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:

[F1 Article 1

Requirements concerning food chain information for the purpose of Regulation (EC) No 853/2004

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

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) 2019/1139 of 3 July 2019 amending Regulation (EC) No 2074/2005 as regards official controls on food of animal origin in relation to requirements concerning food chain information and fishery products and to the reference to

recognised testing methods for marine biotoxins and to testing methods for raw milk and heat-treated cow's milk (Text with EEA relevance).

[F1 Article 2

Requirements concerning fishery products for the purpose of Regulation (EC) No 853/2004

Requirements concerning fishery products as referred to in Article 11(9) of Regulation (EC) No 853/2004 are set out in Annex II to this Regulation.**]**

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) 2019/1139 of 3 July 2019 amending Regulation (EC) No 2074/2005 as regards official controls on food of animal origin in relation to requirements concerning food chain information and fishery products and to the reference to recognised testing methods for marine biotoxins and to testing methods for raw milk and heat-treated cow's milk (Text with EEA relevance).

[F1 Article 3

Recognised testing methods for marine biotoxins for the purpose of Regulation (EC) No 853/2004

The recognised testing methods for detecting marine biotoxins as referred to in Article 11(4) of Regulation (EC) No 853/2004 are as set out in Annex V to Implementing Regulation (EU) 2019/627.**]**

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) 2019/1139 of 3 July 2019 amending Regulation (EC) No 2074/2005 as regards official controls on food of animal origin in relation to requirements concerning food chain information and fishery products and to the reference to recognised testing methods for marine biotoxins and to testing methods for raw milk and heat-treated cow's milk (Text with EEA relevance).

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.

F2 Article 5

[F2 Lists of establishments for the purpose of Regulation (EC) No 882/2004]

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Textual Amendments

F2 Deleted by Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls (Text with EEA relevance).

F3 Article 6

[F3[F4Model health certificates and documents for imports of certain products of animal origin for the purpose of Regulations (EC) Nos 853/2004 and 854/2004]]

. . . . . .

Textual Amendments

F3 Deleted by Commission Implementing Regulation (EU) 2019/628 of 8 April 2019 concerning model official certificates for certain animals and goods and amending Regulation (EC) No 2074/2005 and Implementing Regulation (EU) 2016/759 as regards these model certificates (Text with EEA relevance).

F4 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).

[F1 Article 6a

Testing methods for raw milk and heat-treated cow's milk

The analytical methods set out in Annex III to Implementing Regulation (EU) 2019/627 shall be used by food business operators to check compliance with the limits set out in Part III of Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004 and to ensure appropriate application of a pasteurisation process to dairy products as referred to in Part II of Chapter II of Section IX of Annex III to that Regulation.**]**

Textual Amendments

F1 Substituted by Commission Implementing Regulation (EU) 2019/1139 of 3 July 2019 amending Regulation (EC) No 2074/2005 as regards official controls on food of animal origin in relation to requirements concerning food chain information and fishery products and to the reference to recognised testing methods for marine biotoxins and to testing methods for raw milk and heat-treated cow's milk (Text with EEA relevance).

F2 Article 6b

[F2[F5Requirements concerning official controls for the inspection of meat for the purpose of Regulation (EC) No 854/2004]

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Textual Amendments

F2 Deleted by Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls (Text with EEA relevance).

F5 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).

F2 Article 6c

[F6Requirements concerning the official controls on fishery products caught by vessels flying the flag of Member States entering the Union after being transferred in third countries with or without storage]]

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Textual Amendments

F2 Deleted by Commission Implementing Regulation (EU) 2019/627 of 15 March 2019 laying down uniform practical arrangements for the performance of official controls on products of animal origin intended for human consumption in accordance with Regulation (EU) 2017/625 of the European Parliament and of the Council and amending Commission Regulation (EC) No 2074/2005 as regards official controls (Text with EEA relevance).

F6 Inserted by Commission Regulation (EU) 2017/1973 of 30 October 2017 amending Regulation (EC) No 2074/2005 as regards official controls on fishery products caught by vessels flying the flag of a Member State and introduced into Union after being transferred in third countries and establishing a model health certificate for those products (Text with EEA relevance).

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.

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.

[F2]SECTION II

[F2]OBLIGATIONS ON COMPETENT AUTHORITIES

[F2]CHAPTER I

PROVISION OF FOOD CHAIN INFORMATION

1. . . . . .

2. . . . . .

3. . . . . .

[F2]CHAPTER II

FEEDBACK TO HOLDING OF PROVENANCE]

1. . . . . .

2. . . . . .

[F2]Appendix to Annex I

[[F2]MODEL DOCUMENT]

[[F2]]

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.

F2SECTION II

[F2OBLIGATIONS ON THE COMPETENT AUTHORITIES

F2CHAPTER 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 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:

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2. . . . . .

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

. . . . . .

4. The sample must consist of about 100 g of flesh, taken from at least three different points and mixed together by grinding.

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F2CHAPTER II

SPECIES CATEGORIES FOR WHICH TVB-N LIMIT VALUES ARE FIXED

1. . . . . .

2. . . . . .

3. . . . . .

F2CHAPTER III

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

Reference procedure

1. Purpose and area of application

. . . . . .

2. Definition

. . . . . .

3. Brief description

. . . . . .

4. Chemicals

. . . . . .

5. Instruments and accessories

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6. Execution

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7. Calculation of TVB-N

F2 . . . . . .

F2 . . . . . .

