taken into account when a decision is made on the method to be used in order to cover the full range of toxins.
2. A single mouse bioassay involving acetone extraction may be used to detect okadaic acid, dinophysistoxins, pectenotoxins and yessotoxins. This assay may be supplemented, if necessary, with liquid/liquid partition steps with ethyl acetate/water or dichloromethane/water to remove potential interferences. Azaspiracid detection at regulatory levels by means of this procedure shall involve the use of the whole body as the test portion.

<sup>(1)</sup> OJ L 358, 18.12.1986, p. 1.

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3. Three mice shall be used for each test. Where two out of three mice die within 24 hours of inoculation with an extract equivalent to 5 g hepatopancreas or 25 g whole body, this shall be considered a positive result for the presence of one or more toxins as referred to in Chapter V(2)(c), (d) and (e) of Section VII of Annex III to Regulation (EC) No 853/2004 at levels above those laid down.
4. A mouse bioassay with acetone extraction followed by liquid/liquid partition with diethylether may be used to detect okadaic acid, dinophysistoxins, pectenotoxins and azaspiracids but it cannot be used to detect yessotoxins as losses of these toxins may take place during the partition step. Three mice shall be used for each test. Where two out of three mice die within 24 hours of inoculation with an extract equivalent to 5 g hepatopancreas or 25 g whole body, this shall be considered a positive result for the presence of okadaic acid, dinophysistoxins, pectenotoxins and azaspiracids at levels above those laid down in Chapter V(2)(c) and (e) of Section VII of Annex III to Regulation (EC) No 853/2004.
5. A rat bioassay may be used to detect okadaic acid, dinophysistoxins and azaspiracids. Three rats shall be used for each test. A diarrhetic response in any of the three rats shall be considered a positive result for the presence of okadaic acid, dinophysistoxins and azaspiracids at levels above those laid down in Chapter V(2)(c) and (e) of Section VII of Annex III to Regulation (EC) No 853/2004.

**B. Alternative detection methods**

1. A series of methods, such as high-performance liquid chromatography (HPLC) with fluorimetric detection, liquid chromatography (LC), mass spectrometry (MS), immunoassays and functional assays, such as the phosphatase inhibition assay, shall be used as alternatives or supplementary to the biological testing methods, provided that either alone or combined they can detect at least the following analogues, that they are not less effective than the biological methods and that their implementation provides an equivalent level of public health protection:
  - okadaic acid and dinophysistoxins: a hydrolysis step may be required to detect the presence of DTX3,
  - pectenotoxins: PTX1 and PTX2,
  - yessotoxins: YTX, 45 OH YTX, homo YTX, and 45 OH homo YTX,
  - azaspiracids: AZA1, AZA2 and AZA3.
2. If new analogues of public health significance are discovered, they should be included in the analysis. Standards must be available before chemical analysis is possible. Total toxicity shall be calculated using conversion factors based on the toxicity data available for each toxin.
3. The performance characteristics of these methods shall be defined after validation following an internationally agreed protocol.
4. Biological methods shall be replaced by alternative detection methods as soon as reference materials for detecting the toxins prescribed in Chapter V of Section VI of Annex III to Regulation (EC) No 853/2004 are readily available, the methods have been validated and this Chapter has been amended accordingly.

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*ANNEX IV*

**CALCIUM CONTENT OF MECHANICALLY SEPARATED MEAT**

The calcium content of MSM as referred to in Regulation (EC) No 853/2004 shall:

1. not exceed 0,1 % (=100 mg/100 g or 1 000 ppm) of fresh product;
2. be determined by a standardised international method.

*ANNEX V***LISTS OF APPROVED FOOD ESTABLISHMENTS**

## CHAPTER I

**ACCESS TO LISTS OF APPROVED FOOD ESTABLISHMENTS**

In order to assist Member States in making up-to-date lists of approved food establishments available to other Member States and to the public, the Commission shall provide a website to which each Member State shall provide a link to its national website.

## CHAPTER II

**FORMAT FOR NATIONAL WEBSITES****A. Masterlist**

1. Each Member State shall provide the Commission with a linking address to a single national website containing the masterlist of lists of approved food establishments for products of animal origin as defined in point 8(1) of Annex I to Regulation (EC) No 853/2004.
2. The masterlist referred to in point 1 shall consist of one sheet and shall be completed in one or more official languages of the Community.

**B. Operational chart**

1. The website containing the masterlist shall be developed by the competent authority or, where appropriate, one of the competent authorities referred to in Article 4 of Regulation (EC) No 882/2004.
2. The masterlist shall include links to:
  - (a) other web pages located on the same website;
  - (b) where certain lists of approved food establishments are not maintained by the competent authority referred to in point 1, websites managed by other competent authorities, units or where appropriate, bodies.

## CHAPTER III

**LAYOUT AND CODES FOR LISTS OF APPROVED ESTABLISHMENTS**

Layouts, including relevant information and codes, shall be established to ensure wide availability of the information concerning approved food establishments and to improve the readability of the lists.

## CHAPTER IV

**TECHNICAL SPECIFICATIONS**

The tasks and activities referred to in Chapters II and III shall be performed in accordance with the technical specifications published by the Commission.

