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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)

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)

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⁽¹⁾, 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⁽²⁾, 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⁽³⁾, 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⁽⁴⁾, 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.

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- (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⁽⁵⁾ 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 intended for human consumption and amending Council Directives 89/662/EEC and 92/118/EEC and Council Decision 95/408/EC⁽⁶⁾. 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

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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 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.

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- 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 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

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- 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 Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs⁽⁷⁾. 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.

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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.

I^{F1}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

- 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.
- 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.]

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Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) No 809/2011 of 11 August 2011 amending Regulation (EC) No 2074/2005 as regards documentation accompanying imports of frozen fishery products directly from a freezer vessel (Text with EEA relevance).

I^{F2}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.]

Textual Amendments

F2 Inserted by Commission Regulation (EC) No 1664/2006 of 6 November 2006 amending Regulation (EC) No 2074/2005 as regards implementing measures for certain products of animal origin intended for human consumption and repealing certain implementing measures (Text with EEA relevance).

IF3 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.]

Textual Amendments

F3 Inserted by Commission Regulation (EC) No 1244/2007 of 24 October 2007 amending Regulation (EC) No 2074/2005 as regards implementing measures for certain products of animal origin intended for human consumption and laying down specific rules on official controls for the inspection of meat (Text with EEA relevance).

Article 7

Derogation from Regulation (EC) No 852/2004 for foods with traditional characteristics

- 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.

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- 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.

- 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.

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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

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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.

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Appendix to Annex I

MODEL DOCUMENT

1.	Identification	n details				
	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	em findings				
	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)				

a Microbiological, chemical, serological, etc. (include results as attached).

b 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.

c Microbiological, chemical, serological, etc. (include results as attached).

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		parasites, foreign objects, etc	
	3.4.	other results (e.g.	
	3.3.	laboratory results ^c	
		date of slaughter	
		partially or totally condemned carcase (give reason)	
		organ or site of the animal(s) affected	
		type/class/age	
		number of animals affected	
	3.2.	disease (codes can be used ^b	
		date of slaughter	
		organ or site of animal(s) affected	
		type/class/age	
		number of animals affected	
	3.1.	(macroscopic) findings	
3.	Post-mortem	findings	
	2.4.	laboratory results ^a	
		date of inspection	
		observations	
		type/class/age	
		number of animals affected	

a Microbiological, chemical, serological, etc. (include results as attached).

b 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.

c Microbiological, chemical, serological, etc. (include results as attached).

ANNEX II SECTION I CHAPTER I

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5.	Contact detail	ils		
	5.1.	slaughterhouse (approval number)		
		name		
		full address		
		telephone number		
	5.2.	electronic address if available		
6.	Official veterinarian (print name)			
		signature and stamp		
7.	Date			
8.	Number of pa	Number of pages attached to this form:		

- a Microbiological, chemical, serological, etc. (include results as attached).
- b 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.
- c 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.

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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

- [F4]. 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.]

Status: Point in time view as at 01/04/2012.

Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EC) No 2074/2005. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

Textual Amendments

- Substituted by Commission Regulation (EC) No 1022/2008 of 17 October 2008 amending Regulation (EC) No 2074/2005 as regards the total volatile basic nitrogen (TVB-N) limits (Text with EEA relevance).
- 2. Distillation as referred to in point 1 must be performed using apparatus which complies with the diagram in Chapter IV.
- The routine methods which may be used to check the TVB-N limit are as follows: 3.
- microdiffusion method described by Conway and Byrne (1933),
- direct distillation method described by Antonacopoulos (1968),
- distillation of an extract deproteinised by trichloracetic 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.).
- Salmo salar, species belonging to the Merlucciidae family, species belonging to the 3. 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.

Status: Point in time view as at 01/04/2012.

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3. Brief description

The volatile nitrogenous bases are extracted from a sample using a solution of 0,6 mol perchloric acid. After alkalinisation 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) phenolphtalein 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.

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

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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;

Steam distillation (b)

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 alkalinisation, several drops of phenolphtalein 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 ± 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:

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

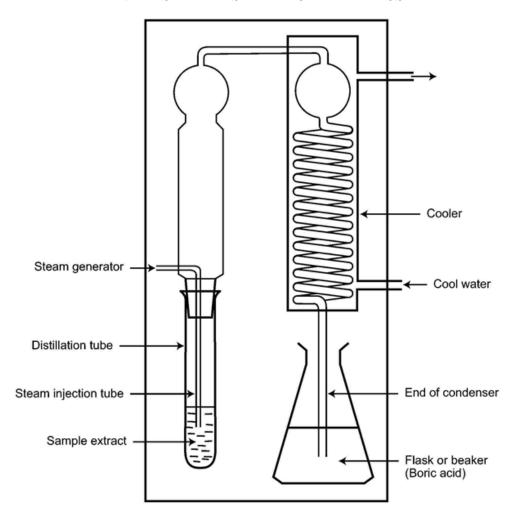
- 1. Duplicate analyses are required. The applied method is correct if the difference between duplicates is not greater than 2 mg/100 g.
- 2. Check the equipment by distilling solutions of NH₄Cl equivalent to 50 mg TVB-N/100
- 3. Standard deviation of reproducibility $S_r = 1.2 \text{ mg}/100 \text{ g}$. Standard deviation of comparability $S_R = 2,50 \text{mg}/100 \text{ g}$.

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CHAPTER IV

TVB-N STEAM DISTILLATION APPARATUS



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⁽⁸⁾, elements of replacement, refinement and reduction must be taken into account when biological methods are used.

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Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EC) No 2074/2005. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

[F5CHAPTER 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.]

Textual Amendments

F5 Substituted by Commission Regulation (EC) No 1664/2006 of 6 November 2006 amending Regulation (EC) No 2074/2005 as regards implementing measures for certain products of animal origin intended for human consumption and repealing certain implementing measures (Text with EEA relevance).

[F6CHAPTER 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.]

Textual Amendments

F6 Substituted by Commission Regulation (EC) No 1244/2007 of 24 October 2007 amending Regulation (EC) No 2074/2005 as regards implementing measures for certain products of animal origin intended for human consumption and laying down specific rules on official controls for the inspection of meat (Text with EEA relevance).

F⁷CHAPTER III

LIPOPHILIC TOXIN DETECTION METHODS

A. Chemical methodology

Status: Point in time view as at 01/04/2012.

Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EC) No 2074/2005. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

(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: OA, DTX1, DTX2, DTX3 including their esters,

group toxins

—pectenotoxins : PTX1 and PTX2,

group toxins

—yessotoxins : YTX, 45 OH YTX, homo YTX, and 45 OH homo YTX,

group toxins

—azaspiracids : AZA1, AZA2 and AZA3.

group toxins

- (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:
- 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.

Status: Point in time view as at 01/04/2012.

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- (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.
- (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.]

