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.

(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

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.

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

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.

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.

Article 6

Model health certificates for frogs' legs, snails, gelatine and collagen for the purpose of Regulation (EC) No 853/2004

The model health certificates for imports of frogs' legs, snails, gelatine and collagen as referred to in Article 6(1)(d) of Regulation (EC) No 853/2004 and of raw materials for the production of gelatine and collagen are as set out in Annex VI to this Regulation.

Article 7

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

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

a recognised historically as traditional products, or

b manufactured according to codified or registered technical references to the traditional process, or according to traditional production methods, or

c protected as traditional food products by a Community, national, regional or local law.

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

a Chapter II(1) of Annex II to Regulation (EC) No 852/2004 as regards the premises where such products are exposed to an environment necessary for the part-development of their characteristics. Such premises may in particular comprise walls, ceilings and doors that are not smooth, impervious, non-absorbent or of corrosion-resistant material and natural geological walls, ceilings and floors;

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

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

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

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.

Done at Brussels, 5 December 2005.

For the Commission

Markos KYPRIANOU

Member of the Commission

ANNEX I

FOOD CHAIN INFORMATION

SECTION I

OBLIGATIONS ON FOOD BUSINESS OPERATORS

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

SECTION II

OBLIGATIONS ON COMPETENT AUTHORITIES

CHAPTER I

PROVISION OF FOOD CHAIN INFORMATION

1. The competent authority at the place of dispatch shall inform the dispatching food business operator of the minimum elements of food chain information to be supplied to the slaughterhouse in accordance with Section III of Annex II to Regulation (EC) No 853/2004.

2. The competent authority at the place of slaughter shall verify that:

(a) the food chain information is consistently and effectively communicated between the food business operator who raised or kept the animals before dispatch and the slaughterhouse operator;

(b) the food chain information is valid and reliable;

(c) feedback of relevant information to the holding, if applicable, is provided.

3. Where animals are dispatched for slaughter to another Member State, the competent authorities at the place of dispatch and the place of slaughter shall cooperate to ensure that the information provided by the dispatching food business operator is easily accessible to the slaughterhouse operator receiving it.

CHAPTER II

FEEDBACK TO HOLDING OF PROVENANCE

1. The official veterinarian may use the model document laid down in Appendix I for the relevant inspection results that must be communicated to the holding where the animals were raised before slaughter in the same Member State in accordance with Chapter I of Section II of Annex I to Regulation (EC) No 854/2004.

2. The competent authority is responsible for communicating the relevant inspection results in cases where the animals are raised on a holding in another Member State

and must use a version of the model document laid down in the Appendix in both the language of the dispatching country and the language of the recipient country.

Appendix to Annex I

MODEL DOCUMENT

1.	**Identification 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*** **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).

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

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).

5.	**Contact details**		
	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 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.

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

1. Unprocessed fishery products belonging to the species categories listed in Chapter II 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.

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

2. Distillation as referred to in point 1 must be performed using apparatus which complies with the diagram in Chapter IV.

3. The routine methods which may be used to check the TVB-N limit are as follows:

— microdiffusion method described by Conway and Byrne (1933),

— direct distillation method described by Antonacopoulos (1968),

— distillation of an extract deproteinised by 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.).

3. *Salmo salar,* species belonging to the *Merlucciidae* family, species belonging to the *Gadidae* family.

CHAPTER III

DETERMINATION OF THE CONCENTRATION OF TVB-N IN FISH AND FISHERY PRODUCTS

Reference procedure

1. Purpose and area of application

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

2. Definition

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

The concentration shall be expressed in mg/100 g.

3. Brief description

The volatile nitrogenous bases are extracted from a sample using a solution of 0,6 mol perchloric acid. After 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 g +0,1 g of the ground sample is weighed out into a suitable container. This is mixed with 90,0 ml perchloric acid solution as specified in point 4(a), homogenised for two minutes with a blender as described in point 5(b), and then filtered.

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

(b) *Steam distillation*

50,0 ml of the extract obtained in accordance with point (a) is put into an apparatus for steam distillation as described in point 5(e). For a later check on the extract's 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:

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

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

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

M = Weight of sample in g.

