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► **B**

**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
► <b><u>M4</u></b>	Commission Regulation (EC) No 1250/2008 of 12 December 2008	L 337	31	16.12.2008
► <b><u>M5</u></b>	Commission Regulation (EU) No 15/2011 of 10 January 2011	L 6	3	11.1.2011
► <b><u>M6</u></b>	Commission Implementing Regulation (EU) No 809/2011 of 11 August 2011	L 207	1	12.8.2011
► <b><u>M7</u></b>	Commission Implementing Regulation (EU) No 1012/2012 of 5 November 2012	L 306	1	6.11.2012
► <b><u>M8</u></b>	Commission Regulation (EU) No 218/2014 of 7 March 2014	L 69	95	8.3.2014
► <b><u>M9</u></b>	Commission Implementing Regulation (EU) 2015/2295 of 9 December 2015	L 324	5	10.12.2015
► <b><u>M10</u></b>	Commission Implementing Regulation (EU) 2016/759 of 28 April 2016	L 126	13	14.5.2016
► <b><u>M11</u></b>	Commission Regulation (EU) 2017/1973 of 30 October 2017	L 281	21	31.10.2017

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- **C1** Corrigendum, OJ L 214, 9.8.2013, p. 11 (1012/2012)

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

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(Text with EEA relevance)

*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.

*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.

**▼ M6***Article 6***Model health certificates and documents for imports of certain products of animal origin for the purpose of Regulations (EC) Nos 853/2004 and 854/2004**

1. The models of the health certificates and documents, 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 set out in that Annex.

2. The model of the document to be signed by the captain, that may replace the document required under Article 14 of Regulation (EC) No 854/2004 when fishery products are imported directly from a freezer vessel, as provided for in Article 15(3) of that Regulation, is set out in Annex VI to this Regulation.

**▼ M1***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.

**▼ M11***Article 6c***Requirements concerning the official controls on fishery products caught by vessels flying the flag of Member States entering the Union after being transferred in third countries with or without storage**

1. Fishery products intended for human consumption caught by vessels flying the flag of a Member State, unloaded, with or without storage, in third countries before entering the Union by a different means of transportation, must be accompanied by a health certificate issued by the competent authority of that third country and completed in accordance with the model health certificate set out in Appendix VIII to Annex VI.

2. The third country where the transfer takes place must be listed as provided for in Article 11(1) of Regulation (EC) No 854/2004.

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3. If the fishery products referred to in paragraph 1 are unloaded and transported to storage facility located in the third country referred to in that paragraph, that storage facility shall appear in a list as provided for in Article 12 of Regulation (EC) No 854/2004.

4. If the fishery products referred to in paragraph 1 are loaded in a vessel flying the flag of a third country, that third country must be listed as provided for in Article 11(1) of Regulation (EC) No 854/2004 and the vessel must appear in a list as provided for in Article 12 of Regulation (EC) No 854/2004.

Container vessels used to transport containerised fishery products are excluded from this requirement.

**▼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 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.

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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 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.

**▼B***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
- 

**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>
- 

<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).



*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.

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## 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****▼M3**

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;
  - (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*.

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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 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 alkalising substances the resulting free bases cannot escape.

**▼ B**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  $10 \text{ g} \pm 0,1 \text{ g}$  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  $2 \text{ }^{\circ}\text{C}$  and  $6 \text{ }^{\circ}\text{C}$ ;

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

The pH of the end point should be  $5,0 \pm 0,1$ .