Textual Amendments

F7 Substituted by Commission Regulation (EU) No 15/2011 of 10 January 2011 amending Regulation (EC) No 2074/2005 as regards recognised testing methods for detecting marine biotoxins in live bivalve molluscs (Text with EEA relevance).

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 CHAPTER II

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Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EC) No 2074/2005. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

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.

ANNEX V CHAPTER II Document Generated: 2023-10-20

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Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EC) No 2074/2005. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

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.

[F5ANNEX VI

[FIMODEL HEALTH CERTIFICATES AND DOCUMENTS FOR IMPORTS OF CERTAIN PRODUCTS OF ANIMAL ORIGIN

SECTION I

CHAPTER 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.

CHAPTER II

GELATINE

Without prejudice to other specific Union 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.

CHAPTER III

COLLAGEN

Without prejudice to other specific Union legislation, in particular to legislation on transmissible spongiform encephalopathy's 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.

ANNEX VI SECTION II

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Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EC) No 2074/2005. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

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.

CHAPTER 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.

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.]

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ANNEX VI SECTION II

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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

CO	UNTRY	Veterinary certificate to EU		
	I.1. Consignor Name	I.2. Certificate reference number I.2.a.		
	Address	I.3. Central Competent Authority		
ment	Postal code Tel No.	I.4. Local Competent Authority		
Part I: Details of dispatched consignment	I.5. Consignee Name	1.6.		
00 0	Address			
tche	Postal code Tel No.			
lispa	I.7. Country of origin ISO code I.8.	I.9. Country of destination ISO code I.10.		
s of c	I.11. Place of origin	1.12.		
etails	Name Approval number			
t : D	Address			
Par				
	I.13. Place of loading	1.14. Date of departure		
	I.15. Means of transport	I.16. Entry BIP in EU		
	Aeroplane Ship Railway wagon Road vehicle Other			
	Identification: Documentary references:	1.17.		
	I.18. Description of commodity	I.19. Commodity code (HS code) 0208 20		
		I.20. Quantity		
	I.21. Temperature of product Ambient C Chilled C	I.22. Number of packages		
	I.23. Identification of container/Seal number	I.24. Type of packaging		
	I.25. Commodities certified for			
	Human consumption			
	1.26.	I.27. For import or admission into EU		
	I.28. Identification of the commodities			
		of establishments		
	Species Treatment type Manufact (Scientific name)	turing plant Number of packages Net weight		

ANNEX VI SECTION II

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Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EC) No 2074/2005. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

COUNT	ΓRY				Frogs' legs
	IL.	Health attestation	II.a.	Certificate reference number	II.b.
Part II: Certification		I, the undersigned, declare that I am aware of the (EC) No 853/2004 and certify that the frogs' legs described that they: — come from (an) establishment(s) implementing a No 852/2004 and — originate from frogs that have been bled, prepare hygienic manner in accordance with the requirent	cribed ab	nove were produced in accordange in the HACCP prince where appropriate, chilled frozer	ce with those requirements, in particular iples in accordance with Regulation (EC) or processed, packaged and stored in a
	Notes Part I:	ne (in capitals):	ns or con and reloa ber: only cessed.	ntainer and lorries), flight number ding. where applicable. of the other particulars in the cer	
	Stan	np:			

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Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EC) No 2074/2005. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

PART B

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

CO	JNTRY	Ve	terinary certificate to EU
	I.1. Consignor	I.2. Certificate reference number	I.2.a.
	Name		
		I.3. Central Competent Authority	
	Address		
Ĭ	Postal code	I.4. Local Competent Authority	
Part I: Details of dispatched consignment	Tel No.		
로	I.5. Consignee	1.6.	
Siç	Name		
ä			
ၓ	Address		
eq	Postal code		
- S	Tel No.		
ate	I.7. Country of origin ISO code I.8.	I.9. Country of destination ISO code	1.10.
Sp	in. country of origin	I I I I I I I I I I I I I I I I I I I	1.10.
5			
of o	I.11. Place of origin	1.12.	
S			
a.			
)e	Name Approval number		
	Address		
モ			
a			
_			
	I.13. Place of loading	I.14. Date of departure	
	I.15. Means of transport	I.16. Entry BIP in EU	
	Aeroplane Ship Railway wagon		
	Road vehicle Other		
	Identification:	1.17.	
	Documentary references:		
	I.18. Description of commodity	I.19. Commodity code ((HS code)
		·	I.20. Quantity
	I.21. Temperature of product		I.22. Number of packages
	Ambient Chilled Chilled	Frozen	
	I.23. Identification of container/Seal number		I.24. Type of packaging
	I.25. Commodities certified for		
	Human consumption		
	1.26.	I.27. For import or admission into EU	
	I.28. Identification of the commodities		
	Approval number	of establishments	
	Species Treatment type Manufact	uring plant Number of pa	ackages Net weight
	(Scientific name)		

ANNEX VI SECTION II

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Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EC) No 2074/2005. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

COUNT	K1			Silalis						
	II.	Health attestation	II.a. Certificate reference number	II.b.						
uo		I, the undersigned, declare that I am aware of the rel No 853/2004 and certify that the snails described above								
Part II: Certification		 come from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004 								
Cer		and								
art II:		 have been handled and, where appropriate, sh manner in accordance with the requirements of A 								
-										
	Natas									
	Notes Part I:									
	_	Box reference I.11: Place of origin: name and address of Box reference I.15: Registration number (railway wagor		(aircraft) or name (ship). Separate						
	_	information is to be provided in case of unloading and rebox reference I.19: Use the appropriate HS codes: 03.0	07.60, 16.05.							
	_	Box reference I.23: Identification of container/seal number Box reference I.28: Treatment type: chilled, frozen, shell								
	Part II:	The colour of the stamp and signature must be different	to that of the other particulars in the certi	ficate.						
	Official ins	pector								
	Nam Date	e (in capitals):		alification and title: nature:						
	Stam		Sig							

measures... ANNEX VI SECTION II

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Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EC) No 2074/2005. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

Appendix II to Annex VI

PART A

MODEL HEALTH CERTIFICATE FOR IMPORTS OF GELATINE INTENDED FOR HUMAN CONSUMPTION

CO	UN	TRY				Vet	terinary certificate to EU
	1.1.	Consignor Name			I.2. Certificate refere	nce number	I.2.a.
		Address			I.3. Central Competent Authority		
nent		Postal code Tel No.			I.4. Local Competent Authority		
Part I: Details of dispatched consignment	1.5.	Consignee Name			1.6.		
og po		Address Postal code					
tche		Tel No.					
lispa	1.7.	Country of origin	ISO code	1.8.	I.9. Country of destina	ation ISO code	1.10.
s of c	I.11	. Place of origin			1.12.		
Detail		Name Address		Approval number			
1		Address					
Pa							
	1.13	. Place of loading			1.14. Date of departure		
	1.15	. Means of transport			I.16. Entry BIP in EU		
		Aeroplane Road vehicle		ip ☐ Railway wagon ☐ er ☐			
		Identification:	041		L17.		
		Documentary references:					
	I.18	. Description of commodity				I.19. Commodity code (HS code) 35.03
							I.20. Quantity
	1.21	. Temperature of product Ambient		Chilled		Frozen 🗆	I.22. Number of packages
	1.23	Ambient . Identification of container/S		Chilled		Frozen 🗀	I.24. Type of packaging
	1.25	. Commodities certified for					
		Human consumption					
	1.26	l.			I.27. For import or ad	Imission into EU	
	1.28	. Identification of the commo	dities				
		Species (Scientific name)	Tre		r of establishments turing plant	Number of pa	ockages Net weight

Status: Point in time view as at 01/04/2012.

Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EC) No 2074/2005. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

IRY		Gelatine intend	led for human consumption
II.	Health attestation	II.a. Certificate reference number	II.b.
	No 853/2004 and certify that the gelatine described about the comes from (an) establishment(s) implementing to No 852/2004. has been produced from raw material which met No 853/2004. has been manufactured in compliance with the No 853/2004. satisfies the criteria of Section XIV, Chapter IV of on microbiological criteria for foodstuffs, and (¹) if from ruminant origin, does not contain and is no either (¹) specified risk material as defined in Annex XI, mechanically recovered meat obtained from but 31 March 2001 the bovine, ovine and caprine ani	ove was produced in accordance with those a programme based on the HACCP principation the requirements of Section XIV, Chapter of conditions set out in Section XIV, Chapter of Annex III to Regulation (EC) No 853/200 out derived from: section A, to Regulation (EC) No 999/2 ones of bovine, ovine or caprine animals mals, from which this product is derived, h	e requirements, in particular that it: ples in accordance with Regulation (EC) s I and II of Annex III to Regulation (EC) oter III of Annex III to Regulation (EC) 4 and to Regulation (EC) No 2073/2005 001 produced after 31 March 2001, or produced after 31 March 2001, After ave not been slaughtered after stunning
	nervous tissue by means of an elongated rod-sha	aped instrument introduced into the crania	I cavity.
Part II:	Box reference I.15: Registration number (railway wag information is to be provided in case of unloading and r Box reference I.23: Identification of container/seal number (railway wag information is to be provided in case of unloading and reference I.23: Identification of container/seal number (railway wag information is to be provided in case of unloading and reference I.25: Identification of container/seal number (railway wag information is to be provided in case of unloading and reference I.25: Identification number (railway wag information is to be provided in case of unloading and reference I.25: Identification of containers in the case of unloading and reference I.25: Identification of containers in the case of unloading and reference I.25: Identification of containers in the case of unloading and reference I.25: Identification of containers in the case of unloading and reference I.25: Identification of containers in the case of unloading and reference I.25: Identification of containers in the case of unloading and reference I.25: Identification of containers in the case of unloading and reference I.25: Identification of containers in the case of unloading and reference I.25: Identification of containers in the case of unloading and reference I.25: Identification of containers in the case of unloading and reference I.25: Identification of unloadin	ons or container and lorries), flight num eloading. ber: only where applicable.	ber (aircraft) or name (ship). Separate
(¹) (²) (³)	,		ficate.
Nam Date	e (in capitals):		alification and title: nature:
	Notes Part I:	II. Health attestation I, the undersigned, declare that I am aware of the rel No 853/2004 and certify that the gelatine described about the comes from (an) establishment(s) implementing the No 852/2004, — has been produced from raw material which met No 853/2004, — has been manufactured in compliance with the No 853/2004, — satisfies the criteria of Section XIV, Chapter IV of on microbiological criteria for foodstuffs, and (¹) — if from ruminant origin, does not contain and is not either (¹) specified risk material as defined in Annex XI, mechanically recovered meat obtained from both 31 March 2001 the bovine, ovine and caprine and by means of gas injected into the cranial cavity of nervous tissue by means of an elongated rod-short or bovine, ovine and caprine materials other the in	II. Health attestation II.a. Certificate reference number I, the undersigned, declare that I am aware of the relevant provisions of Regulations (EC) No No 853/2004 and certify that the gelatine described above was produced in accordance with thos — comes from (an) establishment(s) implementing a programme based on the HACCP princi No 853/2004, — has been produced from raw material which met the requirements of Section XIV, Chapten No 853/2004, — has been manufactured in compliance with the conditions set out in Section XIV, Chapten No 853/2004, — satisfies the criteria of Section XIV, Chapter IV of Annex III to Regulation (EC) No 853/200 on microbiological criteria for foodstuffs, and (¹) — if from ruminant origin, does not contain and is not derived from: either (¹) specified risk material as defined in Annex XI, section A, to Regulation (EC) No 999/2 mechanically recovered meat obtained from bones of bovine, ovine or caprine animals 31 March 2001 the bovine, ovine and caprine animals, from which this product is derived, he by means of gas injected into the cranial cavity or killed by the same method or slaughter nervous tissue by means of an elongated rod-shaped instrument introduced into the crania or bovine, ovine and caprine materials other than those derived from animals born, in

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PART B

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

co	UN	TRY					V	eterinary certificate to EU	
	1.1.	Consignor Name				I.2. Certificate refer	I.2. Certificate reference number I.2.a.		
		Address				1.3. Central Competent Authority			
ment		Postal code Tel No.				I.4. Local Competer	nt Authority		
ısign	1.5.	Consignee Name				1.6.			
cor		Address							
tchec	Postal code Tel No.								
dispa	1.7.	Country of origin	ISO code	I.8. Region of origin	Code	I.9. Country of desti	nation ISO code	l.10.	
s of c	l.11	. Place of origin				I.12.	'		
Part I: Details of dispatched consignment		Name Address		Approval number					
Part I:									
	1.13	. Place of loading				I.14. Date of departure			
	1.15	. Means of transport				I.16. Entry BIP in EU			
		Aeroplane Road vehicle		p ☐ Railwayw er ☐	agon 🗆				
		Identification: Documentary references:				1.17.			
	1.18	. Description of commodity					I.19. Commodity cod	e (HS code)	
								I.20. Quantity	
	1.21	. Temperature of product Ambient		Chill	ed \square	I.22. Number of packages			
	1.23	. Identification of container/S	eal number				I.24. Type of packaging		
	1.25	. Commodities certified for	_						
		Human consumption							
	1.26.					I.27. For import or a	dmission into EU		
	1.28	. Identification of the commo	dities						
				,	Approval numbe	er of establishments			
		Species (Scientific name)	Nature	of commodity	Manufa	cturing plant	Number of	packages Net weight	

Status: Point in time view as at 01/04/2012.

Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EC) No 2074/2005. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

COUNTRY Raw materials for the production of gelatine intended for human consumption Health attestation Certificate reference number II.b. I, the undersigned, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/ 2004 and (EC) No 854/2004 and certify that the raw material described above complies with those requirements, in particular that: bones, hides and skins of domestic and farmed ruminant animals, pig skins, poultry skin and tendons and sinews described Part II: Certification above derive from animals which have been slaughtered in a slaughterhouse and whose carcases have been found fit for human consumption following ante- and post-mortem inspection (1) wild game hides and skins described above derive from killed animals whose carcases have been found fit for human consumption following post-mortem inspection (1) fish skin and bones described above come from plants manufacturing fish products for human consumption authorised for export (1) and (1) if from ruminant origin, the raw material does not contain and is not derived from: either (1) specified risk material as defined in Annex XI, section A, to Regulation (EC) No 999/2001 produced after 31 March 2001, or mechanically recovered meat obtained from bones of bovine, ovine or caprine animals produced after 31 March 2001. After 31 March 2001 the bovine, ovine and caprine animals, from which this product is derived, have not been slaughtered after stunning by means of gas injected into the cranial cavity or killed by the same method or slaughtered by laceration after stunning of central nervous tissue by means of an elongated rod-shaped instrument introduced into the cranial cavity bovine, ovine and caprine materials other than those derived from animals born, continuously reared and slaughtered Notes Part I: Box reference I.8: Region of origin: if appropriate. Box reference I.11: Place of origin: name and address of the dispatch establishment. Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship). Separate information is to be provided in case of unloading and reloading. Box reference I.19; Use the appropriate HS codes: 05.05, 05.06, 05.11.91, 05.11.99. Box reference I.23: Identification of container/seal number: only where applicable. Box reference I.28: Nature of commodity: (hides), (skins), (bones), (tendons) and (sinews); Manufacturing plant: includes slaughterhouse, factory vessel, cutting plant, game handling establishment and processing plant. Part II: Delete as appropriate. (2) (3) As listed in point 15(b) of Annex XI to Regulation (EC) No 999/2001 as amended. The colour of the stamp and signature must be different to that of the other particulars in the certificate. Official veterinarian Name (in capitals): Qualification and title: Date: Signature: Stamp:

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Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EC) No 2074/2005. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

Appendix III to Annex VI

PART A

MODEL HEALTH CERTIFICATE FOR IMPORTS OF COLLAGEN INTENDED FOR HUMAN CONSUMPTION

CO	UN	ITRY				Ve	terinary certificate to EU
	1.1.	Consignor Name			I.2. Certificate refere	nce number	I.2.a.
		Address			I.3. Central Competent Authority		
nent		Postal code Tel No.			I.4. Local Competent	Authority	
Part I: Details of dispatched consignment	1.5.	Consignee Name			1.6.		
20	Address						
ched		Postal code Tel No.					
lispat	I.7. Country of origin ISO code I.8.				I.9. Country of destina	ation ISO code	1.10.
of d	I.11	. Place of origin			I.12.		
etails		Name		Approval number			
t:D		Address					
Par	Ē						
	1.13	. Place of loading			1.14. Date of departure		
	1.15	. Means of transport			I.16. Entry BIP in EU		
		Aeroplane Road vehicle		ip ☐ Railway wagon ☐			
		Identification: Documentary references:			1.17.		
	1.18	Description of commodity				I.19. Commodity code ((HS code) 35.04
							I.20. Quantity
	1.21	. Temperature of product Ambient		Chilled	ı	Frozen 🗆	I.22. Number of packages
	1.23	l. Identification of container/S	eal number		I.24. Type of packaging		
	1.25	. Commodities certified for					
		Human consumption					
	1.26	i.			I.27. For import or ad	mission into EU	
	1.28	. Identification of the commo	dities		•		
				Approval number	of establishments		
		Species (Scientific name)	Tre	eatment type Manufact	turing plant	Number of pa	nckages Net weight

ANNEX VI SECTION II

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Status: Point in time view as at 01/04/2012.

Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EC) No 2074/2005. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

COUN	ΓRY	Collagen intended for human consumption	
	II.	Health attestation	II.a. Certificate reference number II.b.
Part II: Certification		No 853/2004 and certify that the collagen described about the comes from (an) establishment(s) implementing a No 852/2004. — has been produced from raw material which may (EC) No 853/2004, — has been manufactured in compliance with the (EC) No 853/2004, and	relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004 and (Edahove was produced in accordance with those requirements, in particular that it: g a programme based on the HACCP principles in accordance with Regulation (Edahove was produced in accordance with those requirements, in particular that it: 1. **The product of the produced in accordance with those requirements, in particular that it: 2. **The produced in accordance with those requirements, in particular that it: 2. **The produced in accordance with those requirements, in particular that it: 2. **The produced in accordance with those requirements, in particular that it: 3. **The produced in accordance with those requirements, in particular that it: 3. **The produced in accordance with those requirements, in particular that it: 3. **The produced in accordance with those requirements, in particular that it: 4. **The produced in accordance with Regulation (Edahove was produced in accordance was produced in accordance with Regulation (Edahove was produced in accordance was produced in accordance was produced in acco
	Notes Part I: Part II: Official ve	Separate information is to be provided in case of unload Box reference I.23: Identification of container/seal numb Box reference I.28: Treatment type: date of manufacture. The colour of the stamp and signature must be different terinarian e (in capitals):	/ wagons or container and lorries), flight number (aircraft) or name (ship ading and reloading. mber: only where applicable. ure (dd/mm/yyyy).

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Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EC) No 2074/2005. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

PART B

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

COUNTRY Veterinary certificate to EU									
	1.1.	Consignor Name				I.2. Certificate refere	ence number	I.2.a.	
_		Address				I.3. Central Competent Authority			
ment		Postal code Tel No.				I.4. Local Competent Authority			
sign	1.5.	.5. Consignee Name				1.6.			
cor		Address							
chec		Postal code Tel No.							
Part I: Details of dispatched consignment	1.7.	Country of origin	ISO code	I.8. Region of origin	Code	I.9. Country of destin	nation ISO code	1.10.	
s of	I.11	. Place of origin				I.12.			
Detail		Name Address							
=======================================									
Pa									
	I.13. Place of loading					I.14. Date of departure			
	I.15. Means of transport					I.16. Entry BIP in EU			
	Aeroplane Ship Railway wagon Road vehicle Other								
		Identification: Documentary references: I.18. Description of commodity				L17.			
	1.18					I.19. Commodity code (HS code)			
								I.20. Quantity	
	1.21	I.21. Temperature of product Ambient Chilled Chilled					Frozen	I.22. Number of packages	
	I.23. Identification of container/Seal number						I.24. Type of packaging		
	1.25. Commodities certified for								
		Human consumption							
	1.26.				1.27. For import or admission into EU				
	1.28	. Identification of the commo							
	Approval number of establishments								
						turing plant	Number of p	ackages Net weight	

Status: Point in time view as at 01/04/2012.