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F2CHAPTER IV

TVB-N STEAM DISTILLATION APPARATUS]

F2 . . . . . .**]**

F2ANNEX III

[F2RECOGNISED TESTING METHODS FOR DETECTING MARINE BIOTOXINS

[F2 . . . . . .

F2 . . . . . .

[F2]CHAPTER I

[[F7]PARALYTIC SHELLFISH POISON (PSP) DETECTION METHOD]

1. . . . . .

2. . . . . .

Textual Amendments

F7 Substituted by Commission Regulation (EU) 2017/1980 of 31 October 2017 amending Annex III to Regulation (EC) No 2074/2005 as regards paralytic shellfish poison (PSP) detection method (Text with EEA relevance).

[F2]CHAPTER II

[[F8]AMNESIC SHELLFISH POISON (ASP) DETECTION METHOD]

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F2 . . . . . .]

Textual Amendments

F8 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).

[F2]CHAPTER III

[[F9]LIPOPHILIC TOXIN DETECTION METHODS]]

A. **Chemical methodology**

(1) The EU-RL LC-MS/MS method shall be the reference method for the detection of marine toxins as referred to in Chapter V(2)(c), (d) and (e) of Section VII of Annex III, to Regulation (EC) No 853/2004. This method shall determine at least the following compounds:

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(2) . . . . . .

(3) . . . . . .

(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:

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B. **Biological methods**

(1) . . . . . .

(2) . . . . . .

(3) . . . . . .

(4) . . . . . .

(5) . . . . . .

(6) . . . . . .

C. . . . . .

Textual Amendments

F9 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.

[F2]ANNEX V

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Textual Amendments

F10 Substituted by Commission Implementing Regulation (EU) 2015/2295 of 9 December 2015 amending Regulation (EC) No 2074/2005 as regards lists of approved food establishments (Text with EEA relevance).

[F3]ANNEX VI

[F3][F11][F4]MODEL HEALTH CERTIFICATES AND DOCUMENTS FOR IMPORTS OF CERTAIN PRODUCTS OF ANIMAL ORIGIN

Textual Amendments

F11 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).

[F3]SECTION I

[F3]CHAPTER I

[F12FROGS' LEGS AND SNAILS

[F3. . . . . .

Textual Amendments

F12 Deleted by Commission Implementing Regulation (EU) 2016/759 of 28 April 2016 drawing up lists of third countries, parts of third countries and territories from which Member States are to authorise the introduction into the Union of certain products of animal origin intended for human consumption, laying down certificate requirements, amending Regulation (EC) No 2074/2005 and repealing Decision 2003/812/EC (Text with EEA relevance).

[F3]CHAPTER II

GELATINE

F3. . . . . .

[F3]CHAPTER III

COLLAGEN]

F3. . . . . .

[F3]CHAPTER IV

FISHERY PRODUCTS

F3. . . . . .

F3CHAPTER V

LIVE BIVALVE MOLLUSCS

F3 . . . . . .

F3CHAPTER VI

[F12HONEY AND OTHER APICULTURE PRODUCTS]]

F3 . . . . . .

F3SECTION II

MODEL DOCUMENT TO BE SIGNED BY THE CAPTAIN

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[F3]Appendix I to Annex VI

[F3]PART A

[F12]MODEL HEALTH CERTIFICATE FOR IMPORTS OF CHILLED, FROZEN OR PREPARED FROGS' LEGS INTENDED FOR HUMAN CONSUMPTION

F3 . . . . . .

F3 . . . . . .

[F3]PART B

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

F3 . . . . . .

F3 . . . . . .

[F3]Appendix II to Annex VI

[F3]PART A

MODEL HEALTH CERTIFICATE FOR IMPORTS OF GELATINE INTENDED FOR HUMAN CONSUMPTION

F3 . . . . . .

F3 . . . . . .

[F3]PART B

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

F3 . . . . . .

F3 . . . . . .

[F3]Appendix III to Annex VI

[F3]PART A

MODEL HEALTH CERTIFICATE FOR IMPORTS OF COLLAGEN INTENDED FOR HUMAN CONSUMPTION

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[F3]PART B

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

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[F3]Appendix IV to Annex VI

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

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[F3]Appendix V to Annex VI

[F3]PART A

[[F13]MODEL HEALTH CERTIFICATE FOR IMPORTS OF LIVE BIVALVE MOLLUSCS ECHINODERMS, TUNICATES AND MARINE GASTROPODS INTENDED FOR HUMAN CONSUMPTION]

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Textual Amendments

F13 Substituted by Commission Regulation (EC) No 1250/2008 of 12 December 2008 amending Regulation (EC) No 2074/2005 as regards certification requirements for import of fishery products, live bivalve molluscs, echinoderms, tunicates and marine gastropods intended for human consumption (Text with EEA relevance).

[F3]PART B

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

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[F3]Appendix VI to Annex VI

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

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[F3]Appendix VII to Annex VI

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

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[F3]Appendix VIII to Annex VI

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

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[F2]ANNEX VIa

[F2[F14]TESTING METHODS FOR RAW MILK AND HEAT-TREATED MILK

Textual Amendments

F14 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).

[F2]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:

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2. The use of alternative analytical methods is acceptable:

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[F2]CHAPTER II

DETERMINATION OF ALKALINE PHOSPHATASE ACTIVITY]]

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[F2]ANNEX VIb

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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[8].;

(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 123, 24.4.1998, p. 1.’;

Status:
Point in time view as at 31/12/2020.

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.