(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

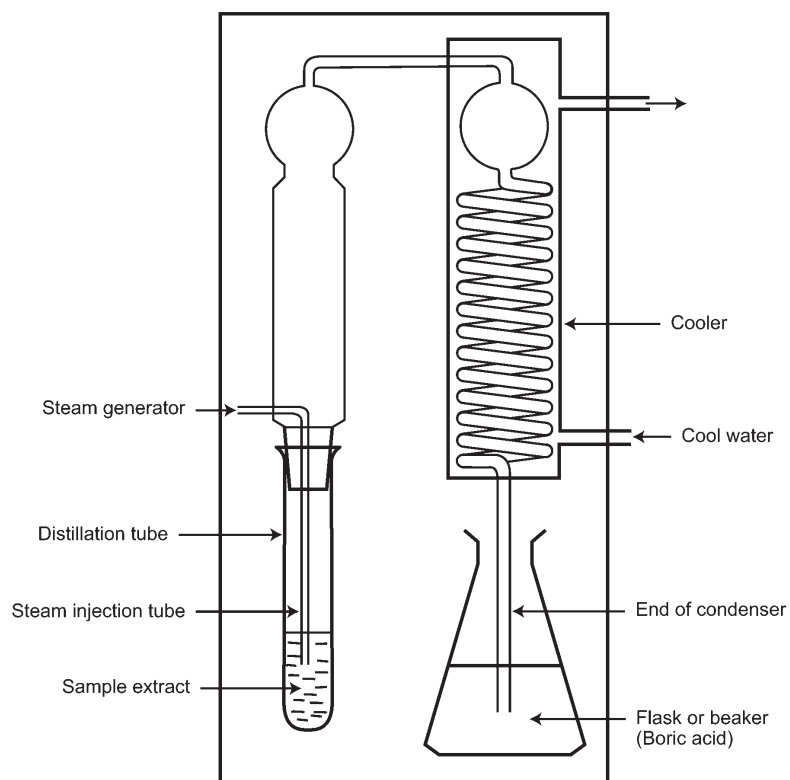
$M$  = Weight of sample in g.

**▼B****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.

## 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.

**▼ M5**

## CHAPTER III

**LIPOPHILIC TOXIN DETECTION METHODS****A. Chemical methodology**

- (1) The EU-RL LC-MS/MS method shall be the reference method for the detection of 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. This method shall determine at least the following compounds:

— okadaic acid group toxins: OA, DTX1, DTX2, DTX3 including their esters,

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

**▼ M5**

- pectenotoxins group toxins: PTX1 and PTX2,
  - yessotoxins group toxins: YTX, 45 OH YTX, homo YTX, and 45 OH homo YTX,
  - azaspiracids group toxins: AZA1, AZA2 and AZA3.
- (2) Total toxicity equivalence shall be calculated using toxicity equivalent factors (TEFs) as recommended by EFSA.
  - (3) If new analogues of public health significance are discovered, they should be included in the analysis. Total toxicity equivalence shall be calculated using toxicity equivalent factors (TEFs) as recommended by EFSA.
  - (4) Other methods, such as liquid chromatography (LC) mass spectrometry (MS) method, high-performance liquid chromatography (HPLC) with appropriate detection, immunoassays and functional assays, such as the phosphatase inhibition assay, can be used as alternatives or supplementary to the EU-RL LC-MS/MS method, provided that:
    - (a) either alone or combined they can detect at least the analogues as identified in point A(1) of this Chapter; more appropriate criteria shall be defined when necessary;
    - (b) they fulfil the method performance criteria stipulated by the EU-RL. Such methods should be intra-laboratory validated and successfully tested under a recognised proficiency test scheme. The EU-RL shall support activities toward inter-laboratory validation of the technique to allow for formal standardisation;
    - (c) their implementation provides an equivalent level of public health protection.

**B. Biological methods**

- (1) To allow Member States to adapt their methods to the LC-MS/MS method as defined in point A(1) of this Chapter, 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 still used until 31 December 2014 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.
- (2) 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.
- (3) A single mouse bioassay involving acetone extraction may be used to detect okadaic acid, dinophysistoxins, azaspiracids, 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.
- (4) 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.

**▼ M5**

- (5) 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.
  - (6) 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.
- C. After the period established in point B(1) of this Chapter, the mouse bioassay shall be used only during the periodic monitoring of production areas and relaying areas for detecting new or unknown marine toxins on the basis of the national control programmes elaborated by the Member States.



**▼B**

*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.

**▼ M9***ANNEX V***Lists of approved establishments**

## CHAPTER I

**ACCESS TO LISTS OF APPROVED 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 or inform in case those lists are published through the TRACES system.

## 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 Union.

**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.

**C. Listing through the TRACES system**

By way of derogation from Parts A and B, Member States may provide the lists through the TRACES system.

## 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*

▼ M6

**MODEL HEALTH CERTIFICATES AND DOCUMENTS FOR IMPORTS  
OF CERTAIN PRODUCTS OF ANIMAL ORIGIN**

SECTION I

▼ M10

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▼ M6

**CHAPTER 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.

**CHAPTER 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.

▼ M10

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▼ M6

SECTION II

*MODEL DOCUMENT TO BE SIGNED BY THE CAPTAIN*

The document to be signed by the captain, that may replace that required under Article 14 of Regulation (EC) No 854/2004 when frozen fishery products are imported directly from a freezer vessel, as provided for in Article 15(3) of that Regulation, shall comply with the model document laid down in Appendix VII to this Annex.