**▼M1***ANNEX VI***MODEL HEALTH CERTIFICATES FOR IMPORTS FOR FROGS' LEGS,  
SNAILS, GELATINE AND COLLAGEN**

## 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.

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## 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**

<b>Part I: Details of dispatched consignment</b>	I.1. Consignor Name		I.2. Certificate reference number		I.2.a.		
	Address Postal code Tel No.		I.3. Central Competent Authority				
	I.5. Consignee Name		I.6.				
	Address Postal code Tel No.						
	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		Approval number				I.12.
	I.13. Place of loading		I.14. Date of departure				
	I.15. Means of transport Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/> Identification: Documentary references:		I.16. Entry BIP in EU		I.17.		
	I.18. Description of commodity		I.19. Commodity code (HS code) <b>0208 20</b>		I.20. Quantity		
	I.21. Temperature of product Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>		I.22. Number of packages				
	I.23. Identification of container/Seal number		I.24. Type of packaging				
	I.25. Commodities certified for Human consumption <input type="checkbox"/>						
	I.26.		I.27. For import or admission into EU <input type="checkbox"/>				
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

<b>Part II: Certification</b>	<b>II. Health attestation</b>	<b>II.a. Certificate reference number</b>	<b>II.b.</b>
	<p>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:</p> <ul style="list-style-type: none"> <li>— come from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004</li> <li>and</li> <li>— 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</li> </ul>		
<b>Notes</b>			
<b>Part I:</b>			
— 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.			
<b>Part II:</b>			
— 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:			

▼ **M1**

## 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**

<b>Part I: Details of dispatched consignment</b>	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.11. Place of origin  Name Address	Approval number		I.12.		
	I.13. Place of loading		I.14. Date of departure			
	I.15. Means of transport Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/> 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 <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>		I.22. Number of packages			
I.23. Identification of container/Seal number		I.24. Type of packaging				
I.25. Commodities certified for  Human consumption <input type="checkbox"/>						
I.26.		I.27. For import or admission into EU <input type="checkbox"/>				
I.28. Identification of the commodities  Species (Scientific name)      Treatment type      Approval number of establishments      Manufacturing plant      Number of packages      Net weight						



COUNTRY

Snails

<b>Part II: Certification</b>	<b>II. Health attestation</b>	II.a. Certificate reference number	II.b.
	<p>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:</p> <ul style="list-style-type: none"> <li>— come from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004</li> <li>and</li> <li>— 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</li> </ul>		
<b>Notes</b>			
<b>Part I:</b>			
— 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.			
<b>Part II:</b>			
— 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:			

▼ **M1**

## Appendix II to Annex VI

## PART A

**MODEL HEALTH CERTIFICATE FOR IMPORTS OF GELATINE  
INTENDED FOR HUMAN CONSUMPTION****COUNTRY****Veterinary certificate to EU**

<b>Part I: Details of dispatched consignment</b>	I.1. Consignor Name		I.2. Certificate reference number		I.2.a.	
	Address Postal code Tel No.		I.3. Central Competent Authority			
	I.5. Consignee Name		I.6.			
	Address Postal code Tel No.					
	I.7. Country of origin	ISO code	I.8.	I.9. Country of destination	ISO code	I.10.
	I.11. Place of origin		I.12.			
	Name		Approval number			
	Address					
	I.13. Place of loading		I.14. Date of departure			
	I.15. Means of transport Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/>		I.16. Entry BIP in EU			
	Identification: Documentary references:		I.17.			
	I.18. Description of commodity		I.19. Commodity code (HS code) 35.03		I.20. Quantity	
	I.21. Temperature of product Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>				I.22. Number of packages	
I.23. Identification of container/Seal number				I.24. Type of packaging		
I.25. Commodities certified for Human consumption <input type="checkbox"/>						
I.26.		I.27. For import or admission into EU <input type="checkbox"/>				
I.28. Identification of the commodities		Approval number of establishments				
Species (Scientific name)	Treatment type	Manufacturing plant	Number of packages	Net weight		



## COUNTRY

## Gelatine intended for human consumption

<b>Part II: Certification</b>	<b>II. Health attestation</b>	<b>II.a. Certificate reference number</b>	<b>II.b.</b>
	<p>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:</p> <ul style="list-style-type: none"> <li>— comes from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004,</li> <li>— 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,</li> <li>— has been manufactured in compliance with the conditions set out in Section XIV, Chapter III of Annex III to Regulation (EC) No 853/2004,</li> <li>— 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 <sup>(1)</sup></li> <li>— if from ruminant origin, does not contain and is not derived from: either <sup>(1)</sup> <p>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.</p> <p>or</p> <p>bovine, ovine and caprine materials other than those derived from animals born, continuously reared and slaughtered in .....<sup>(2)</sup> <sup>(3)</sup>.</p> </li> </ul>		
<b>Notes</b>			
<b>Part I:</b>			
— 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).			
<b>Part II:</b>			
<sup>(1)</sup> Delete as appropriate.			
<sup>(2)</sup> Insert the name of the country.			
<sup>(3)</sup> 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:			

▼ **M1**

## PART B

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

**COUNTRY****Veterinary certificate to EU**

<b>Part I: Details of dispatched consignment</b>	I.1. Consignor Name		I.2. Certificate reference number		I.2.a.		
	Address Postal code Tel No.		I.3. Central Competent Authority				
	I.5. Consignee Name		I.6.				
	Address Postal code Tel No.						
	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 Address			I.12.  Approval number			
	I.13. Place of loading			I.14. Date of departure			
	I.15. Means of transport Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/> 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 <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>				I.22. Number of packages		
	I.23. Identification of container/Seal number				I.24. Type of packaging		
	I.25. Commodities certified for  Human consumption <input type="checkbox"/>						
I.26.			I.27. For import or admission into EU <input type="checkbox"/>				
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