COUNT	KI	Raw materials for the	e production of collagen intend	aed for numan consumption		
	11.	Health attestation	II.a. Certificate reference number	II.b.		
				'		
		I, the undersigned, declare that I am aware of the	relevant provisions of Regulations (EC	C) No 178/2002, (EC) No 852/2004,		
Part II: Certification		(EC) No 853/2004 and 854/2004 and certify that the raw				
ij		hides and aking of demostic and formed rumine	at animals/sig skips, banco and intestings	/noultry skip and honos/tondons and		
g		 hides and skins of domestic and farmed rumina sinews described above derive from animals whi 				
Œ		found fit for human consumption following ante-		ouse and whose careases have been		
Ţ			,,			
ပ္ပ		and/or				
<u></u>						
=		 wild game hides and skins described above 	derive from killed animals whose carcas	ses have been found fit for human		
a		consumption following post-mortem inspection (),			
ď						
		and/or				
		 fish skin and bones described above derive to 	from plants manufacturing fish products	for human consumption authorised		
		for export (1).				
	1					
	Notes					
	Part I:					
	Part I:					
	-	Box reference I.8: Region of origin: if appropriate.				
	-	Box reference I.11: Place of origin: name and address of	of the dispatch establishment.			
	_		ns or container and lorries), flight number (aircraft) or name (ship). Separate			
		information is to be provided in case				
	-	Box reference I.19: Use the appropriate HS codes: 05.0	04, 05.05, 05.06, 05.11.91, 05.11.99.			
	_	Box reference I.23: Identification of container/seal num	ber: only where applicable.			
	_	Box reference I.28: Nature of commodity: (hides) (skins	s), (bones), (intestines), (tendons) and sine	ews);		
			hterhouse, factory vessel, cutting plant, ga			
		processing plant.				
	_					
	Part II:					
	(1)	Delete as appropriate.				
	_	The colour of the stamp and signature must be differen	t to that of the other particulars in the certi	ficate.		
	Official ve	terinarian				
			_	- 155 15		
	ı	ne (in capitals):		alification and title:		
	Date Stan		Sig	nature:		
	Stan	np.				

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Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EC) No 2074/2005. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

[F8 Appendix IV to Annex VI MODEL HEALTH CERTIFICATE FOR IMPORTS OF FISHERY PRODUCTS INTENDED FOR HUMAN CONSUMPTION]

CO	OUNTRY Veterinary certificate to EU					
	l.1.	Consignor Name		I.2. Certificate	reference number	I.2.a.
		Address		I.3. Central Co	ompetent Authority	
		Postal code		L4 Local Con	npetent Authority	
		Tel. No		1.4. Local Coll	inpeterit Additionty	
nment	1.5.	Consignee		1.6.		
lsig		Name				
2		Address				
ped		Postal code				
atcl		Tel. No				
Part I: Details of dispatched consignment	1.7.	Country of origin ISO code I.8	B. Region of origin Code	I.9. Country o	f destination ISO co	ode I.10.
ails						
Det	1.11	. Place of origin		1.12.		
≓			oval number			
Par		Address				
	140	Disco of leading		Idd Data of	damankura	
	1.13	3. Place of loading		I.14. Date of	departure	
	1.15	6. Means of transport		I.16. Entry BIP in EU		
		Aeroplane Ship Road vehicle Othe	Railway wagon ☐ r ☐			
		ntification:		l.17.		
	Do	cumentary references:				
	1.18	3. Description of commodity			I.19. Commodity code	(HS code)
					1.3	20. Quantity
	1.21	. Temperature of product			1.3	22. Number of packages
		Ambient	Chilled	Froz	en 🗆	
	1.23	3. Identification of container/seal number			1.3	24. Type of packaging
	1.25	. Commodities certified for				
		Human consumption				
	I.26. I.27. For import or admission into EU					
	1.28	3. Identification of the commodities				
		Species		Approval numbe	er of establishments	
		(Scientific name) Nature of comm				of packages Net weight
		, , , , , , , , , , , , , , , , , , , ,	,			

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Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EC) No 2074/2005. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

COUNTRY Fishery products

Health attestation II.a. Certificate reference number II.b. 11.1 (1) Public health attestation I, the undersigned, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) No 852/2004, (EC) No 853/2004 and (EC) No 854/2004 and certify that the fishery products described above were produced in accordance with those requirements, in particular that they: come from (an) establishment(s) implementing a programme based on the HACCP principles in accordance with Regulation (EC) No 852/2004: Certification 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; Part - 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. 11.2 (2)(4)Animal health attestation for fish and crustaceans of aquaculture origin (3)(4)[Requirements for susceptible species to Epizootic ulcerative syndrome (EUS), Epizootic haematopoietic necrosis (EHN), Taura syndrome and Yellowhead disease 11.2.1 I, the undersigned official inspector, hereby certify that the aquaculture animals or products thereof referred to in Part I of this certificate: (5)originate from a country/territory, zone or compartment declared free from (4)[EUS] (4)[EHN (4)[Taura syndrome] (4)[Yellowhead disease] 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 official services, (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] (3)(4)[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 1122 compartment declared disease free or subject to a surveillance or eradication programme for the relevant disease I, the undersigned official inspector, hereby certify that the aquaculture animals or products thereof referred to in Part I of this certificate: (6)originate from a country/territory, zone or compartment declared free from (4)[VHS] (4)[IHN] (4)[ISA] (4)[KHV] (4)[White spot disease] 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] Transport and labelling requirements 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 II.2.3.3 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:

"(4)[Fish](4)[Crustaceans] intended for human consumption in the Community".

Name (in capital letters):

Date:

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Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EC) No 2074/2005. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