▼ M10

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▼ M7

## Appendix IV to Annex VI

## Model health certificate for imports of fishery products intended for human consumption

		Veterinary certificate to EU		
Part I: Details of dispatched consignment	I.1. Consignor Name Address Tel.		I.2. Certificate reference No I.2.a.	
			I.3. Central competent authority	
			I.4. Local competent authority	
	I.5. Consignee Name Address Postcode Tel.		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 Documentation 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. Seal/Container No		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"/>		
▶ <sup>(1)</sup> 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 ◀	

▶<sup>(1)</sup> C1



COUNTRY		Fishery products	
II. Health information		II.a. Certificate reference number	II.b.
Part II: Certification	II.1. <b>(<sup>1</sup>) Public health attestation</b>		
	I, the undersigned, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) 852/2004, (EC) 853/2004 and (EC) 854/2004 and certify that the fishery products described above were produced in accordance with those requirements, in particular that they:		
	— come from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004;		
	— have been caught and handled on board vessels, landed, handled and where appropriate prepared, processed, frozen and thawed hygienically in compliance with the requirements laid down in Section VIII, Chapters I to IV of Annex III to Regulation (EC) No 853/2004;		
	— satisfy the health standards laid down in Section VIII, Chapter V of Annex III to Regulation (EC) No 853/2004 and the criteria laid down in Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs;		
	— have been packaged, stored and transported in compliance with Section VIII, Chapters VI to VIII of Annex III to Regulation (EC) No 853/2004;		
	— have been marked in accordance with Section I of Annex II to Regulation (EC) No 853/2004;		
	— the guarantees covering live animals and products thereof, if from aquaculture origin, provided by the residue plans submitted in accordance with Directive 96/23/EC, and in particular Article 29 thereof, are fulfilled; and		
	— have satisfactorily undergone the official controls laid down in Annex III to Regulation (EC) No 854/2004.		
	II.2. <b>(<sup>2</sup>) (<sup>4</sup>) Animal health attestation for fish and crustaceans of aquaculture origin</b>		
II.2.1. <b>(<sup>3</sup>) (<sup>4</sup>) [Requirements for susceptible species to Epizootic haematopoietic necrosis (EHN), Taura syndrome and Yellowhead disease]</b>			
I, the undersigned official inspector, hereby certify that the aquaculture animals or products thereof referred to in Part I of this certificate:			
<b>(<sup>5</sup>)</b> originate from a country/territory, zone or compartment declared free from <b>(<sup>4</sup>) [EHN (<sup>4</sup>) [Taura syndrome] (<sup>4</sup>) [Yellowhead disease]]</b> in accordance with Chapter VII of Directive 2006/88/EC or the relevant OIE Standard by the competent authority of my country,			
(i) where the relevant diseases are notifiable to the competent authority and reports of suspicion of infection of the relevant disease must be immediately investigated by the competent authority,			
(ii) all introduction of species susceptible to the relevant diseases come from an area declared free of the disease, and			
(iii) species susceptible to the relevant diseases are not vaccinated against the relevant diseases]			
II.2.2. <b>(<sup>3</sup>) (<sup>4</sup>) [Requirements for species susceptible to Viral haemorrhagic septicaemia (VHS), Infectious haematopoietic necrosis (IHN), Infectious salmon anaemia (ISA), Koi herpes virus (KHV) and White spot disease intended for a Member State, zone or compartment declared disease free or subject to a surveillance or eradication programme for the relevant disease]</b>			
I, the undersigned official inspector, hereby certify that the aquaculture animals or products thereof referred to in Part I of this certificate:			
<b>(<sup>6</sup>)</b> originate from a country/territory, zone or compartment declared free from <b>(<sup>4</sup>) [VHS] (<sup>4</sup>) [IHN] (<sup>4</sup>) [ISA] (<sup>4</sup>) [KHV] (<sup>4</sup>) [White spot disease]]</b> in accordance with Chapter VII of Directive 2006/88/EC or the relevant OIE Standard by the competent authority of my country,			
(i) where the relevant diseases are notifiable to the competent authority and reports of suspicion of infection of the relevant disease must be immediately investigated by the competent authority,			
(ii) all introduction of species susceptible to the relevant diseases come from an area declared free of the disease, and			
(iii) species susceptible to the relevant diseases are not vaccinated against the relevant diseases]			
II.2.3. <b>Transport and labelling requirements</b>			
I, the undersigned official inspector, hereby certify that:			
II.2.3.1.	the aquaculture animals referred to above are placed under conditions, including with a water quality, that do not alter their health status;		
II.2.3.2.	the transport container or well boat prior to loading is clean and disinfected or previously unused; and		