<b>Part II: Certification</b>	<b>II. Health attestation</b>	II.a. Certificate reference number	II.b.
	<p>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:</p> <ul style="list-style-type: none"> <li>— 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 carcasses have been found fit for human consumption following ante- and post-mortem inspection <sup>(1)</sup> and/or</li> <li>— wild game hides and skins described above derive from killed animals whose carcasses have been found fit for human consumption following post-mortem inspection <sup>(1)</sup> and/or</li> <li>— fish skin and bones described above come from plants manufacturing fish products for human consumption authorised for export <sup>(1)</sup> and <sup>(1)</sup></li> <li>— if from ruminant origin, the raw material does not contain and is not derived from: <ul style="list-style-type: none"> <li>either <sup>(1)</sup> 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</li> <li>or bovine, ovine and caprine materials other than those derived from animals born, continuously reared and slaughtered in.....<sup>(2)</sup> <sup>(3)</sup>.</li> </ul> </li> </ul>		
<b>Notes</b>			
<b>Part I:</b>			
— 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.			
<b>Part II:</b>			
<sup>(1)</sup> Delete as appropriate.			
<sup>(2)</sup> Insert the name of the country.			
<sup>(3)</sup> 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:			



▼ **M1**

## Appendix III to Annex VI

## PART A

**MODEL HEALTH CERTIFICATE FOR IMPORTS OF COLLAGEN  
INTENDED FOR HUMAN CONSUMPTION****COUNTRY****Veterinary certificate to EU**

<b>Part I: Details of dispatched consignment</b>	I.1. Consignor Name		I.2. Certificate reference number		I.2.a.	
	Address Postal code Tel No.		I.3. Central Competent Authority			
	I.5. Consignee Name		I.6.			
	Address Postal code Tel No.					
	I.7. Country of origin	ISO code	I.8.	I.9. Country of destination	ISO code	I.10.
	I.11. Place of origin		I.12.			
	Name		Approval number			
	Address					
	I.13. Place of loading		I.14. Date of departure			
	I.15. Means of transport Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/>		I.16. Entry BIP in EU			
	Identification: Documentary references:		I.17.			
	I.18. Description of commodity		I.19. Commodity code (HS code) <b>35.04</b>		I.20. Quantity	
	I.21. Temperature of product Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>				I.22. Number of packages	
I.23. Identification of container/Seal number				I.24. Type of packaging		
I.25. Commodities certified for Human consumption <input type="checkbox"/>						
I.26.		I.27. For import or admission into EU <input type="checkbox"/>				
I.28. Identification of the commodities		Approval number of establishments				
Species (Scientific name)	Treatment type	Manufacturing plant	Number of packages	Net weight		



COUNTRY

Collagen intended for human consumption

<b>Part II: Certification</b>	<b>II. Health attestation</b>	<b>II.a. Certificate reference number</b>	<b>II.b.</b>
	<p>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:</p> <ul style="list-style-type: none"> <li>— comes from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004,</li> <li>— 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,</li> <li>— has been manufactured in compliance with the conditions set out in Section XV, Chapter III of Annex III to Regulation (EC) No 853/2004,</li> </ul> <p>and</p> <ul style="list-style-type: none"> <li>— 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 foodstuffs.</li> </ul>		
<b>Notes</b>			
<b>Part I:</b>			
— 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).			
<b>Part II:</b>			
— The colour of the stamp and signature must be different to that of the other particulars in the certificate.			
<b>Official veterinarian</b>			
Name (in capitals):		Qualification and title:	
Date:		Signature:	
Stamp:			

▼ **M1**

## PART B

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

**COUNTRY****Veterinary certificate to EU**

<b>Part I: Details of dispatched consignment</b>	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 Address				I.12.				
					Approval number				
	I.13. Place of loading				I.14. Date of departure				
	I.15. Means of transport Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/>				I.16. Entry BIP in EU				
	Identification: Documentary references:				I.17.				
	I.18. Description of commodity						I.19. Commodity code (HS code)		
									I.20. Quantity
	I.21. Temperature of product Ambient <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>								I.22. Number of packages
	I.23. Identification of container/Seal number								I.24. Type of packaging
I.25. Commodities certified for  Human consumption <input type="checkbox"/>									
I.26.				I.27. For import or admission into EU <input type="checkbox"/>					
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

<b>Part II: Certification</b>	<b>II. Health attestation</b>	<b>II.a. Certificate reference number</b>	<b>II.b.</b>
	<p>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:</p> <ul style="list-style-type: none"> <li>— 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 carcasses have been found fit for human consumption following ante- and post-mortem inspection <sup>(1)</sup>,</li> </ul> <p style="text-align: center;">and/or</p> <ul style="list-style-type: none"> <li>— wild game hides and skins described above derive from killed animals whose carcasses have been found fit for human consumption following post-mortem inspection <sup>(1)</sup>,</li> </ul> <p style="text-align: center;">and/or</p> <ul style="list-style-type: none"> <li>— fish skin and bones described above derive from plants manufacturing fish products for human consumption authorised for export <sup>(1)</sup>.</li> </ul>		
<b>Notes</b>			
<b>Part I:</b>			
— 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.			
<b>Part II:</b>			
<sup>(1)</sup> 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**