COUNT	RY		Fishery produc
II.	Health attestation	II.a. Certificate reference number	II.b.
Notes			
Part I:			
— Вох	reference I.8: Region of origin: For frozen or processed bivalve mollu	uscs, indicate the production area.	
— Вох	reference I.11: Place of origin: name and address of the dispatch es	tablishment.	
	reference I.15: Registration number (railway wagons or container and levided in the event of unloading and reloading.	orries), flight number (aircraft) or name	e (ship). Separate information is to b
— Вох	reference I.19: use the appropriate HS codes: 03.01, 03.02, 03.03, 03.03	3.04, 03.05, 03.06, 03.07, 05.11.91, 1	5.04, 15.18.00, 16.03, 16.04, 16.05
— Вох	reference I.23: Identification of container/Seal number: Where there is	s a serial number of the seal it has t	o be indicated.
— Вох	reference I.28: Nature of commodity: Specify whether aquaculture or	wild origin.	
Tre	atment type: Specify whether live, chilled, frozen or processed.		
Mai	nufacturing plant: includes factory vessel, freezer vessel, cold store, pr	rocessing plant.	
Part II	:		
	t II.1 of this certificate does not apply to countries with special public or Community legislation.	health certification requirements laid	down in equivalence agreements of
(2) Par	t II.2 of this certificate does not apply to:		
	non-viable crustaceans, which means crustaceans no longer able to su obtained,	rvive as living animals if returned to the	ne environment from which they wer
	fish which are slaughtered and eviscerated before dispatch,	death for house and a second line of the set of	with an arrange of the state of
	aquaculture animals and products thereof, which are placed on the ma are packed in retail-sale packages which comply with the provisions f	for such packages in Regulation (EC)	No 853/2004,
.,	crustaceans destined for processing establishments authorised in according purification centres or similar businesses which are equipped with an of the effluent is subject to other types of treatment reducing the risk	effluent treatment system inactivating of transmitting diseases to the nat	the pathogens in question, or wher tural waters to an acceptable leve
(e)	crustaceans which are intended for further processing before human packed and labelled for that purpose in accordance with Regulation (age at the place of processing an
	ts II.2.1 and II.2.2 of this certificate only apply to species susceptible to d in Annex IV to Directive 2006/88/EC.	one or more of the diseases referred t	to in the title. Susceptible species ar
	ep as appropriate.		
	consignments of species susceptible to EUS, EHN, Taura syndrome ar be authorised into any part of the Community.	nd/or Yellowhead disease this stateme	ent must be kept for the consignmer
Wh thes app	be authorised into a Member State, zone or compartment (boxes I.9 and tespot disease or with a surveillance or eradication programme establises attainents must be kept if the consignment contain species sus ly(ies). Data on the disease status of each farm and mollusc farming of currence with the disease status of each farm and mollusc farming of currence with the disease status of each farm and mollusc farming of the currence with the disease status of each farm and mollusc farming of the currence with the curr	thed in accordance with Article 44(1) of acceptible to the disease(s) for which	or (2) of Directive 2006/88/EC, one of disease freedom or programme(s
— The	colour of the stamp and signature must be different to that of the other	ner particulars in the certificate.	
Official	inspector		

Qualification and title:

Signature:'

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[F8Appendix V to Annex VI

PART A

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

CO	UNTRY Veterinary certificate to EU					
	J.1.	Consignor Name		I.2. Certificate	reference number	I.2.a.
		Address		I.3. Central Co	ompetent Authority	
		Postal code		I.4 Local Con	npetent Authority	
l		Tel. No		1.4. 2000. 001	npotonit / tathonty	
dispatched consignment	1.5.	Consignee Name		1.6.		
lsig		TVAITIO				
8		Address				
ped	Postal code Tel. No					
atc						
of dis	1.7.	Country of origin ISO code	I.8. Region of origin Code	I.9. Country o	f destination ISO o	code I.10.
Part I: Details of	144	Place of exists		140		
Def	1.11	. Place of origin		1.12.		
==			proval number			
Pa		Address				
	1.13	. Place of loading		I.14. Date of	departure	
	1.15. Place of loading					
	1.15	. Means of transport		I.16. Entry BIP in EU		
		Aeroplane Ship	Railway wagon			
			ther	147		
		ntification:		1.17.		
		cumentary references:		***************************************		
	1.18	. Description of commodity			I.19. Commodity code	03 07
						I.20. Quantity
	1.21					.22. Number of packages
	1.23	. Identification of container/Seal number	er			.24. Type of packaging
	1.25	. Commodities certified for				
		Human consumption				
	1.26			I.27. For impo	rt or admission into EU	
	1.28	. Identification of the commodities				
			annered accombance of a stabilishman			
		.,	proval number of establishmer	IIO	Number of parties	Not welst
		(Scientific name)	Manufacturing plant		Number of packag	ges Net weight

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Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EC) No 2074/2005. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

COUNTRY

Live bivalve molluscs, echinoderms, tunicates and marine gastropods

-	UNIKI		marine gastropod	ls			
	II.	Health attestation	II.a. Certificate reference number	II.b.			
	II.1	(¹)Public health attestation for live bivalve molluscs, echinoc	derms, tunicates and marine gastro	opods			
		I, the undersigned, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC) No No 853/2004 and (EC) No 854/2004 and certify that the (4)[live bivalve molluscs] (4)[live echinoderms] (4)[live tunicate gastropods] described above were produced in accordance with those requirements, in particular that they:					
_		 come from (an) establishment(s) implementing a programme No 852/2004; 	based on the HACCP principles in	n accordance with Regulation (EC)			
tification		 have been harvested, where necessary relayed and transport Regulation (EC) No 853/2004; 	orted in accordance with Section VII	, Chapters I and II of Annex III to			
- have been harvested, where necessary relayed and transported in accordance with Section VII, Chapters I and II of Regulation (EC) No 853/2004; - were handled, where necessary purified, and packaged in compliance with Section VII, Chapters III and IV of Annex III to Room No 853/2004; - satisfy the health standards laid down in Section VII, Chapter V of Annex III to Regulation (EC) No 853/2004 and the criter							
— satisfy the health standards laid down in Section VII, Chapter V of Annex III to Regulation (EC) No 853/2004 and th Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs;				53/2004 and the criteria laid down in			
		 have been packaged, stored and transported in compliance No 853/2004; 	with Section VII, Chapters VI and V	VIII of Annex III to Regulation (EC)			
		 have been marked and labelled in accordance with Section I No 853/2004; 	of Annex II and Section VII, Chapter	VII of Annex III to Regulation (EC)			
		 in the case of pectinidae harvested outside classified producti Chapter IX of Annex III to Regulation (EC) No 853/2004, and 		quirements laid down in Section VII,			
L		/2004.					
	II.2	$(^2)(^4)Animal health attestation for live bivalve molluscs of aquivalent of the contraction of the $	uaculture origin				
	II.2.1	$(^3)(^4)[\mbox{Requirements for species susceptible to Bonamia exition}]$	osa, Perkinsus marinus and Micro	cytos mackini			
		I, the undersigned official inspector, hereby certify that the live bit	valve molluscs referred to in Part I o	f this certificate:			
		(5)originate from a country/territory, zone or compartment declar mackini] in accordance with Chapter VII of Directive 2006/88/EC					
		 where the relevant diseases are notifiable to the competent autimmediately investigated by the official services, and 	hority and reports of suspicion of infec	ction of the relevant disease must be			
		- all introduction of species susceptible to the relevant diseases	s come from an area declared free o	f the disease.]			
	II.2.2	$(^3)(^4)$ [Requirements for species susceptible to Marteilia refri compartment declared disease free or subject to a surveilla					
		I, the undersigned official inspector, hereby certify that the live bi	valve molluscs referred to above:				
		(6)originate from a country/territory, zone or compartment declared Chapter VII of Directive 2006/88/EC or the relevant OIE Standard					
		(i) where the relevant diseases are notifiable to the competent disease must be immediately investigated by the official servi		uspicion of infection of the relevant			
		(ii) all introduction of species susceptible to the relevant diseases	s come from an area declared free of	f the disease.]			
	II.2.3	Transport and labelling requirements					
		I, the undersigned official inspector, hereby certify that:					
	II.2.3.1	the live bivalve molluscs referred to above are placed under cond	ditions, 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	i			
	II.2.3.3	the consignment is identified by a legible label on the exterior of the with the relevant information referred to in boxes I.7 to I.11 of Pa					
	I						

"Live bivalve molluscs intended for human consumption in the Community".