COUNTRY		Fishery products	
II.	Health information	II.a. Certificate reference number	II.b.
II.2.3.3.	<p>the consignment is identified by a legible label on the exterior of the container, or when transported by well boat, in the ship's manifest, with the relevant information referred to in boxes I.7 to I.11 of Part I of this certificate, and the following statement:</p> <p>"<sup>(4)</sup> [Fish] <sup>(4)</sup> [Crustaceans] intended for human consumption in the Union".</p> <p><b>Notes</b></p> <p><b>Part I:</b></p> <p>— Box reference I.8: Region of origin: For frozen or processed bivalve molluscs, indicate the production area.</p> <p>— Box reference I.11: Place of origin: name and address of the dispatch establishment.</p> <p>— 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.</p> <p>— Box reference I.19: Use the appropriate Harmonised System (HS) codes of the World Customs Organisation of the following headings: 0301, 0302, 0303, 0304, 0305, 0306, 0307, 0308, 05.11, 15.04, 1516, 1518, 1603, 1604, 1605 or 2106.</p> <p>— Box reference I.23: Identification of container/Seal number: Where there is a serial number of the seal it has to be indicated.</p> <p>— Box reference I.28: <i>Nature of commodity</i>: Specify whether aquaculture or wild origin.</p> <p style="padding-left: 40px;"><i>Treatment type</i>: Specify whether live, chilled, frozen or processed.</p> <p style="padding-left: 40px;"><i>Manufacturing plant</i>: includes factory vessel, freezer vessel, cold store, processing plant.</p> <p><b>Part II:</b></p> <p><sup>(1)</sup> Part II.1 of this certificate does not apply to countries with special public health certification requirements laid down in equivalence agreements or other Union legislation.</p> <p><sup>(2)</sup> Part II.2 of this certificate does not apply to:</p> <p>(a) non-viable crustaceans, which means crustaceans no longer able to survive as living animals if returned to the environment from which they were obtained,</p> <p>(b) fish which are slaughtered and eviscerated before dispatch,</p> <p>(c) aquaculture animals and products thereof, which are placed on the market for human consumption without further processing, provided that they are packed in retail-sale packages which comply with the provisions for such packages in Regulation (EC) No 853/2004,</p> <p>(d) crustaceans destined for processing establishments authorised in accordance with Article 4(2) of Directive 2006/88/EC, or for dispatch centres, purification centres or similar businesses which are equipped with an effluent treatment system inactivating the pathogens in question, or where the effluent is subject to other types of treatment reducing the risk of transmitting diseases to the natural waters to an acceptable level,</p> <p>(e) crustaceans which are intended for further processing before human consumption without temporary storage at the place of processing and packed and labelled for that purpose in accordance with Regulation (EC) No 853/2004.</p> <p><sup>(3)</sup> Parts II.2.1 and II.2.2 of this certificate only apply to species susceptible to one or more of the diseases referred to in the heading of the point concerned. Susceptible species are listed in Annex IV to Directive 2006/88/EC.</p> <p><sup>(4)</sup> Keep as appropriate.</p> <p><sup>(5)</sup> For consignments of species susceptible to EHN, Taura syndrome and/or Yellowhead disease this statement must be kept for the consignment to be authorised into any part of the Union.</p>		

▼ M7

COUNTRY		Fishery products
II.	Health information	II.a. Certificate reference No
		II.b.
<p>(<sup>6</sup>) To be authorised into a Member State, zone or compartment (boxes I.9 and I.10 of Part I of the certificate) declared free from VHS, IHN, ISA, KHV or Whitespot disease or with a surveillance or eradication programme drawn up in accordance with Article 44(1) or (2) of Directive 2006/88/EC, one of these statements must be kept if the consignment contain species susceptible to the disease(s) for which disease freedom or programme(s) apply(ies). Data on the disease status of each farm and mollusc farming area in the Union are accessible at <a href="http://ec.europa.eu/food/animal/liveanimals/aquaculture/index_en.htm">http://ec.europa.eu/food/animal/liveanimals/aquaculture/index_en.htm</a>.</p> <p>— The colour of the stamp and signature must be different to that of the other particulars in the certificate.</p>		
<p>Official inspector</p> <p>Name (in capital letters):</p> <p>Date:</p> <p>Stamp:</p> <p>Qualification and title:</p> <p>Signature:</p>		