<b>Part I: Details of dispatched consignment</b>	I.1. Consignor Name		I.2. Certificate reference number		I.2.a.		
	Address Postal code Tel No.		I.3. Central Competent Authority				
	I.5. Consignee Name		I.6.				
	Address Postal code Tel No.						
	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 Address			I.12.			
	Approval number						
	I.13. Place of loading			I.14. Date of departure			
	I.15. Means of transport Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/> 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 <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>				I.22. Number of packages		
I.23. Identification of container/Seal number				I.24. Type of packaging			
I.25. Commodities certified for  Human consumption <input type="checkbox"/>							
I.26.			I.27. For import or admission into EU <input type="checkbox"/>				
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

<b>Part II: Certification</b>	<b>II. Health attestation</b>	<b>II.a. Certificate reference number</b>	<b>II.b.</b>
	<p><b>II.1. Public health attestation</b></p> <p>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:</p> <ul style="list-style-type: none"> <li>— come from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004,</li> <li>— 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,</li> <li>— 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,</li> <li>— have been packaged, stored and transported in compliance with Section VIII, Chapters VI to VIII of Annex III to Regulation (EC) No 853/2004,</li> <li>— have been marked in accordance with Section I of Annex II to Regulation (EC) No 853/2004</li> <li>— 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</li> </ul> <p style="text-align: center;">and</p> <ul style="list-style-type: none"> <li>— have satisfactorily undergone the official controls laid down in Annex III to Regulation (EC) No 854/2004.</li> </ul>		
	<p><b>II.2. <sup>(1)</sup> [Animal health attestation for products of aquaculture origin]</b></p> <p>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:</p> <ul style="list-style-type: none"> <li>— <sup>(1)</sup>[<sup>(2)</sup> if from species susceptible <sup>(3)</sup> to ISA and/or EHN, they: <ul style="list-style-type: none"> <li>— <sup>(1)</sup> [originate from a source <sup>(4)</sup> considered free from ISA and/or EHN in accordance with the relevant EU legislation or OIE Standard <sup>(5)</sup>],</li> <li>— <sup>(1)</sup> [have been slaughtered and eviscerated]].</li> </ul> </li> <li>— <sup>(1)</sup>[<sup>(6)</sup> if from species susceptible <sup>(3)</sup> to VHS and/or IHN, they: <ul style="list-style-type: none"> <li>— <sup>(1)</sup> originate from a source <sup>(4)</sup> considered free from <sup>(1)</sup> VHS/<sup>(1)</sup> IHN in accordance with the relevant EU legislation or OIE Standard <sup>(5)</sup>],</li> <li>— <sup>(1)</sup> [have been slaughtered and eviscerated]]].</li> </ul> </li> </ul>		



## 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.

(<sup>1</sup>) Delete as appropriate.

(<sup>2</sup>) 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.

(<sup>3</sup>) Known susceptible species

Disease	Susceptible host species
---------	--------------------------

EHN	Redfin perch ( <i>Perca fluviatilis</i> ), rainbow trout ( <i>Oncorhynchus mykiss</i> )
-----	---

ISA	Atlantic salmon ( <i>Salmo salar</i> ), rainbow trout ( <i>Oncorhynchus mykiss</i> ), brown trout ( <i>Salmo trutta</i> ),
-----	--

VHS	Atlantic cod ( <i>Gadus morhua</i> ), Atlantic herring ( <i>Clupea harengus</i> ), brown trout ( <i>Salmo trutta</i> ), chinook salmon ( <i>Oncorhynchus tshawytscha</i> ), coho salmon ( <i>O. kisutch</i> ), grayling ( <i>Thymallus thymallus</i> ), haddock ( <i>Melanogrammus aeglefinus</i> ), Pacific cod ( <i>Gadus macrocephalus</i> ), Pacific herring ( <i>Clupea harengus pallasii</i> ), pike ( <i>Esox lucius</i> ), rainbow trout ( <i>Oncorhynchus mykiss</i> ), rockling ( <i>Rhinonemus cimbrius</i> ), sprat ( <i>Sprattus sprattus</i> ), turbot ( <i>Scophthalmus maximus</i> ), whitefish ( <i>Coregonus</i> sp.)
-----	---

IHN	Rainbow or steelhead trout ( <i>Oncorhynchus mykiss</i> ), the Pacific salmon species (chinook salmon ( <i>O. tshawytscha</i> ), sockeye salmon ( <i>O. nerka</i> ), chum salmon ( <i>O. keta</i> ), masou salmon ( <i>O. masou</i> ), pink salmon ( <i>O. rhodurus</i> ) and coho salmon ( <i>O. kisutch</i> )), and Atlantic salmon ( <i>Salmo salar</i> ).
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(<sup>4</sup>) Source may be a country, zone, or an individual farm.

(<sup>5</sup>) 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.