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COUNTRY

Live bivalve molluscs, echinoderms, tunicates and marine gastropods

			-
II.	Health attestation	II.a. Certificate reference number	II.b.
Notes	.		
Part I	:		
— Во	x reference I.8: Region of origin: indicate the production area.		
— Во	x reference I.11: Place of origin: name and address of the dispatch es	tablishment.	
	ox reference I.15: Registration number (railway wagons or container and loovided in the event of unloading and reloading.	orries), flight number (aircraft) or name	e (ship). Separate information is to be
— Во	x reference I.23: Identification of container/Seal number: Where there is	s a serial number of the seal it has t	o be indicated.
— Во	x reference I.28: Manufacturing plant: includes dispatch centre, purifica	tion centre.	
Part I	l:		
	rt II.1 does not apply to countries with special public health certification islation.	requirements laid down in Equivaler	nce Agreements or other Community
(2) Do	rt II.2 does not apply to:		
. ,	in in.2 does not apply to. in non-viable molluscs, which means molluscs no longer able to survivi obtained,	e as living animals if returned to the	environment from which they were
(b)	live bivalve molluscs placed on the market for human consumption packages which comply with the provisions for such packages in Reg		that they are packed in retail-sale
(c)	live bivalve molluscs destined for processing establishments authorise centres, purification centres or similar businesses which are equipped where the effluent is subject to other types of treatment reducing the	with an effluent treatment system inac	tivating the pathogens in question, or
(d)	live bivalve molluscs which are intended for further processing before and packed an labelled for that purpose in accordance with Regulation		y storage at the place of processing
	rts II.2.1 and II.2.2 only apply to species susceptible to one or more of the to Directive 2006/88/EC.	ne diseases referred to in the title. Su	sceptible species are listed in Annex
(4) Ke	ep as appropriate.		
	r consignments of species susceptible to Bonamia exitiosa, Perkinsunsignment to be authorised into any part of the Community.	s marinus and Microcytos mackini t	his statement must be kept for the
Bo the ap	be authorised into a Member State, zone or compartment (boxes I.9 an inamia ostreae or with a surveillance or eradication programme establish ses statements must be kept if the consignment contain species sus ply(ies). Data on the disease status of each farms and mollusc farming p://ec.europa.eu/food/animal/liveanimals/aquaculture/index_en.htm	ed in accordance with Article 44 (1) of ceptible to the disease(s) for which	or (2) of Directive 2006/88/EC, one of disease freedom or programme(s)
— Th	e colour of the stamp and signature must be different to that of the other	ner particulars in the certificate.	
Officia	al inspector		
1	Name (in capital letters):	Qualification and title:	
ı	Date:	Signature:'	
	Stamp:		

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Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EC) No 2074/2005. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

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⁽⁹⁾, and where the PSP level in the edible parts of these molluses 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): Date: Stamp:	Qualification and title: Signature:

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Changes to legislation: There are outstanding changes not yet made to Commission Regulation (EC) No 2074/2005. Any changes that have already been made to the legislation appear in the content and are referenced with annotations. (See end of Document for details)

Appendix VI to Annex VI MODEL HEALTH CERTIFICATE FOR IMPORTS OF HONEY AND OTHER APICULTURE PRODUCTS INTENDED FOR HUMAN CONSUMPTION

СО	UNTRY	Veterinary certificate to EU			
	I.1. Consignor	I.2. Certificate reference number I.2.a.			
	Name	I.3. Central Competent Authority			
Ţ	Address				
Part I: Details of dispatched consignment	Postal code Tel No.	I.4. Local Competent Authority			
ign	I.5. Consignee	1.6.			
ous	Name				
Ö	Address				
he	Postal code Tel No.				
atc	I.7. Country of origin ISO code I.8.	I.9. Country of destination ISO code I.10.			
disp					
ð	I.11. Place of origin	1.12.			
ails					
Det	Name Address				
Ξ	Addieso				
art					
_					
	I.13. Place of loading	I.14. Date of departure			
	I.15. Means of transport Aeroplane □ Ship □ Railway wagon □	I.16. Entry BIP in EU			
	Road vehicle Other				
	Identification:	1.17.			
	Documentary references:	Litto Committee of (MO ords)			
	I.18. Description of commodity	I.19. Commodity code (HS code)			
		I.20. Quantity			
	I.21. Temperature of product	I.22. Number of packages			
	Ambient Chilled Chilled	Frozen			
	I.23. Identification of container/Seal number	I.24. Type of packaging			
	I.25. Commodities certified for				
	Human consumption				
	1.26.	I.27. For import or admission into EU			
	I.28. Identification of the commodities				
	Approval number	of establishments			
		uring plant Number of packages Net weight			
	(Scientific name)	•			

Status: Point in time view as at 01/04/2012.

COUNTRY Honey and apiculture p			apiculture products				
	II.	Health at	testation	II.a.	Certificate reference number	II.b.	
Part II: Certification		I, the undersigned, declare that I am aware of the relevant provisions of Regulations (EC) No 178/2002, (EC No 853/2004 and certify that honey and apiculture products described above were produced in accordance with particular that they: — come from (an) establishment(s) implementing a programme based on the HACCP principles in acc (EC) No 852/2004, — have been handled and, where appropriate, prepared, packaged and stored in a hygienic manner requirements of Annex II to Regulation (EC) No 852/2004 and					with those requirements, in accordance with Regulation
_		_	the guarantees covering live animals and Directive 96/23/EC, and in particular Article			idue plans sul	omitted in accordance with
	N-4						
	Notes Part I:						
	_	Box refere	ence I.11: Place of origin: name and address o	of the d	snatch establishment		
	_	Box refere	ence I.15: Registration number (railway wagor information is to be provided in case of unload	ns or co	ntainer and lorries), flight numb	er (aircraft) or r	name (ship).
	_	Box refere	ence I.19: Use the appropriate HS codes: 04.0 ence I.23: Identification of container/seal number	09, 04.1	0.		
		BOX Telefe	ence 1.25. Identification of container/sear humin	Jei. Oili	у where аррисавіе.		
	Part II:						
	_	The colou	r of the stamp and signature must be different	t to that	of the other particulars in the c	ertificate.	
	06						
	Official ins						
	Date		ls):			Qualification an Signature:	.d title:
	Stan	np:					