▼ **M4**

## Appendix V to Annex VI

## PART A

**MODEL HEALTH CERTIFICATE FOR IMPORTS OF LIVE BIVALVE MOLLUSCS ECHINODERMS, TUNICATES AND MARINE GASTROPODS INTENDED FOR HUMAN CONSUMPTION**

COUNTRY		Veterinary certificate to EU		
Part I: Details of dispatched consignment	I.1. Consignor Name  Address Postal code Tel. No		I.2. Certificate reference number	I.2.a.
			I.3. Central Competent Authority	
			I.4. Local Competent Authority	
	I.5. Consignee Name  Address Postal code Tel. No		I.6.	
	I.7. Country of origin	ISO code	I.8. Region of origin	Code
			I.9. Country of destination	ISO code
			I.10.	
	I.11. Place of origin Name 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)				
Approval number of establishments Manufacturing plant		Number of packages		
		Net weight		





COUNTRY		Live bivalve molluscs, echinoderms, tunicates and marine gastropods	
II.	Health attestation	II.a. Certificate reference number	II.b.
Part II: Certification	II.1	<p><b>(<sup>1</sup>)Public health attestation for live bivalve molluscs, echinoderms, tunicates and marine gastropods</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 (<sup>4</sup>)[live bivalve molluscs] (<sup>4</sup>)[live echinoderms] (<sup>4</sup>)[live tunicates] (<sup>4</sup>)[live marine gastropods] 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, and</li> <li>— have satisfactorily undergone the official controls laid down in Annex II to Regulation (EC) No 854/2004.</li> </ul>	
	II.2	<p><b>(<sup>2</sup>)(<sup>4</sup>)Animal health attestation for live bivalve molluscs of aquaculture origin</b></p>	
	II.2.1	<p><b>(<sup>3</sup>)(<sup>4</sup>)[Requirements for species susceptible to <i>Bonamia exitiosa</i>, <i>Perkinsus marinus</i> and <i>Microcytos mackini</i>]</b></p> <p>I, the undersigned official inspector, hereby certify that the live bivalve molluscs referred to in Part I of this certificate:</p> <p>(<sup>5</sup>)originate from a country/territory, zone or compartment declared free from (<sup>4</sup>)[<i>Bonamia exitiosa</i>] (<sup>4</sup>)[<i>Perkinsus marinus</i>] (<sup>4</sup>)[<i>Microcytos mackini</i>] in accordance with Chapter VII of Directive 2006/88/EC or the relevant OIE Standard by the competent authority of my country,</p> <ul style="list-style-type: none"> <li>— where the relevant diseases are notifiable to the competent authority and reports of suspicion of infection of the relevant disease must be immediately investigated by the official services, and</li> <li>— all introduction of species susceptible to the relevant diseases come from an area declared free of the disease.]</li> </ul>	
	II.2.2	<p><b>(<sup>3</sup>)(<sup>4</sup>)[Requirements for species susceptible to <i>Marteilia refringens</i> and <i>Bonamia ostreae</i> intended for a Member State, zone or compartment declared disease free or subject to a surveillance or eradication programme for the relevant disease]</b></p> <p>I, the undersigned official inspector, hereby certify that the live bivalve molluscs referred to above:</p> <p>(<sup>6</sup>)originate from a country/territory, zone or compartment declared free from (<sup>4</sup>)[<i>Marteilia refringens</i>] (<sup>4</sup>)[<i>Bonamia ostreae</i>] in accordance with Chapter VII of Directive 2006/88/EC or the relevant OIE Standard by the competent authority of my country,</p> <ul style="list-style-type: none"> <li>(i) where the relevant diseases are notifiable to the competent authority and reports of suspicion of infection of the relevant disease must be immediately investigated by the official services, and</li> <li>(ii) all introduction of species susceptible to the relevant diseases come from an area declared free of the disease.]</li> </ul>	
	II.2.3	<p><b>Transport and labelling requirements</b></p> <p>I, the undersigned official inspector, hereby certify that:</p> <p>II.2.3.1 the live bivalve molluscs referred to above are placed under conditions, including with a water quality, that do not alter their health status,</p> <p>II.2.3.2 the transport container or well boat prior to loading is clean and disinfected or previously unused; and</p> <p>II.2.3.3 the consignment is identified by a legible label on the exterior of the micro container, or when transported by well boat, in the ship's manifest, with the relevant information referred to in boxes I.7 to I.11 of Part I of this certificate, and the following statement:</p> <p>"Live bivalve molluscs intended for human consumption in the Community".</p>	