Remarks

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

2. Check the equipment by distilling solutions of NH_4Cl equivalent to 50 mg TVB-N/100 g.

3. Standard deviation of reproducibility S_r = 1,2 mg/100 g. Standard deviation of comparability S_R = 2,50mg/100 g.

CHAPTER IV

TVB-N STEAM DISTILLATION APPARATUS

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

Part II: Certification

II. Health information	II.a. Certificate reference number	II.b. Local reference number

1. 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 854/2004 and certify that the raw material described above complies with those requirements, in particular that:

— bones, hides and skins of farmed ruminant animals, pigskins, poultry skin and tendons and sinews described above derive from animals which have been slaughtered in a slaughterhouse and whose carcases have been found fit for human consumption following ante- and post-mortem inspection (2),

and/or

— wild game hides and skins described above derive from slaughtered animals whose carcases have been found fit for human consumption following post-mortem inspection (2),

and/or

— fish skin and bones described above come from plants manufacturing fish products for human consumption authorised for export (2),

and

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

either (2)

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

or

bovine, ovine and caprine materials other than those derived from animals born, continuously reared and slaughtered in ……(3)(4).

Notes

(1) Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship). This information is to be updated in case of unloading and reloading.
(2) Delete as appropriate.
(3) Insert the name of the country.
(4) As listed in point 15(b) of Annex XI to Regulation (EC) No 999/2001 as amended.
(5) The colour of the stamp and signature must be different from that of the other particulars in the certificate.

Official veterinarian or official inspector

Name (in capitals): Qualification and title
Local veterinary unit: No of relevant LVU:
Date: Signature (5):
Stamp (5)

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.

CHAPTER I

PARALYTIC SHELLFISH POISON (PSP) DETECTION METHOD

1. The paralytic shellfish poison (PSP) content of edible parts of molluscs (the whole body or any part edible separately) must be detected in accordance with the biological testing method or any other internationally recognised method. The biological testing method may be carried out in association, if necessary, with another method for detecting Saxitoxin and any of its analogues for which standards are available.

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

CHAPTER II

AMNESIC SHELLFISH POISON (ASP) DETECTION METHOD

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

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

CHAPTER III

LIPOPHILIC TOXIN DETECTION METHODS

A. Biological methods

1. A series of mouse bioassay procedures, differing in the test portion (hepatopancreas or whole body) and in the solvents used for extraction and purification, may be used for detecting marine toxins as referred to in Chapter V(2)(c), (d) and (e) of Section VII of Annex III, to Regulation (EC) No 853/2004. Sensitivity and selectivity depend on the choice of solvents used for extraction and purification and this should be taken into account when a decision is made on the method to be used in order to cover the full range of toxins.

2. A single mouse bioassay involving acetone extraction may be used to detect okadaic acid, dinophysistoxins, pectenotoxins and yessotoxins. This assay may be supplemented, if necessary, with liquid/liquid partition steps with ethyl acetate/water or dichloromethane/water to remove potential interferences. Azaspiracid detection at

regulatory levels by means of this procedure shall involve the use of the whole body as the test portion.

3. Three mice shall be used for each test. Where two out of three mice die within 24 hours of inoculation with an extract equivalent to 5 g hepatopancreas or 25 g whole body, this shall be considered a positive result for the presence of one or more toxins as referred to in Chapter V(2)(c), (d) and (e) of Section VII of Annex III to Regulation (EC) No 853/2004 at levels above those laid down.

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

5. A rat bioassay may be used to detect okadaic acid, dinophysistoxins and azaspiracids. Three rats shall be used for each test. A diarrhetic response in any of the three rats shall be considered a positive result for the presence of okadaic acid, dinophysistoxins and azaspiracids at levels above those laid down in Chapter V(2)(c) and (e) of Section VII of Annex III to Regulation (EC) No 853/2004.

B. Alternative detection methods

1. A series of methods, such as high-performance liquid chromatography (HPLC) with fluorimetric detection, liquid chromatography (LC), mass spectrometry (MS), immunoassays and functional assays, such as the phosphatase inhibition assay, shall be used as alternatives or supplementary to the biological testing methods, provided that either alone or combined they can detect at least the following analogues, that they are not less effective than the biological methods and that their implementation provides an equivalent level of public health protection:

— okadaic acid and dinophysistoxins: a hydrolysis step may be required to detect the presence of DTX3,

— pectenotoxins: PTX1 and PTX2,

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

— azaspiracids: AZA1, AZA2 and AZA3.