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[F9Appendix 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]]

TT 4 1	U	THE EUROPEAN UNION FROM A F	KEEZEK VESSELJJ			
	l.1.	Consignor	I.2. Certificate reference No I.2.a.			
		Name	1.3.			
		Address	1.4.			
ŧ		Postal code	1.4.			
nme		Tel.				
nsig	1.5.	Consignee	1.6.			
8		Name				
atche		Address				
disp		Postal code				
s of		Tel.				
Part I : Details of dispatched consignment	1.7.	Country of ISO code I.8. origin	I.9. Country of destination ISO code I.10.			
Part	1.11.	Place of origin	1.12.			
-		Name Assessed assesses				
		Name Approval number				
	I.13.		1.14.			
	l.15.		I.16. Entry BIP in EU			
	_		1.17.			
	I.18.		I.19. Commodity code (HS code)			
			I.20. Quantity			
	I.21.		I.22. Number of packages			
	1.23.		I.24. Type of packaging			
	1.25.	Commodities certified for:	<u>'</u>			
		Human consumption				
	1.26.		I.27. For import or admission into EU			
	1.28.	Identification of the commodities				
		Species Number of (Scientific name)	f packages Net weight			

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	COUNTRY					Fishery products			
	I.(bis)	Ot	her information						
		Fishing area(s):							
		IMO/Lloyd's number (if issued) or call sign of the vessel:							
		Fis	shing Period: Sta	tart date://	Stop date://				
	II.	Не	alth attestation		II.a. Certificate reference number	II.b.			
_	II.1.	Pu	blic health attestation						
		I, t	he undersigned, declare	that					
		_	the vessel appears on the	he list of vessels from which impo	orts to the European Union are permi	tted (being "EU-listed");			
Callo		_	the vessel has a program	mme based on the HACCP princi	iples in order to control hazards;				
alt III. Vertilikation		-		nere fishery products are handled, good repair and condition;	equipment, containers and the cold s	torage for fishery products are kept			
Lair		_			on and from the effects of the sun or a ey have been handled in a way that pr				
		_	the fishery products have	re not been contaminated by fuel,	bilge water or pests;				
		-	the products have been	washed immediately and thoroug	ave been carried out hygienically as s hly. Viscera and parts that may const products intended for human consum	titute a danger to public health has			
		_	only clean seawater has	been used as alternative to pota	able water for the handling and washi	ng of the fishery product;			
		_			ination for the purpose of detecting vis				
		_	freezing has been carrie	ed out hygienically as soon as pos	ssible after capture;				
		-			of not more than - 18 °C in all parts canned food may be kept at a tem				
		_	frozen blocks have been	n hygienically and adequately wra	pped before landing;				
		_	the packages have been	n marked with an identification mar	k indicating the approval number of the	ne freezer vessel and the flag state;			
		-	the wrapping material is of contamination.	not a source of contamination and	has been stored in such a manner th	at it has not been exposed to a risk			
	Notes part	rt I:							
		-		e and address (street, town and where of/ the responsible for the ve	region/province/state, as applicable), essel.	telephone and fax numbers or the			
		_	Box reference I.2: A uni	ique document number according	to your own classification.				
		_	Box reference I.5:						
			The name and address	(street, town and post code) of					
			— the physical or legal	person to whom the consignment	t is imported directly to the Member	State of destination.			

ANNEX VIa CHAPTER I

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COUNTRY		Fishery products
	— Box reference I.7: The country of which the vessel issuing this document is flying the flag.	
	 Box reference I.11: The name of the freezer vessel and approval number as listed in accordance with Article 1 No 854/2004 from which the fishery products are imported directly. 	2 of Regulation (EC)
	 Box reference I.19: Use the appropriate harmonised system (HS) code of the World Customs Organisatio 03.03. 	n under the chapter
	— Box reference I.20: Total net weight in kilo as sum from I.28.	
	— Box reference I.22: Sum from I.28.	
	— Box reference I.25: Tick the box "Human consumption".	
	— Box reference I.27: Tick the box if final destination is EU.	
	— Box reference I.28: List the various species with scientific name, number of packages and net weight.	
Captain of	the freezer vessel	
	Name (in capital letters):	
	Date: Signature:	
	Stamp:	

[F2ANNEX 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.

ANNEX VIb
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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.]

[F3ANNEX 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.

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- (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;
- (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;

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- (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 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.

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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 183/2005 of the European Parliament and of the Council⁽¹⁰⁾; 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 852/2004;
- (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.]

ANNEX VII

AMENDMENTS TO REGULATION (EC) No 853/2004

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

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- 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. Carcases and other parts of the body intended for human consumption must be completely skinned, except in the case of porcine animals, the heads of ovine and caprine animals and calves 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:

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

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- (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⁽¹¹⁾.;
 - (ii) in Chapter II(II), point 1 is replaced by the following:

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- 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 timetemperature 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

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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:

CHAPTE Wrapping and packaging containing gelatine must bear the words V: "gelatine fit for human consumption" and must indicate the date LABELLEN Oreparation.

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:
 - 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

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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, 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.

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- (1) OJ L 139, 30.4.2004, p. 1. Corrected by OJ L 226, 25.6.2004, p. 3.
- (2) OJ L 139, 30.4.2004, p. 55. Corrected by OJ L 226, 25.6.2004, p. 22.
- (3) OJ L 139, 30.4.2004, p. 206. Corrected by OJ L 226, 25.6.2004, p. 83.
- (4) OJ L 165, 30.4.2004, p. 1. Corrected by OJ L 191, 28.5.2004, p. 1.
- (5) Not yet published in the Official Journal.
- (6) OJ L 157, 30.4.2004, p. 33. Corrected by OJ L 195, 2.6.2004, p. 12.
- (7) See page 1 of this Official Journal.
- (8) OJ L 358, 18.12.1986, p. 1.
- (9) [F5See page 53 of this Official Journal.]
- (10) $[^{\text{F3}}\text{OJ L 35}, 8.2.2005, p. 1.]$
- (11) OJ L 123, 24.4.1998, p. 1.';

Textual Amendments

- **F3** Inserted by Commission Regulation (EC) No 1244/2007 of 24 October 2007 amending Regulation (EC) No 2074/2005 as regards implementing measures for certain products of animal origin intended for human consumption and laying down specific rules on official controls for the inspection of meat (Text with EEA relevance).
- **F5** Substituted by Commission Regulation (EC) No 1664/2006 of 6 November 2006 amending Regulation (EC) No 2074/2005 as regards implementing measures for certain products of animal origin intended for human consumption and repealing certain implementing measures (Text with EEA relevance).

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