(<sup>6</sup>) 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):

Date:

Stamp:

Qualification and title:

Signature:

▼ **M1**

## 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**

<b>Part I: Details of dispatched consignment</b>	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 Address  Approval number				I.12.					
	I.13. Place of loading				I.14. Date of departure					
	I.15. Means of transport Aeroplane <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/> 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 <input type="checkbox"/>										
I.26.				I.27. For import or admission into EU <input type="checkbox"/>						
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

<b>Part II: Certification</b>	<p><b>II. Health attestation</b></p>	<p>II.a. Certificate reference number</p>	<p>II.b.</p>
	<p><b>II.1. Public health attestation</b></p> <p>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:</p> <ul style="list-style-type: none"> <li>— come from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004,</li> <li>— 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,</li> <li>— 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,</li> <li>— 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,</li> <li>— have been packaged, stored and transported in compliance with Section VII, Chapters VI and VIII of Annex III to Regulation (EC) No 853/2004,</li> <li>— 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,</li> <li>— in the case of <i>pectinidae</i> 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</li> </ul> <p style="text-align: center;">and</p> <ul style="list-style-type: none"> <li>— have satisfactorily undergone the official controls laid down in Annex III to Regulation (EC) No 854/2004.</li> </ul> <p><b>II.2. <sup>(1)</sup> [Animal health attestation</b></p> <p>I, the undersigned, declare that the live molluscs described above originate from a source <sup>(2)</sup> where there are no unresolved abnormal mortality in the mollusc population, and certify, in particular that:</p> <ul style="list-style-type: none"> <li>— <sup>(1)</sup><sup>(3)</sup> if from species susceptible <sup>(4)</sup> to infections with <i>Bonamia exitiosa</i>, <i>Mikrocytos roughleyi</i>, <i>Marteilia sydneyi</i>, <i>Mikrocytos mackini</i>, <i>Perkinsus marinus</i>, <i>P. olsenii/atlanticus</i>; <i>Haplosporidium nelsoni</i>, <i>H. costale</i> and/or <i>Candidatus Xenohaliotis californiensis</i>, they: <ul style="list-style-type: none"> <li>— <sup>(1)</sup> [originate from a source <sup>(2)</sup> considered free from bonamiosis (<i>Bonamia exitiosa</i> and <i>Mikrocytos roughleyi</i>); marteiliosis (<i>Marteilia sydneyi</i>); mikrocytosis (<i>Mikrocytos mackini</i>); perkinsosis (<i>Perkinsus marinus</i> and <i>P. olsenii/atlanticus</i>); haplosporidiosis (<i>Haplosporidium nelsoni</i> and <i>H. costale</i>) and Withering syndrome (<i>Candidatus Xenohaliotis californiensis</i>) in accordance with the relevant EU legislation or OIE Standard <sup>(5)</sup>],</li> <li>— <sup>(1)</sup> [are dispatched as unprocessed or processed products]],</li> </ul> </li> <li>— <sup>(1)</sup><sup>(6)</sup> if from species susceptible <sup>(3)</sup> to infections with <i>Marteilia refringens</i> or <i>Bonamia ostrea</i>, they: <ul style="list-style-type: none"> <li>— <sup>(1)</sup> [originate from a source <sup>(2)</sup> considered free from <sup>(1)</sup> <i>Marteilia refringens</i> / <sup>(1)</sup> <i>Bonamia ostrea</i> in accordance with the relevant EU legislation or OIE Standard <sup>(6)</sup>],</li> <li>— <sup>(1)</sup> [are dispatched as unprocessed or processed products]], ]</li> </ul> </li> </ul>		



## 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.
- (<sup>1</sup>) Delete as appropriate
- (<sup>2</sup>) Source may be a country, zone, or an individual farm.
- (<sup>3</sup>) 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. olsenii/atlanticus*); haplosporidiosis (*Haplosporidium nelsoni* and *H. costale*) and Withering syndrome (*Candidatus Xenohaliotis californiensis*), whereby one or the two statements must be retained.
- (<sup>4</sup>) Known susceptible species
 

Disease (Infection with)	Susceptible host species
<i>Bonamia exitiosa</i>	<i>Tiostrea chilensis</i> and <i>Ostrea angasi</i>
<i>Bonamia ostrea</i>	<i>Ostrea edulis</i>
<i>Mikrocytos roughleyi</i>	<i>Saccostrea (commercialis) glomerata</i>
<i>Marteilia sydneyi</i>	<i>Saccostrea (commercialis) glomerata</i>
<i>Marteilia refringens</i>	<i>Ostrea edulis</i>
<i>Mikrocytos mackini</i>	<i>Crassostrea gigas</i> ; <i>C. virginica</i> ; <i>Ostrea edulis</i> ; <i>O. conchaphila</i>
<i>Perkinsus marinus</i>	<i>Crassostrea virginica</i> and <i>C. gigas</i>
<i>Perkinsus olsenii/atlanticus</i>	<i>Haliotis ruber</i> ; <i>H. cyclobates</i> ; <i>H. scalaris</i> ; <i>H. laevigata</i> , <i>Ruditapes philippinarum</i> and <i>R. decussatus</i>
<i>Haplosporidium nelsoni</i>	<i>Crassostrea virginica</i> and <i>C. gigas</i>
<i>Haplosporidium costale</i>	<i>Crassostrea virginica</i>
<i>Xenohaliotis californiensis</i>	black abalone ( <i>Haliotis cracherodii</i> ), red abalone ( <i>H. rufescens</i> ), pink abalone ( <i>H. corrugata</i> ), green abalone ( <i>H. fulgens</i> ) and white abalone ( <i>H. sorenseni</i> )
- (<sup>5</sup>) 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.
- (<sup>6</sup>) 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):  
Date:  
Stamp:

Qualification and title  
Signature:

▼ M1

## 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 <sup>(1)</sup>, 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:	

<sup>(1)</sup> See page 53 of this Official Journal.