2. If new analogues of public health significance are discovered, they should be included in the analysis. Standards must be available before chemical analysis is possible. Total toxicity shall be calculated using conversion factors based on the toxicity data available for each toxin.

3. The performance characteristics of these methods shall be defined after validation following an internationally agreed protocol.

4. Biological methods shall be replaced by alternative detection methods as soon as reference materials for detecting the toxins prescribed in Chapter V of Section VI of Annex III to Regulation (EC) No 853/2004 are readily available, the methods have been validated and this Chapter has been amended accordingly.

ANNEX IV

CALCIUM CONTENT OF MECHANICALLY SEPARATED MEAT

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

1. not exceed 0,1 % (=100 mg/100 g or 1 000 ppm) of fresh product;

2. be determined by a standardised international method.

ANNEX V

LISTS OF APPROVED FOOD ESTABLISHMENTS

CHAPTER I

ACCESS TO LISTS OF APPROVED FOOD ESTABLISHMENTS

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

CHAPTER II

FORMAT FOR NATIONAL WEBSITES

A. Masterlist

1. Each Member State shall provide the Commission with a linking address to a single national website containing the masterlist of lists of approved food establishments for products of animal origin as defined in point 8(1) of Annex I to Regulation (EC) No 853/2004.

2. The masterlist referred to in point 1 shall consist of one sheet and shall be completed in one or more official languages of the Community.

B. Operational chart

1. The website containing the masterlist shall be developed by the competent authority or, where appropriate, one of the competent authorities referred to in Article 4 of Regulation (EC) No 882/2004.

2. The masterlist shall include links to:

(a) other web pages located on the same website;

(b) where certain lists of approved food establishments are not maintained by the competent authority referred to in point 1, websites managed by other competent authorities, units or where appropriate, bodies.

CHAPTER III

LAYOUT AND CODES FOR LISTS OF APPROVED ESTABLISHMENTS

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

CHAPTER IV

TECHNICAL SPECIFICATIONS

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

ANNEX VI

MODEL HEALTH CERTIFICATES FOR IMPORTS FOR FROGS' LEGS, SNAILS, GELATINE AND COLLAGEN

SECTION I

FROGS' LEGS AND SNAILS

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

SECTION II

GELATINE

Without prejudice to other specific Community legislation, at least including but not limited to legislation on transmissible spongiform encephalopathies and hormones, health certificates as referred to in Article 6(1)(d) of Regulation (EC) No 853/2004 for imports of gelatine and raw materials for the production of gelatine shall comply with the models laid down respectively in Part A and Part B of Appendix II to this Annex.

SECTION III

COLLAGEN

Without prejudice to other specific Community legislation, at least including but not limited to legislation on transmissible spongiform encephalopathies and hormones, health certificates as referred to in Article 6(1)(d) of Regulation (EC) No 853/2004 for imports of collagen and raw materials for the production of collagen shall comply with the models laid down respectively in Part A and Part B of Appendix III to this Annex.

Appendix I to Annex VI

PART A

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

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor ☐ Name Address Postal code		I.2.	I.2.a. Local reference number:
		I.3. Central Competent Authority	
		I.4. Local Competent Authority	
I.5. Consignee Name Address Postal code		I.6.	
I.7. Country of origin ISO code	I.8. Region of origin Code	I.9. Country of destination ISO code	I.10. Region of destination Code
I.11. Place of origin Establishment/vessel ☐ Name Approval number Address Name Approval number Address Name Approval number Address		I.12. Place of destination Establishment/vessel ☐ Custom warehouse ☐ Name Approval number Address Postal code	
I.13.		I.14. Estimated date and time of arrival	
I.15. Means of transport (1) Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification: Documentary references:		I.16. I.17.	
I.18. Animal species/Product		I.19. Commodity code (HS code)	
			I.20. Quantity
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐			I.22. Number of packages
I.23. Identification of container/Seal number			I.24. Type of packaging
I.25. Animals certified as/products certified for: Human consumption ☐			
I.26.		I.27. For import or admission into EU ☐ Definitive import ☐	

