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COMMISSION REGULATION (EC) No 2074/2005

of 5 December 2005

laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004

(Text with EEA relevance)

(OJ L 338, 22.12.2005, p. 27)

Amended by:

		Official Journal		
		No	page	date
►M1	Commission Regulation (EC) No 1664/2006 of 6 November 2006	L 320	13	18.11.2006
►M2	Commission Regulation (EC) No 1244/2007 of 24 October 2007	L 281	12	25.10.2007
►M3	Commission Regulation (EC) No 1022/2008 of 17 October 2008	L 277	18	18.10.2008
►M4	Commission Regulation (EC) No 1250/2008 of 12 December 2008	L 337	31	16.12.2008
►M5	Commission Regulation (EU) No 15/2011 of 10 January 2011	L 6	3	11.1.2011
►M6	Commission Implementing Regulation (EU) No 809/2011 of 11 August 2011	L 207	1	12.8.2011
►M7	Commission Implementing Regulation (EU) No 1012/2012 of 5 November 2012	L 306	1	6.11.2012
►M8	Commission Regulation (EU) No 218/2014 of 7 March 2014	L 69	95	8.3.2014
►M9	Commission Implementing Regulation (EU) 2015/2295 of 9 December 2015	L 324	5	10.12.2015
►M10	Commission Implementing Regulation (EU) 2016/759 of 28 April 2016	L 126	13	14.5.2016
►M11	Commission Regulation (EU) 2017/1973 of 30 October 2017	L 281	21	31.10.2017
►M12	Commission Regulation (EU) 2017/1980 of 31 October 2017	L 285	8	1.11.2017
►M13	Commission Implementing Regulation (EU) 2019/627 of 15 March 2019	L 131	51	17.5.2019
►M14	Commission Implementing Regulation (EU) 2019/628 of 8 April 2019	L 131	101	17.5.2019
►M15	Commission Implementing Regulation (EU) 2019/1139 of 3 July 2019	L 180	12	4.7.2019

Corrected by:

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

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COMMISSION REGULATION (EC) No 2074/2005

of 5 December 2005

laying down implementing measures for certain products under Regulation (EC) No 853/2004 of the European Parliament and of the Council and for the organisation of official controls under Regulation (EC) No 854/2004 of the European Parliament and of the Council and Regulation (EC) No 882/2004 of the European Parliament and of the Council, derogating from Regulation (EC) No 852/2004 of the European Parliament and of the Council and amending Regulations (EC) No 853/2004 and (EC) No 854/2004

(Text with EEA relevance)

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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.

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.

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.

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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.

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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.

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Article 7

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

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

(a) recognised historically as traditional products, or

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

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

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

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

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

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

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

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

(a) provide a short description of the requirements that have been adapted;

(b) describe the foodstuffs and establishments concerned; and

(c) give any other relevant information.

Article 8

Amendments to Regulation (EC) No 853/2004

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

Article 9

Amendments to Regulation (EC) No 854/2004

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

Article 10

Entry into force and applicability

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

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

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

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ANNEX I

FOOD CHAIN INFORMATION

SECTION I

OBLIGATIONS ON FOOD BUSINESS OPERATORS

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

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ANNEX II

FISHERY PRODUCTS

SECTION I

OBLIGATIONS ON FOOD BUSINESS OPERATORS

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

CHAPTER I

DEFINITIONS

1. ‘Visible parasite’ means a parasite or a group of parasites which has a dimension, colour or texture which is clearly distinguishable from fish tissues.

2. ‘Visual inspection’ means non-destructive examination of fish or fishery products with or without optical means of magnifying and under good light conditions for human vision, including, if necessary, candling.

3. ‘Candling’ means, in respect of flat fish or fish fillets, holding up fish to a light in a darkened room to detect parasites.

CHAPTER II

VISUAL INSPECTION

1. Visual inspection shall be performed on a representative number of samples. The persons in charge of establishments on land and qualified persons on board factory vessels shall determine the scale and frequency of the inspections by reference to the type of fishery products, their geographical origin and their use. During production, visual inspection of eviscerated fish must be carried out by qualified persons on the abdominal cavity and livers and roes intended for human consumption. Depending on the system of gutting used, the visual inspection must be carried out:

   (a) in the case of manual evisceration, in a continuous manner by the handler at the time of evisceration and washing;

   (b) in the case of mechanical evisceration, by sampling carried out on a representative number of samples being not less than 10 fish per batch.

2. The visual inspection of fish fillets or fish slices must be carried out by qualified persons during trimming and after filleting or slicing. Where an individual examination is not possible because of the size of the fillets or the filleting operations, a sampling plan must be drawn up and kept available for the competent authority in accordance with Chapter II(4) of Section VIII of Annex III to Regulation (EC) No 853/2004. Where candling of fillets is necessary from a technical viewpoint, it must be included in the sampling plan.

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ANNEX IV

CALCIUM CONTENT OF MECHANICALLY SEPARATED MEAT

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

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

2. be determined by a standardised international method.

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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’;

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(d) Section IX is amended as follows:

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

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

(*) OJ L 123, 24.4.1998, p. 1.’;

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

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

(a) Pasteurisation is achieved by a treatment involving:

(i) a high temperature for a short time (at least 72 °C for 15 seconds);

(ii) a low temperature for a long time (at least 63 °C for 30 minutes); or

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

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

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

(i) involving a continuous flow of heat at a high temperature for a short time (not less than 135 °C in combination with a suitable holding time) such that there are no viable micro-organisms or spores capable of growing in the treated product when kept in an aseptic closed container at ambient temperature; and

(ii) sufficient to ensure that the products remain microbiologically stable after incubating for 15 days at 30 °C in closed containers or for 7 days at 55 °C in closed containers or after any other method demonstrating that the appropriate heat treatment has been applied.’;

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

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

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

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(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.’

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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.’