▼ **M1**

## 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**

<b>Part I: Details of dispatched consignment</b>	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 <input type="checkbox"/> Ship <input type="checkbox"/> Railway wagon <input type="checkbox"/> Road vehicle <input type="checkbox"/> Other <input type="checkbox"/> 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 <input type="checkbox"/> Chilled <input type="checkbox"/> Frozen <input type="checkbox"/>				I.22. Number of packages	
	I.23. Identification of container/Seal number				I.24. Type of packaging	
I.25. Commodities certified for  Human consumption <input type="checkbox"/>						
I.26.		I.27. For import or admission into EU		<input type="checkbox"/>		
I.28. Identification of the commodities		Approval number of establishments				
Species (Scientific name)	Treatment type	Manufacturing plant	Number of packages	Net weight		



COUNTRY

Honey and apiculture products

<b>Part II: Certification</b>	II. <b>Health attestation</b>	II.a. Certificate reference number	II.b.
	<p>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:</p> <ul style="list-style-type: none"> <li>— come from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004,</li> <li>— 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</li> </ul> <p>and</p> <ul style="list-style-type: none"> <li>— 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.</li> </ul>		
<b>Notes</b>			
<b>Part I:</b>			
<ul style="list-style-type: none"> <li>— Box reference I.11: Place of origin: name and address of the dispatch establishment.</li> <li>— 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.</li> <li>— Box reference I.19: Use the appropriate HS codes: 04.09, 04.10.</li> <li>— Box reference I.23: Identification of container/seal number: only where applicable.</li> </ul>			
<b>Part II:</b>			
<ul style="list-style-type: none"> <li>— The colour of the stamp and signature must be different to that of the other particulars in the certificate.</li> </ul>			
Official inspector			
Name (in capitals):		Qualification and title:	
Date:		Signature:	
Stamp:			

**▼M1***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.

▼ M2*ANNEX VIb***REQUIREMENTS APPLICABLE TO THE OFFICIAL CONTROLS FOR THE INSPECTION OF MEAT**

1. For the purpose of this Annex, the following definitions shall apply:
  - (a) ‘controlled housing conditions and integrated production systems’ means a type of animal husbandry where animals are kept under conditions in compliance with criteria set out in the Appendix;
  - (b) ‘young bovine animal’ means a bovine animal of either gender, which is not older than eight months;
  - (c) ‘young ovine animal’ means an ovine animal of either gender, not having any permanent incisor erupted and not older than 12 months;
  - (d) ‘young caprine animal’ means a caprine animal of either gender, not older than six months of age;
  - (e) ‘herd’ means an animal or group of animals kept on a holding as an epidemiological unit; if more than one herd is kept on a holding, each of these herds shall form a distinct epidemiological unit;
  - (f) ‘holding’ means any establishment, construction or, in the case of an openair farm, any place situated within the territory of the same Member State, in which animals are held, kept or handled;
  - (g) ‘establishment carrying out discontinuous slaughter or game handling activities’ means a slaughterhouse or game handling establishment designated by the competent authority on the basis of a risk analysis, in which, in particular, the slaughter or game handling activities do not take place either during the entire working day or during subsequent working days of the week.
2. Post-mortem inspections in establishments carrying out discontinuous slaughter or game handling activities.
  - (a) In accordance with point 2(b) of Chapter II of Section III of Annex I to Regulation (EC) No 854/2004, the competent authority may decide that the official veterinarian need not be present at all times during post-mortem inspection, provided that the following conditions are complied with:
    - (i) the establishment concerned is an establishment carrying out discontinuous slaughter or game handling activities and has sufficient facilities to store meat with abnormalities until a final post-mortem inspection by the official veterinarian can take place;
    - (ii) an official auxiliary carries out the post-mortem inspection;
    - (iii) the official veterinarian is present in the establishment at least once a day when slaughter activities take place or have taken place;
    - (iv) the competent authority has put in place a procedure to assess on a regular basis the performance of official auxiliaries in these establishments, including:
      - monitoring individual performance,
      - verification of documentation with regard to inspection findings and comparison with the corresponding carcasses,
      - checks of carcasses in the storage room.
  - (b) The risk analysis carried out by the competent authority as referred to in point 1(g) to identify the establishments that may benefit from the derogation as laid down in point 2(a) shall at least take account of the following elements:
    - (i) the number of animals slaughtered or handled per hour or per day;
    - (ii) the species and class of animals slaughtered or handled;
    - (iii) the throughput of the establishment;
    - (iv) the historical performance of slaughter or handling activities;
    - (v) the effectiveness of any additional measures in the food chain for procurement of animals for slaughter taken to guarantee food safety;

▼ M2

- (vi) the effectiveness of the HACCP-based system in place;
- (vii) audit records;
- (viii) the competent authority's historical records of ante-mortem and post-mortem inspections.