I.28. Identification of the animals/products

Species (Scientific name)	Nature of cuts/ treatment type	Approval number of establishments/vessel: Factory vessel	Cutting plant/ manufacturing plant	Freezer vessel	Quantity	Net weight

COUNTRY **Collagen intended for human consumption**

Part II: Certification

II. Health information	II.a. Certificate reference number	II.b. Local reference number

1. Health attestation

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

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

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

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

and

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

Notes

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

(2) The colour of the stamp and signature must be different from that of the other particulars in the certificate.

Official veterinarian or official inspector

Name (in capitals): Qualification and title
Local veterinary unit: No of relevant LVU:
Date: Signature [2]:
Stamp [2])

PART B

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

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor ☐ Name Address Postal code			I.2.	I.2.a. Local reference number:	
			I.3. Central Competent Authority		
			I.4. Local Competent Authority		
I.5. Consignee Name Address Postal code			I.6.		
I.7. Country of origin	ISO code	I.8. Region of origin Code	I.9. Country of destination	ISO code	I.10. Region of destination Code
I.11. Place of origin Establishment ☐ Name Approval number Address Name Approval number Address Name Approval number Address			I.12. Place of destination Establishment ☐ Custom warehouse ☐ Name Approval number Address Postal code		
I.13.			I.14. Estimated date and time of arrival		
I.15. Means of transport (1) Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification: Documentary references:			I.16. I.17.		
I.18. Animal species/Product			I.19. Commodity code (HS code) I.20. Quantity		
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐			I.22. Number of packages		
I.23. Identification of container/Seal number			I.24. Type of packaging		
I.25. Animals certified as/products certified for: Human consumption ☐					
I.26.			I.27. For import or admission into EU ☐ Definitive import ☐		

I.28. Identification of the animals/products

Species (Scientific name)	Nature of cuts/ treatment type	Abattoir/ factory vessel	Approval number of establishments: Cutting plant/ manufacturing plant	Freezer vessel	Quantity	Net weight

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

Part II: Certification

II. Health information	II.a. Certificate reference number	II.b. Local reference number

1. 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 854/2004 and certify that the raw material described above complies with those requirements, in particular that:

— hides and skins of farmed ruminant animals/pigskins, bones and intestines/poultry skin and bones/tendons and sinews described above derive from animals which have been slaughtered in a slaughterhouse and whose carcases have been found fit for human consumption following ante- and post-mortem inspection (2),

and/or

— wild game hides and skins described above derive from slaughtered animals whose carcases have been found fit for human consumption following post-mortem inspection (2),

and/or

— fish skin and bones described above derive from plants manufacturing fish products for human consumption authorised for export (2).

Notes

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

(2) Delete as appropriate.

(3) The colour of the stamp and signature must be different from that of the other particulars in the certificate.