▼ **M4**

COUNTRY		Live bivalve molluscs, echinoderms, tunicates and marine gastropods	
II. Health attestation	II.a. Certificate reference number	II.b.	
<p><b>Notes</b></p> <p><b>Part I:</b></p> <p>— Box reference I.8: Region of origin: indicate the production area.</p> <p>— Box reference I.11: Place of origin: name and address of the dispatch establishment.</p> <p>— 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.</p> <p>— Box reference I.23: Identification of container/Seal number: Where there is a serial number of the seal it has to be indicated.</p> <p>— Box reference I.28: Manufacturing plant: includes dispatch centre, purification centre.</p> <p><b>Part II:</b></p> <p>(<sup>1</sup>) Part II.1 does not apply to countries with special public health certification requirements laid down in Equivalence Agreements or other Community legislation.</p> <p>(<sup>2</sup>) Part II.2 does not apply to:</p> <p>(a) non-viable molluscs, which means molluscs no longer able to survive as living animals if returned to the environment from which they were obtained,</p> <p>(b) live bivalve molluscs placed on the market for human consumption without further processing, provided that they are packed in retail-sale packages which comply with the provisions for such packages in Regulation (EC) No 853/2004,</p> <p>(c) live bivalve molluscs destined for processing establishments authorised in accordance with Article 4(2) of Directive 2006/88/EC, or for dispatch centres, purification centres or similar businesses which are equipped with an effluent treatment system inactivating the pathogens in question, or where the effluent is subject to other types of treatment reducing the risk of transmitting diseases to the natural waters to an acceptable level,</p> <p>(d) live bivalve molluscs which are intended for further processing before human consumption without temporary storage at the place of processing and packed and labelled for that purpose in accordance with Regulation (EC) No 853/2004.</p> <p>(<sup>3</sup>) Parts II.2.1 and II.2.2 only apply to species susceptible to one or more of the diseases referred to in the title. Susceptible species are listed in Annex IV to Directive 2006/88/EC.</p> <p>(<sup>4</sup>) Keep as appropriate.</p> <p>(<sup>5</sup>) For consignments of species susceptible to <i>Bonamia exitiosa</i>, <i>Perkinsus marinus</i> and <i>Microcytos mackini</i> this statement must be kept for the consignment to be authorised into any part of the Community.</p> <p>(<sup>6</sup>) To be authorised into a Member State, zone or compartment (boxes I.9 and I.10 of Part I of the certificate) declared free from <i>Marteilia refringens</i> or <i>Bonamia ostreae</i> or with a surveillance or eradication programme established in accordance with Article 44 (1) or (2) of Directive 2006/88/EC, one of these statements must be kept if the consignment contain species susceptible to the disease(s) for which disease freedom or programme(s) apply(ies). Data on the disease status of each farms and mollusc farming areas in the Community are accessible at <a href="http://ec.europa.eu/food/animal/liveanimals/aquaculture/index_en.htm">http://ec.europa.eu/food/animal/liveanimals/aquaculture/index_en.htm</a></p> <p>— The colour of the stamp and signature must be different to that of the other particulars in the certificate.</p>			
<p><b>Official inspector</b></p> <p>Name (in capital letters):</p> <p>Date:</p> <p>Stamp:</p> <p>Qualification and title:</p> <p>Signature:</p>			

**▼ 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:	

**▼ M10**

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

▼ **M6**

## Appendix VII to Annex VI

**MODEL DOCUMENT, TO BE SIGNED BY THE CAPTAIN, ACCOMPANYING IMPORTS WHEN FROZEN FISHERY PRODUCTS ARE IMPORTED DIRECTLY INTO THE EUROPEAN UNION FROM A FREEZER VESSEL**

<b>Part I : Details of dispatched consignment</b>	I.1. Consignor		I.2. Certificate reference No		I.2.a.	
	Name		I.3.			
	Address		I.4.			
	Postal code					
	Tel.					
	I.5. Consignee		I.6.			
	Name					
	Address					
	Postal code					
	Tel.					
	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			
	I.13.		I.14.			
I.15.		I.16. Entry BIP in EU				
		I.17.				
I.18.		I.19. Commodity code (HS code)				
		I.20. Quantity				
I.21.		I.22. Number of packages				
I.23.		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)		Number of packages		Net weight		