## 3. Requirements for a risk-based meat inspection without incisions.

- (a) In accordance with point 2 of Part B of Chapter IV of Section IV of Annex I to Regulation (EC) No 854/2004, the competent authority may limit the post-mortem inspection procedures of fattening pigs to a visual inspection, provided that the following conditions are complied with:
  - (i) the food business operator ensures that the animals are kept under controlled housing conditions and integrated production systems as laid down in the Appendix to this Annex;
  - (ii) the food business operator does not benefit from the transitional arrangements with regard to food chain information as laid down in Article 8 of Commission Regulation (EC) No 2076/2005;
  - (iii) the competent authority implements or orders the implementation of regular serological and/or microbiological monitoring of a selected number of animals based on a risk analysis of food safety hazards which are present in live animals and relevant at the holding level.
- (b) By way of derogation from the specific requirements of Chapters I and II of Section IV of Annex I to Regulation (EC) No 854/2004, the post-mortem inspection procedures of young bovine, ovine and caprine animals may be reduced to a visual inspection with limited palpation, provided that the following conditions are complied with:
  - (i) the food business operator ensures that young bovine animals are kept under controlled housing conditions and in an integrated production system as laid down in the Appendix to this Annex;
  - (ii) the food business operator ensures that young bovine animals are reared in an officially bovine tuberculosis-free herd;
  - (iii) the food business operator does not benefit from the transitional arrangements with regard to food chain information as laid down in Article 8 of Regulation (EC) No 2076/2005;
  - (iv) the competent authority implements or orders the implementation of regular serological and/or microbiological monitoring of a selected number of animals based on a risk analysis of food safety hazards which are present in live animals and relevant at the holding level;
  - (v) post-mortem inspection of young bovine animals includes at all times palpation of the retropharyngeal, bronchial and mediastinal lymph nodes.
- (c) In the case of any abnormality detected, the carcass and offal shall be subjected to a full post-mortem inspection as provided for in Chapters I and II of Section IV of Annex I to Regulation (EC) No 854/2004. However, the competent authority may decide on the basis of a risk analysis that meat with certain minor abnormalities as defined by the competent authorities, which pose no risk to animal or human health, does not need to be subjected to a full post-mortem inspection.
- (d) Young bovine, ovine and caprine animals and weaned pigs that do not go directly from the holding of birth to a slaughterhouse may be moved on one occasion to another holding (for rearing or fattening) prior to dispatch to a slaughterhouse. In such cases:
  - (i) regulated assembly centres may be used for young bovine, ovine or caprine animals between the holding of origin and the rearing or fattening holding, as well as between these holdings and the slaughterhouse;
  - (ii) traceability shall be ensured at the level of the individual animal or batch of animals.

## 4. Additional requirement for the post-mortem examination of solipeds.

- (a) Fresh meat from solipeds reared in countries not free of glanders in accordance with Article 2.5.8.2 of the *Terrestrial Animal Health Code* of the World Organisation for Animal Health shall not be placed on the market, unless such meat is derived from solipeds examined for glanders



▼ M2

in accordance with point D of Chapter IX of Section IV of Annex I to Regulation (EC) No 854/2004.

- (b) Fresh meat from solipeds in which glanders has been diagnosed shall be declared unfit for human consumption as provided for in point D of Chapter IX of Section IV of Annex I to Regulation (EC) No 854/2004.

**▼ M2***Appendix to Annex VIb*

For the purposes of this Annex, 'controlled housing conditions and integrated production systems' means that the food business operator needs to comply with the criteria set out below:

- (a) all feed has been obtained from a facility which produces feed in accordance with the requirements provided for in Articles 4 and 5 of Regulation (EC) No 1831/2003 of the European Parliament and of the Council<sup>(1)</sup>; when roughage or crops are provided to the animals as feed, it shall be treated appropriately, and where possible, dried and/or pelleted;
- (b) an all-in/all-out system is applied as far as possible. Where animals are introduced into the herd, they shall be kept in isolation as long as required by the veterinary services to prevent introduction of diseases;
- (c) none of the animals has access to outdoor facilities unless the food business operator can show by a risk analysis to the satisfaction of the competent authority that the time period, facilities and circumstances of outdoor access do not pose a danger for introduction of disease in the herd;
- (d) detailed information is available concerning the animals from birth to slaughter and their management conditions as laid down in Section III of Annex II to Regulation (EC) No 853/2004;
- (e) if bedding is provided for the animals, the presence or introduction of disease is avoided by appropriate treatment of the bedding material;
- (f) holding staff comply with the general hygiene provisions as laid down in Annex I to Regulation (EC) No 853/2004;
- (g) procedures are in place that control access to the premises where animals are kept;
- (h) the holding does not provide facilities for tourists or for camping unless the food business operator can show by a risk analysis to the satisfaction of the competent authority that the facilities are sufficiently separated from the animal rearing units that direct and indirect contact between humans and animals is not possible;
- (i) animals do not have access to garbage dumps or household garbage;
- (j) a pest management and control plan is in place;
- (k) silage feeding is not used unless the food business operator can show by a risk analysis to the satisfaction of the competent authority that the feed can not transmit any hazards to the animals;
- (l) effluent and sediment from sewage treatment plants are not released in areas accessible to the animals or be used for fertilising pastures used to grow crops, which are used to feed animals, unless treated appropriately and to the satisfaction of the competent authority.

<sup>(1)</sup> OJ L 35, 8.2.2005, p. 1.