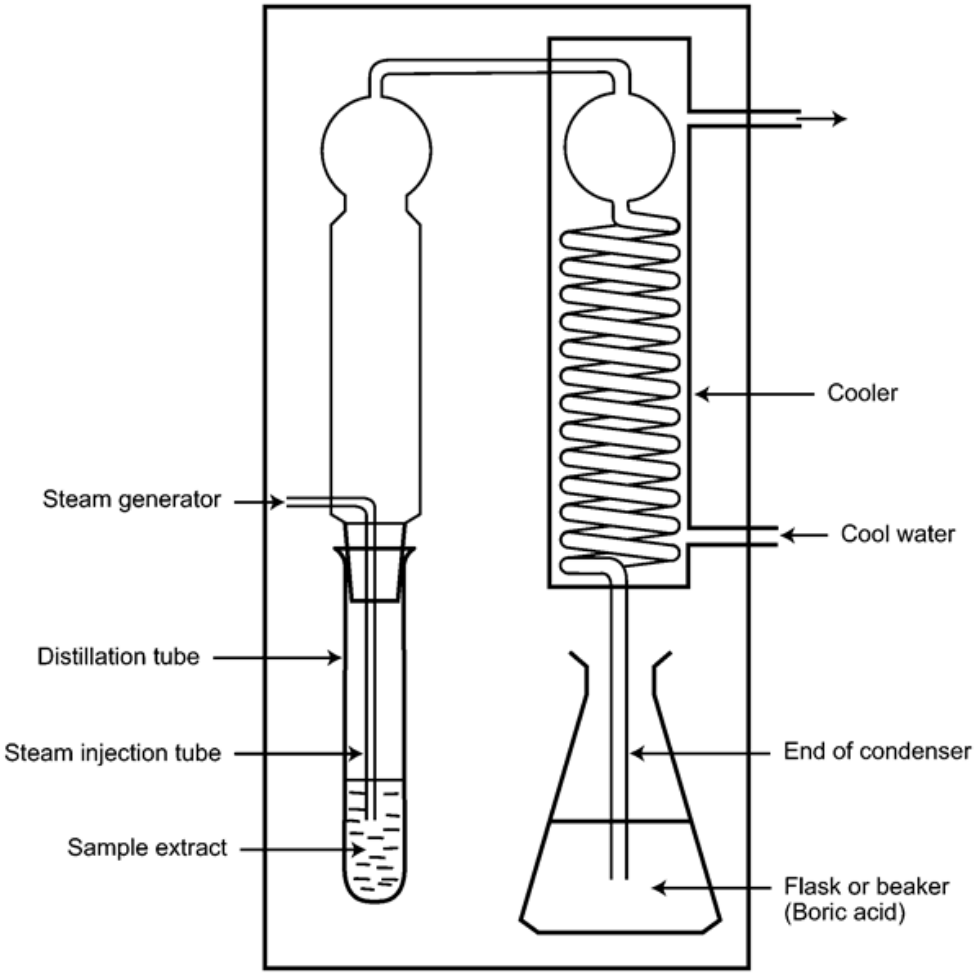
Official veterinarian or official inspector

Name (in capitals): Qualification and title
Local veterinary unit: No of relevant LVU:
Date: Signature (3):
Stamp (3)

Appendix II to Annex VI

PART A

MODEL HEALTH CERTIFICATE FOR IMPORTS OF GELATINE INTENDED FOR HUMAN CONSUMPTION



COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor ☐ Name Address Postal code			I.2.		I.2.a. Local reference number:		
			I.3. Central Competent Authority				
			I.4. Local Competent Authority				
I.5. Consignee Name Address Postal code			I.6.				
I.7. Country of origin	ISO code	I.8. Region of origin	Code	I.9. Country of destination	ISO code	I.10. Region of destination	Code
I.11. Place of origin Establishment/vessel ☐ Name Approval number Address Name Approval number Address Name Approval number Address				I.12. Place of destination Establishment/vessel ☐ Custom warehouse ☐ Name Approval number Address Postal code			
I.13.				I.14. Estimated date and time of arrival			
I.15. Means of transport (2) Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification: Documentary references:				I.16. I.17.			
I.18. Animal species/Product				I.19. Commodity code (HS code) I.20. Quantity			
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐				I.22. Number of packages			
I.23. Identification of container / Seal number				I.24. Type of packaging			
I.25. Animals certified as / products certified for: Human consumption ☐							
I.26.				I.27. For import or admission into EU ☐ Definitive import ☐			

I.28. Identification of the animals/products (1)

Species (Scientific name)	Nature of cuts/ treatment type	Approval number of establishments/vessel: Factory vessel	Cutting plant/ manufacturing plant	Freezer vessel	Quantity	Net weight

PART B

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

COUNTRY **Frogs' legs**

Part II: Certification

II. Health information	II.a. Certificate reference number	II.b. Local reference number

1. Health attestation

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

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

and

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

Notes

(1) Box reference I.28: Treatment type: Chilled, frozen, processed.
(2) Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship). This information is to be updated in the event of unloading and reloading.
(3) The colour of the stamp and signature must be different from that of the other particulars in the certificate.