COUNTRY		Fishery products	
Part II: Certification	I.(bis)	<b>Other information</b>	
		Fishing area(s):  IMO/Lloyd's number (if issued) or call sign of the vessel:  Fishing Period:            Start date: .../.../...            Stop date: .../.../...	
	II.	Health attestation	II.a. Certificate reference number    II.b.
	II.1.	<b>Public health attestation</b>	
		I, the undersigned, declare that <ul style="list-style-type: none"> <li>— the vessel appears on the list of vessels from which imports to the European Union are permitted (being "EU-listed");</li> <li>— the vessel has a programme based on the HACCP principles in order to control hazards;</li> <li>— the part of the vessel where fishery products are handled, equipment, containers and the cold storage for fishery products are kept clean and maintained in good repair and condition;</li> <li>— the fishery products have been protected from contamination and from the effects of the sun or any other source of heat as soon as possible after they have been taken on board, and that they have been handled in a way that prevents bruising and other damage;</li> <li>— the fishery products have not been contaminated by fuel, bilge water or pests;</li> <li>— the slaughter, bleeding, heading, gutting, removing fins, have been carried out hygienically as soon as possible after capture, and the products have been washed immediately and thoroughly. Viscera and parts that may constitute a danger to public health has been removed as soon as possible and kept apart from products intended for human consumption;</li> <li>— only clean seawater has been used as alternative to potable water for the handling and washing of the fishery product;</li> <li>— the fishery products have been subjected to a visual examination for the purpose of detecting visible parasites, and fishery products that are obviously contaminated with parasites are not placed on the market for human consumption;</li> <li>— freezing has been carried out hygienically as soon as possible after capture;</li> <li>— frozen fishery products have been kept at a temperature of not more than – 18 °C in all parts of the product, except whole fish initially frozen in brine intended for the manufacture of canned food may be kept at a temperature of not more than – 9 °C;</li> <li>— frozen blocks have been hygienically and adequately wrapped before landing;</li> <li>— the packages have been marked with an identification mark indicating the approval number of the freezer vessel and the flag state;</li> <li>— the wrapping material is not a source of contamination and has been stored in such a manner that it has not been exposed to a risk of contamination.</li> </ul>	
		<b>Notes part I:</b>	
		<ul style="list-style-type: none"> <li>— Box reference I.1: Name and address (street, town and region/province/state, as applicable), telephone and fax numbers or the e-mail address of the owner of/ the responsible for the vessel.</li> <li>— Box reference I.2: A unique document number according to your own classification.</li> <li>— Box reference I.5:               <ul style="list-style-type: none"> <li>The name and address (street, town and post code) of                   <ul style="list-style-type: none"> <li>— the physical or legal person to whom the consignment is imported directly to the Member State of destination.</li> </ul> </li> </ul> </li> </ul>	

▼ M6

COUNTRY	Fishery products
<ul style="list-style-type: none"> <li>— Box reference I.7: The country of which the vessel issuing this document is flying the flag.</li> <li>— Box reference I.11: The name of the freezer vessel and approval number as listed in accordance with Article 12 of Regulation (EC) No 854/2004 from which the fishery products are imported directly.</li> <li>— Box reference I.19: Use the appropriate harmonised system (HS) code of the World Customs Organisation under the chapter 03.03.</li> <li>— Box reference I.20: Total net weight in kilo as sum from I.28.</li> <li>— Box reference I.22: Sum from I.28.</li> <li>— Box reference I.25: Tick the box "Human consumption".</li> <li>— Box reference I.27: Tick the box if final destination is EU.</li> <li>— Box reference I.28: List the various species with scientific name, number of packages and net weight.</li> </ul>	
<p>Captain of the freezer vessel</p> <p>Name (in capital letters):</p> <p>Date: <span style="float: right;">Signature:</span></p> <p>Stamp:</p>	

▼ **M11**

## Appendix VIII to Annex VI

**Model of health certificate for fishery products intended for human consumption caught by vessels flying the flag of a Member State and transferred in third countries with or without storage**