ANNEX VII

AMENDMENTS TO REGULATION (EC) No 853/2004

Annexes II and III to Regulation (EC) No 853/2004 are amended as follows:

1. Annex II, Section I(B) is amended as follows:

(a) in point 6, the second subparagraph is replaced by the following:

‘BE, CZ, DK, DE, EE, GR, ES, FR, IE, IT, CY, LV, LT, LU, HU, MT, NL, AT, PL, PT, SI, SK, FI, SE and UK’;

(b) point 8 is replaced by the following:

‘8. When applied in an establishment located within the Community, the mark must be oval in shape and include the abbreviation CE, EC, EF, EG, EK, EY, ES, EÜ, EK, EB or WE’;

2. Annex III is amended as follows:

(a) in Section I, Chapter IV, point 8 is replaced by the following:

‘8. Carcasses 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 and the feet of bovine, ovine and caprine animals. Heads and feet must be handled in such a way as to avoid contamination.’

(b) in Section II, the following Chapter VII is added:

‘CHAPTER VII: WATER RETENTION AGENTS

Food business operators shall ensure that poultrymeat that has been treated specifically to promote water retention is not placed on the market as fresh meat but as meat preparations or used for the production of processed products.’

(c) in Section VIII, Chapter V(E), point 1 is replaced by the following:

‘1. Fishery products derived from poisonous fish of the following families must not be placed on the market: *Tetraodontidae*, *Molidae*, *Diodontidae* and *Canthigasteridae*. Fresh, prepared and processed fishery products belonging to the family *Gempylidae*, in particular *Ruvettus pretiosus* and *Lepidocybium flavobrunneum*, may only be placed on the market in wrapped/packaged form and must be appropriately labelled to provide information to the consumer on preparation/cooking methods and on the risk related to the presence of substances with adverse gastrointestinal effects. The scientific name must accompany the common name on the label’;

(d) Section IX is amended as follows:

(i) in Chapter I(II)(B)(1), point (e) is replaced by the following:

‘(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 (\*).

(\*) OJ L 123, 24.4.1998, p. 1.’;

(ii) in Chapter II(II), point 1 is replaced by the following:

‘1. When raw milk or dairy 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

**▼B**

- (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 micro-organisms 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 7 days at 55 °C in closed containers or after any other method demonstrating that the appropriate heat treatment has been applied.’;
- (e) in Section X, Chapter II is amended as follows:
  - (i) in Part III, point 5 is replaced by the following:

‘5. After breaking, each particle of the liquid egg must undergo processing as quickly as possible to eliminate microbiological hazards or to reduce them to an acceptable level. A batch that has been insufficiently processed may immediately undergo processing again in the same establishment if this processing renders it fit for human consumption. Where a batch is found to be unfit for human consumption, it must be denatured to ensure that it is not used for human consumption.’;
  - (ii) in Part V, point 2 is replaced by the following:

‘2. In the case of liquid egg, the label referred to in point 1 must also bear the words: “non-pasteurised liquid egg — to be treated at place of destination” and indicate the date and hour of breaking.’;
- (f) in Section XIV, the following Chapter V is added:

**‘CHAPTER V: LABELLING**

Wrapping and packaging containing gelatine must bear the words “gelatine fit for human consumption” and must indicate the date of preparation.’



ANNEX VIII

AMENDMENTS TO REGULATION (EC) No 854/2004

Annexes I, II and III to Regulation (EC) No 854/2004 are amended as follows:

1. Annex I, Section I, Chapter III(3) is amended as follows:

(a) in point (a), the second subparagraph is replaced by the following:

‘BE, CZ, DK, DE, EE, GR, ES, FR, IE, IT, CY, LV, LT, LU, HU, MT, NL, AT, PL, PT, SI, SK, FI, SE and UK;’

(b) point (c) is replaced by the following:

‘(c) when applied in a slaughterhouse within the Community, the mark must include the abbreviation CE, EC, EF, EG, EK, EY, ES, EÜ, EK, EB or WE;’

2. in Annex II, Chapter II(A), points 4 and 5 are replaced by the following:

‘4. The competent authority may classify as being of Class B areas from which live bivalve molluscs may be collected and only placed on the market for human consumption after treatment in a purification centre or after relaying so as to meet the health standards referred to in paragraph 3. Live bivalve molluscs from these areas must not exceed 4 600*E. coli* per 100 g of flesh and intravalvular liquid. The reference method for this analysis is the five-tube, three dilution Most Probable Number (MPN) test specified in ISO 16649-3. Alternative methods may be used if they are validated against this reference method in accordance with the criteria in EN/ISO 16140.

5. The competent authority may classify as being of Class C areas from which live bivalve molluscs may be collected and only placed on the market after relaying over a long period so as to meet the health standards referred to in paragraph 3. Live bivalve molluscs from these areas must not exceed 46 000*E. coli* per 100 g of flesh and intravalvular liquid. The reference method for this analysis is the five-tube, three dilutions MPN test specified in ISO 16649-3. Alternative methods may be used if they are validated against this reference method in accordance with the criteria in EN/ISO 16140.’;

3. in Annex III, Chapter II(G), point 1 is replaced by the following:

‘1. Fishery products derived from poisonous fish of the following families must not be placed on the market: *Tetraodontidae*, *Moridae*, *Diodontidae* and *Canthigasteridae*. Fresh, prepared and processed fishery products belonging to the family *Gempylidae*, in particular *Ruvettus pretiosus* and *Lepidocybium flavobrunneum*, may only be placed on the market in wrapped/packaged form and must be appropriately labelled to provide information to the consumer on preparation/cooking methods and on the risk related to the presence of substances with adverse gastrointestinal effects. The scientific name must accompany the common name on the label.’