Official veterinarian or official inspector

Name (in capitals):
Local veterinary unit:
Date:
Stamp (3)

Qualification and title
No of relevant LVU:
Signature (3):

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor ☐ Name Address Postal code		I.2.	I.2.a. Local reference number:
		I.3. Central Competent Authority	
		I.4. Local Competent Authority	
I.5. Consignee Name Address Postal code		I.6.	
I.7. Country of origin ISO code	I.8. Region of origin Code	I.9. Country of destination ISO code	I.10. Region of destination Code
I.11. Place of origin Establishment/vessel ☐ Name Approval number Address Name Approval number Address Name Approval number Address		I.12. Place of destination Establishment/vessel ☐ Custom warehouse ☐ Name Approval number Address Postal code	
I.13.		I.14. Estimated date and time of arrival	
I.15. Means of transport (2) Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification: Documentary references:		I.16. I.17.	
I.18. Animal species/Product		I.19. Commodity code (HS code)	I.20. Quantity
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐			I.22. Number of packages
I.23. Identification of container/Seal number			I.24. Type of packaging
I.25. Animals certified as/products certified for: Human consumption ☐			
I.26.		I.27. For import or admission into EU ☐ Definitive import ☐	

I.28. Identification of the animals/products (1)

Species (Scientific name)	Nature of cuts/ treatment type	Approval number of establishments/vessel: Factory vessel	Cutting plant/ manufacturing plant	Freezer vessel	Quantity	Net weight

Appendix III to Annex VI

PART A

MODEL HEALTH CERTIFICATE FOR IMPORTS OF COLLAGEN INTENDED FOR HUMAN CONSUMPTION

COUNTRY **Snails**

Part II: Certification

II. Health information	II.a. Certificate reference number	II.b. Local reference number

1. Health attestation

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

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

and

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

Notes

(1) Box reference I.28: Treatment type: Chilled, frozen, shelled, cooked, prepared, preserved.

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

(3) The colour of the stamp and signature must be different from that of the other particulars in the certificate.

Official veterinarian or official inspector

Name (in capitals):
Local veterinary unit:
Date:
Stamp (3)

Qualification and title
No of relevant LVU:
Signature (3):

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor ☐ Name Address Postal code			I.2.	I.2.a. Local reference number:			
			I.3. Central Competent Authority				
			I.4. Local Competent Authority				
I.5. Consignee Name Address Postal code			I.6.				
I.7. Country of origin	ISO code	I.8. Region of origin	Code	I.9. Country of destination	ISO code	I.10. Region of destination	Code
I.11. Place of origin Establishment/vessel ☐ Name Approval number Address Name Approval number Address Name Approval number Address				I.12. Place of destination Establishment/vessel ☐ Custom warehouse ☐ Name Approval number Address Postal code			
I.13.				I.14. Estimated date and time of arrival			
I.15. Means of transport (1) Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification: Documentary references:				I.16. I.17.			
I.18. Animal species/Product				I.19. Commodity code (HS code) I.20. Quantity			
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐				I.22. Number of packages			
I.23. Identification of container/Seal number				I.24. Type of packaging			
I.25. Animals certified as/products certified for: Human consumption ☐							
I.26.				I.27. For import or admission into EU ☐ Definitive import ☐			

I.28. Identification of the animals/products

Species (Scientific name)	Nature of cuts/ treatment type	Approval number of establishments/vessel: Factory vessel	Cutting plant/ manufacturing plant	Freezer vessel	Quantity	Net weight

PART B

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

COUNTRY **Gelatine intended for human consumption**

Part II: Certification

II. Health information	II.a. Certificate reference number	II.b. Local reference number

1. Health attestation

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

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

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

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

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

and

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

either [2]

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

or

bovine, ovine and caprine materials other than those derived from animals born, continuously reared and slaughtered in ..... [3][4].

Notes

(1) Box reference I.15: Registration number (railway wagons or container and lorries), flight number (aircraft) or name (ship). This information is to be updated in case of unloading and reloading.
(2) Delete one of these as appropriate.
(3) Insert the name of the country.
(4) As listed in point 15(b) of Annex XI to Regulation (EC) No 999/2001 as amended.
(5) The colour of the stamp and signature must be different from that of the other particulars in the certificate.