		<b>Veterinary certificate to the EU</b>	
<b>Part I: Details of dispatched consignment</b>	I.1. Consignor Name Address  Tel.		I.2. Certificate reference number   I.2. a.
			I.3. Central Competent Authority
			I.4. Local Competent authority
	I.5. Consignee Name Address  Postcode Tel.		I.6.
	I.7. Country of origin   ISO code	I.8. Region of origin   Code	I.9. Country of destination   ISO code   I.10.
	I.11. Place of origin  Name Approval/registration number Address		I.12.
	I.13. Place of loading Address		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	

▼ M11

I.23. Seal/Container No		I.24. Type of packaging		
I.25. Commodities certified as:				
Human consumption <input type="checkbox"/>				
I.26.		I.27. For import or admission into EU <input type="checkbox"/>		
I.28. Identification of the commodity				
Species (Scientific name)	Treatment type	Approval/registration number(s) of vessel(s) (*)	Number of packages	Net weight





COUNTRY	Fishery products transferred in third countries							
II. Health information	II.a. Certificate reference number	II.b.						
<p>II.1. Public health attestation</p> <p>I, the undersigned official inspector, declare that I am aware of the relevant provisions of Regulations (EC) Nos 178/2002, (EC) 852/2004, (EC) 853/2004 and (EC) 854/2004 and certify that the fishery products described above</p> <ul style="list-style-type: none"> <li>— have been landed and unloaded hygienically from the approved/registered vessel(s) ..... (indicate approval/registration number(s) and name of the flag Member State(s) in compliance with the relevant requirements laid down in Chapter II of Section VIII, of Annex III to Regulation (EC) No 853/2004;</li> <li>— if applicable, have been stored in approved coldstore(s) ..... (indicate approval number(s) in compliance with the relevant requirements of Chapter VII of Section VIII of Annex III to Regulation (EC) No 853/2004;</li> <li>— if applicable, have been loaded hygienically on the approved vessel(s) ..... (indicate approval number(s) of the Member State(s) or third country(ies) and the name of the flag Member State(s) or third country(ies)) in compliance with the relevant requirements laid down in Chapter I and VIII of Section VIII of Annex III to Regulation (EC) No 853/2004;</li> <li>— if applicable, have been loaded in a container ..... (indicate container number) or in a truck ..... (indicate registration number plate of truck and of trailer) or in an aeroplane ..... (indicate the flight number) in compliance with the requirements laid down in Chapter VIII of Section VIII of Annex III to Regulation (EC) No 853/2004;</li> <li>— are accompanied by the print out(s) (**) of the fishing logbook(s) or relevant parts thereof (**)</li> </ul> <p>(**) Electronic format is also accepted.</p> <p>Notes</p> <p>Part I:</p> <ul style="list-style-type: none"> <li>— Box reference I.7: Indicate the name of the third country of dispatch.</li> <li>— Box reference I.11: Place of origin: indicate the name, address and approval number of the cold store in the third country of dispatch or, if no storage in a coldstore takes place, indicate the name and approval or registration number of the Member State flagged vessel of origin.</li> <li>— Box reference I.15: Indicate the means of transport leaving the third country of dispatch. In case of freezer/reefer vessels, indicate the name of the vessel, approval number and flag State, in case of fishing vessel the registration number and flag State. If the means of transport are containers, trucks or aeroplanes the same indications provided for in the fourth indent of part II.1 must be indicated.</li> <li>— Box reference I.19: Use the appropriate Harmonised System (HS) codes of the World Customs Organisation of the following headings: 0302, 0303, 0304, 0305, 0306, 0307, 0308, 1504, 1516, 1518, 1603, 1604, 1605, 2106</li> <li>— Box reference I.23: Identification of container/seal number: The serial seal number must only be indicated if the seal was affixed to the container under the supervision of the competent authority issuing the certificate.</li> <li>— Box reference I.28: Treatment type: Specify whether chilled, frozen or processed.</li> </ul> <p>(*) includes fishing vessel, factory vessel, freezer and reefer vessel as applicable.</p>								
<p>Official inspector</p> <table style="width: 100%; border: none;"> <tr> <td style="width: 60%;">Name (in capital letters):</td> <td style="width: 40%;">Qualification and title:</td> </tr> <tr> <td>Date:</td> <td>Signature:</td> </tr> <tr> <td>Stamp:</td> <td></td> </tr> </table>			Name (in capital letters):	Qualification and title:	Date:	Signature:	Stamp:	
Name (in capital letters):	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.

**▼ M2**

- (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;
  - (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.

**▼ M8**  
\_\_\_\_\_**▼ M2**

- (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;

**▼ M2**

- (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 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/package 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.’;

**▼B**

(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
- (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.’