Official veterinarian or official inspector

Name (in capitals): Qualification and title
Local veterinary unit: No of relevant LVU:
Date: Signature [5]:
Stamp [5]

COUNTRY **Veterinary certificate to EU**

Part I: Details of dispatched consignment

I.1. Consignor ☐ Name Address Postal code			I.2.	I.2.a. Local reference number:	
			I.3. Central Competent Authority		
			I.4. Local Competent Authority		
I.5. Consignee Name Address Postal code			I.6.		
I.7. Country of origin	ISO code	I.8. Region of origin	Code	I.9. Country of destination ISO code	I.10. Region of destination Code
I.11. Place of origin Establishment ☐ Name Approval number Address Name Approval number Address Name Approval number Address				I.12. Place of destination Establishment ☐ Custom warehouse ☐ Name Approval number Address Postal code	
I.13.				I.14. Estimated date and time of arrival	
I.15. Means of transport (1) Aeroplane ☐ Ship ☐ Railway wagon ☐ Road vehicle ☐ Other ☐ Identification: Documentary references:				I.16. I.17.	
I.18. Animal species/Product				I.19. Commodity code (HS code) I.20. Quantity	
I.21. Temperature of product Ambient ☐ Chilled ☐ Frozen ☐				I.22. Number of packages	
I.23. Identification of container/Seal number				I.24. Type of packaging	
I.25. Animals certified as/products certified for: Human consumption ☐					
I.26.				I.27. For import or admission into EU ☐ Definitive import ☐	

I.28. Identification of the animals/products

Species (Scientific name)	Nature of cuts/ treatment type	Approval number of establishments: Abattoir/ factory vessel	Approval number of establishments: Cutting plant/ manufacturing plant	Approval number of establishments: Freezer vessel	Quantity	Net weight

ANNEX VII

AMENDMENTS TO REGULATION (EC) No 853/2004

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

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

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

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

(b) point 8 is replaced by the following:

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

2. Annex III is amended as follows:

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

8. 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:

CHAPTER VII: WATER RETENTION AGENTS

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

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

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

(d) Section IX is amended as follows:

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

(e) that teat dips or sprays are used only after authorisation or registration in accordance with the procedures laid down in Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market[9].;

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

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

   (a) Pasteurisation is achieved by a treatment involving:

      (i) a high temperature for a short time (at least 72 ^{o}C for 15 seconds);

      (ii) a low temperature for a long time (at least 63 ^{o}C for 30 minutes); or

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

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

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

      (i) involving a continuous flow of heat at a high temperature for a short time (not less than 135 ^{o}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 ^{o}C in closed containers or for 7 days at 55 ^{o}C in closed containers or after any other method demonstrating that the appropriate heat treatment has been applied.;

(e) in Section X, Chapter II is amended as follows:

   (i) in Part III, point 5 is replaced by the following:

      5. After breaking, each particle of the liquid egg must undergo processing as quickly as possible to eliminate microbiological hazards or to reduce them to an acceptable level. A batch that has been insufficiently

processed may immediately undergo processing again in the same establishment if this processing renders it fit for human consumption. Where a batch is found to be unfit for human consumption, it must be denatured to ensure that it is not used for human consumption.;

(ii) in Part V, point 2 is replaced by the following:

2. In the case of liquid egg, the label referred to in point 1 must also bear the words: "non-pasteurised liquid egg — to be treated at place of destination" and indicate the date and hour of breaking.;

(f) in Section XIV, the following Chapter V is added:

CHAPTER V: LABELLING

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

ANNEX VIII

AMENDMENTS TO REGULATION (EC) No 854/2004

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

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

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

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

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

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

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

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

5. The competent authority may classify as being of Class C areas from which live bivalve molluscs may be collected and only placed on the market after relaying over a long period so as to meet the health standards referred to in paragraph 3. Live bivalve molluscs from these areas must not exceed 46 000*E. coli* per 100 g of flesh and intravalvular liquid. The reference method

for this analysis is the five-tube, three dilutions MPN test specified in ISO 16649-3. Alternative methods may be used if they are validated against this reference method in accordance with the criteria in EN/ISO 16140.;

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

1. Fishery products derived from poisonous fish of the following families must not be placed on the market: *Tetraodontidae, 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.

(**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**) OJ L 123, 24.4.1998, p. 1.';